Universidade Estadual de Campinas
Faculdade de Odontologia de Piracicaba

Raissa Micaella Marcello Machado

IMPLANTES DE DIÂMETRO REDUZIDO COMO RETENTORES DE OVERDENTURES MANDIBULARES: UM ANO DE MONITORAMENTO CLÍNICO, BIOLÓGICO E FUNCIONAL

NARROW DIAMETER DENTAL IMPLANTS AS MANDIBULAR OVERDENTURE RETAINERS: ONE YEAR OF CLINICAL, BIOLOGICAL AND FUNCTIONAL MONITORING

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

Thesis presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Doctor in Dental Clinic, in Dental Prosthesis area

Orientadora: Altair Antoninha Del Bel Cury

Este exemplar corresponde à versão final da tese defendida pela aluna Raissa Micaella Marcello Machado e orientada pela Profa. Dra. Altair Antoninha Del Bel Cury

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PROFª. DRª. FERNANDA FAOT

PROF. DR. BRUNO SALLES SOTTO MAIOR

PROFª. DRª. KARINA GONZALES SILVERIO RUIZ

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RESUMO

O uso de implantes de diâmetro reduzido (IDR) e mini-implantes (MI) tem sido bastante difundido, entretanto ainda são necessários estudos que avaliem a sua previsibilidade, comportamento clínico, biológico e funcional como retentores de overdentures mandibulares (OM). Com o intuito de verificar o sucesso clínico e funcional desse tratamento em pacientes desdentados totais com limitada disponibilidade óssea foram delineados quatro diferentes estudos: i) Revisão sistemática (RS) e meta-análise dos estudos que utilizaram MI e IDR como retentores de OM e que reportassem dados sobre sobrevivência, sucesso e perda óssea marginal (POM) para realização da meta-análise; ii) Estudo clínico longitudinal que avaliou o comportamento clínico de 60 IDR como retentores de OM instalados em 30 pacientes com alto tempo de edentulismo cujas mandíbulas foram classificadas como clinicamente atróficas, foram acompanhados até 1 ano após o carregamento. As variáveis de desfechos foram: saúde peri-implantar (índice de placa visível – IPV, cálculo - C, índice gengival - IG, índice de profundidade de sondagem – IPS e índice de sangramento gengival – ISG), estabilidade primária e secundária dos implantes (ISQ), sobrevivência, sucesso, POM, remodelação óssea (RO), e descrição de complicações/manutenções durante o tratamento; iii) Estudo clínico longitudinal com 1 ano de acompanhamento que avaliou a evolução da função mastigatória (FM) e a qualidade de vida relacionada à saúde oral (QVRSO) de 23 desdentados totais, com alto tempo de edentulismo, mandíbulas classificadas como clinicamente atróficas e reabilitados com overdentures mandibulares, por meio dos testes de performance mastigatória (PM) e limiar de deglutição (LD). Nesse estudo também foi avaliada, a QVRSO por meio de três questionários distintos OHIP-EDENT, GOHAI e DIDL. iv) Estudo clínico longitudinal que comparou a FM, a QVRSO e a satisfação de 26 pacientes desdentados totais cujas mandíbulas foram consideradas radiograficamente i) atróficas (PA) e ii) não atróficas (PNA) antes e até 1 ano após o carregamento das OM. Foram utilizados os testes de PM e LD e o questionário DIDL como indicador da QVRSO e da satisfação do paciente. Os resultados do estudo I mostraram que MI e IDR apresentam comportamento clínico semelhante aos implantes de diâmetro

convencional (IDC), sendo que a POM encontradas para MI e IDR foram clinicamente semelhantes aos limites relatados na literatura para IDC. Os IDR apresentam melhor previsibilidade que MI quando carregados convencionalmente. No estudo clinico II observamos que os IDR apresentaram um comportamento clínico semelhante ao já relatado para IDC, diretamente dependente do cuidado do paciente e do monitoramento dos tecidos peri-implantares. O IPS diminuiu gradativamente evidenciando o selamento dos tecidos moles ao redor do componente protético protegendo o osso marginal. A perda óssea marginal 1 ano após o carregamento da OM (-0,23 ± 0,5 mm) foi similar (P>0,05) ao nível ósseo peri-implantar imediatamente após instalação dos implantes (-0,13 ± 0,47 mm). A remodelação óssea após 1 ano de carregamento foi de -0,06 ± 0,64 mm. Em média foi necessário um retorno por paciente para ajuste da base ou troca do O-ring rosa. O estudo clinico referente ao artigo III descreveu melhora significativa na FM e na QVRSO dos desdentados cujas mandíbulas foram consideradas clinicamente atróficas, após a instalação das OM sendo que a melhora funcional já foi notada no primeiro mês pós carregamento e a QVRSO já no terceiro mês pós carregamento. Por fim, os resultados do estudo IV mostraram que o LD dos PA é afetado negativamente enquanto usuários de prótese total, entretanto após 6 meses do carregamento dos implantes as diferenças no LD entre PA e PNA desaparecem. Também, observou-se que PA necessitaram de um tempo maior para se adaptarem ao novo tratamento do que os PNA visto que diferença significativa entre os grupos foi encontrada para o domínio conforto oral aos 3 e 6 meses pós carregamento. Diante dos resultados dos estudos conclui-se que os IDR são uma opção de tratamento segura para pacientes desdentados totais com pouca disponibilidade óssea, visto que eles apresentaram sucesso clínico como retentores de OM, e ainda, a transição de prótese total para OM mostrou melhora significativa no desempenho funcional e impacto positivo na QSVRO e na satisfação do paciente.

Palavras-chave: overdenture; implantes dentários; prótese dentária; mastigação; qualidade de vida.

ABSTRACT

The use of mini-implants (IDR) and mini-implants (IM) has been widespread, however, studies are still needed to assess their predictability, clinical, biological and functional behavior as mandibular overdenture (OM) retainers. In order to verify the clinical and functional success of this treatment in total edentulous patients with limited bone availability, four different studies were delineated: I) Systematic review (SR) and meta-analysis, a systematized search in 6 databases to identify studies using MI and NDI as MO retainers and reporting data on survival, success and marginal bone loss (MBL) for meta-analysis; II) Longitudinal clinical study that evaluated the clinical behavior of 60 NDI as MO retainers installed in 30 patients with clinically atrophic mandible and high edentulism time, were followed for up to 1 year after loading. The outcomes were: peri-implant health (plate index – PI; calculus – C; gingival index - GI; probing depth – PD; bleeding on probing – BoP), Primary and secondary stability of the implants (ISQ), survival, success, MBL, marginal bone level change (MBC), and description of complications/maintenance during the treatment; III) Longitudinal clinical study with 1 year of follow-up, that evaluated the masticatory function (MF) evolution and oral health related quality of life (OHRQoL) of 23 edentulous patients with clinically atrophic mandible and high edentulism time were rehabilitated with mandibular overdenture. The MF was evaluated through masticatory performance (MP) tests and swallowing threshold (ST). And the OHRQoL was evaluated through three different questionnaires OHIP-ENDENT, GOHAI and DIDL. IV) Longitudinal clinical study comparing the MF, OHRQoL and satisfaction of 26 edentulous patients classified as atrophic patients (AP) and non-atrophic patients (NAP) before and up to 1 year after MO loading. The outcomes were MP and ST tests and DIDL questionnaire as an OHRQoL indicator and patient satisfaction. Through the results of study I, it is demonstrate that MI and NDI present clinical behavior similar to those of standard diameter implants (SDI), MBL found for MI and NDI were clinically similar to those reported in the literature for SDI. NDIs show better predictability than MI when conventionally loaded. In the clinical study II, we observed that the NDI present clinical behavior similar to that already reported for SDI, directly dependent of the

patient care and peri-implant tissues monitoring. The PD decreased gradually, evidencing the soft tissues sealing around the attachments protecting the marginal bone. The MBL 1 year after MO loading (-0.23 ± 0.5 mm) was similar (P> 0.05) at the MBL immediately the implant installation (-0.13 ± 0, 47 mm). The MBC after 1-year loading was -0.06 ± 0.64 mm. On average, a return per patient was required to adjust the base or exchange the pink O-ring. The clinical study, referring to article III described a significant improvement in MF and OHRQoL of the clinically atrophic edentulous patients after the MO loading, and the functional improvement was already noticed in the first month after loading and the OHRQoL in the third month after loading. Finally, the results of study IV showed that ST of AP is negatively affected while complete denture (CD) wearers and that only 6 months after loading the differences in ST disappear. Also, it was observed that AP required a longer time to adapt to the new treatment than the NAPs, since significant difference between the groups was found for the oral comfort domain at 3 and 6 months post loading. In view of all the compiled results it is concluded that NDIs are a safe option of treatment for edentulous patients with poor bone availability. Since they were clinically successful as MO retainers, and the transition from CD to MO showed a significant improvement in functional performance and a positive impact on OHRQoL and patient satisfaction.

Key-words: Overdenture; dental implants; Dental prosthesis; mastication; quality of life.

SUMÁRIO

1 INTRODUÇÃO

Durante muito tempo, as próteses totais convencionais (PTC) foram a única maneira de reabilitar um paciente desdentado total. Contudo, o processo fisiológico de reabsorção óssea progressiva do osso alveolar, o qual ocorre de forma mais acentuada na mandíbula, podendo comprometer a retenção e a estabilidade das PTC mandibulares quando em função por um período prolongado de tempo (Tallgren 1972; Atwood 2001). Do ponto de vista funcional, o tempo de edentulismo pode ser um fator determinante para a gravidade de modificações intra-orais como a perda da resiliência e aumento da sensibilidade da fibromucosa, redução da altura e espessura do osso alveolar e alteração do formato do rebordo alveolar (Pan et al., 2010). A consequência clinica desses fatos é que o paciente comumente relata dificuldade de adaptação às próteses, função mastigatória deficiente, dor e completa insatisfação (Naert et al., 2004).

Diante do prognóstico desfavorável das PT mandibulares comumente observado nesta população, e, da observação do alto índice de sucesso e sobrevivência dos implantes osseointegrados, no ano de 2002, com a elaboração do Consenso McGill (Feine et al., 2002) definiu-se que a primeira escolha de tratamento para reabilitação da mandíbula edêntula deveria ser a prótese do tipo “overdenture” implanto-retida, devido aos reais benefícios que ela proporciona ao paciente. Do ponto de vista funcional, estudos acerca da força de mordida (Caloss et al., 2011), da habilidade e performance mastigatória (Bakke et al., 2002) e do controle de coordenação neuromuscular (Ferrario et al., 2005) tem mostrado que o aumento da estabilidade e retenção de próteses mandibulares promove o fechamento voluntário máximo da boca com força e biomecânica equilibrada capaz de reproduzir uma mastigação normal e ativar diversas áreas do córtex cerebral (Miyamoto et al., 2005). Adicionalmente, a presença de implantes também tem resultado em redução da reabsorção óssea (Burns, 2000; Kordatzis et al., 2003).

Posteriormente com o advento do “The York Statement” em 2009, uma declaração adicional acompanhando o consenso McGill, demonstrou substanciais evidências através de ensaios clínicos randomizados,

comprovando a melhoria da satisfação e qualidade de vida dos pacientes portadores de overdentures mandibulares (OM) implanto-retidas quando comparados com o tratamento com PTC (Thomason et al., 2012).

Como a reabsorção do rebordo residual mandibular é um processo crônico e diretamente dependente do tempo de edentulismo (Atwood 1963; Tallgren 1972), com o envelhecimento da população em geral e, especificamente da população desdentada um quadro de atrofia óssea é comumente diagnosticado, impossibilitando na maioria das vezes ao uso de implantes convencionais. Diante deste problema, implantes de diâmetro reduzido ou mini-implantes, denominações utilizadas para descrever todos os implantes com diâmetro menor que 4 mm (Sohrabi et al., 2012). Os mini-implantes apresentam diâmetro entre 1.8 e 2.9 mm, são utilizados em tratamentos ortodônticos e protéticos, estão disponíveis em peça única, e quando utilizados na reabilitação de arcos edêntulos geralmente são carregados imediatamente (Bidra and Almas 2013). Os implantes de diâmetro reduzido apresentam diâmetro entre 3 e 3.5 mm, os implantes de diâmetro extra estreito apresentam diâmetro menor que 3 mm, ambos, são tem sido utilizados em tratamentos protéticos definitivos na região anterior de maxila e mandíbula, e estão disponíveis em 2 peças (implante e componente protético) e podem ser carregados convencionalmente ou imediatamente (Sohrabi et al., 2012; Al-Johany et al., 2017). Este tipo de implante tem se tornado uma modalidade cirúrgica atrativa como retentores para overdentures para se aumentar a retenção e estabilidade de PT mandibulares. Outro benefício direto deste tipo de implante é a adoção de uma técnica cirúrgica simplificada e menos invasiva (Lee et al., 2005; Allum et al., 2008; Degidi et al., 2008; El-Sheikh et al., 2012). Como consequência, quando corretamente indicado os implantes de diâmetro reduzido podem proporcionar ao paciente um tempo menor de tratamento, menor tempo de recuperação e menor custo (El-Sheikh et al., 2012). Além disso, essa técnica também torna possível a reabilitação de pacientes que não poderiam passar por um procedimento cirúrgico mais invasivo, extenso e com tempo de cicatrização prolongado (Klein et al., 2014).

Algumas revisões da literatura (Sohrabi et al., 2012; Ortega-Oller et

al., 2014; Klein et al., 2014) investigaram a previsibilidade da reabilitação com mini-implantes ou implantes de diâmetro reduzido. Porém, essas têm focado isoladamente na análise das taxas de sobrevivência, na técnica cirúrgica, com ou sem retalho, ou ainda na influência do comprimento do implante nas taxas de sucesso e sobrevivência de mini-implantes ou implantes de diâmetro reduzido (Sohrabi et al., 2012; Ortega-Oller et al., 2014; Klein et al., 2014). Além disso, estas revisões descrevem as taxas de sucesso e sobrevivência independentemente do tipo de prótese preconizada para reabilitação. Neste sentido, as taxas de sobrevivência já relatadas para implantes com diâmetro <3.5mm foram de 90% (Sohrabi et al., 2012); 88% (Klein et al., 2014); e de 75% para implantes com diâmetro <3.3 mm (Ortega-Oller et al., 2014). Estas taxas foram semelhantes às já descritas para implantes de diâmetro convencional (Sohrabi et al., 2012). Entretanto, estas revisões não focaram na utilização desses implantes como retentores de overdentures. Neste sentido torna-se necessário analisar em conjunto, os estudos que já utilizaram os implantes de diâmetro reduzido e os mini-implantes como ancoragens de OM, para a determinação da previsibilidade deste tratamento em relação ao sucesso, à sobrevivência e à perda óssea marginal.

Adicionalmente, poucos estudos têm mensurado o desempenho das OM, independente do conceito cirúrgico preconizado por implantes de diâmetro reduzido em pacientes portadores de atrofia óssea severa e moderada (Spitzl et al., 2012; Raghoebar et al., 2011; Guljé et al., 2012). Em geral, esta condição se apresenta em pacientes de idade avançada ou com longo tempo de edentulismo, casos nos quais uma simplicidade e agilidade cirúrgica são de grande importância para a previsibilidade e prognóstico favorável. Com vistas a sanar estes problemas, um novo implante de diâmetro reduzido com técnica cirúrgica mais simplificada e menos invasiva foi desenvolvido com encaixes para overdenture do tipo botão (Bielemann et al. 2017). Entretanto, o seu comportamento antes e após o carregamento oclusal, bem como sua previsibilidade e problemas inerentes a manutenção do sistema ainda não foram descritos na literatura. Sendo assim, se faz necessário um acompanhamento em longo prazo do processo de osseointegração bem como de sua manutenção, e ainda a avaliação dos tecidos peri-implantares.

Do ponto de vista funcional as OM proporcionam inúmeros benefícios, entretanto, poucos estudos (Woda et al., 2011; Witter et al., 2013) tem focado na qualidade e na descrição do que seria uma mastigação eficiente. Além disso, ainda é contraditório a relação entre a função mastigatória e a atrofia óssea mandibular, especialmente quando esses pacientes passam pela transição entre PTC e OM (Witter et al., 2013). Em adição, a condução de mais estudos para determinar o impacto desta modalidade de reabilitação na qualidade de vida de desdentados totais tem sido encorajados uma vez que os altos níveis de satisfação relatados nem sempre correspondem a melhora na qualidade de vida geral e relacionada a saúde oral (Boven et al., 2015). Dessa forma, torna-se importante avaliar de forma objetiva, a função mastigatória, e subjetiva a percepção do paciente frente ao tratamento, comparando as melhorias proporcionadas e os diferentes impactos nas populações com mandíbula radiograficamente atróficas e não atróficas.

Diante da proposta de recentes desenhos de implantes de diâmetro reduzido para suportar próteses do tipo overdentures mandibulares, ainda é necessário buscar bases científicas que possam definir sua previsibilidade quando comparada a outros procedimentos reabilitadores até mesmo menos invasivos como o uso de mini-implantes. Além disso, estudos clínicos com o foco no acompanhamento da performance biológica e funcional de implantes de diâmetro reduzido que preconizam plataformas protéticas tipo cone morse sem aparafusamento ainda são escassos na literatura. Por fim neste contexto, estudos focados na evolução da função mastigatória após o carregamento das overdentures e ainda evidenciando as diferenças entre pacientes portadores ou não de atrofia óssea mandibular também são necessários para diferenciar o comportamento biológico dos implantes ao longo do tempo.

Sendo assim, esta tese teve como objetivos identificar a previsibilidade, o comportamento clínico e radiográfico de mini-implantes e implantes de diâmetro reduzido como retentores de overdentures mandibulares; investigar o comportamento clínico dos tecidos peri-implantares, a taxa de sobrevivência e a presença de complicações durante o primeiro ano de tratamento com OM retidas por 2 implantes de diâmetro reduzido com encaixes

do tipo Equator instaladas em uma população com mandíbula atrófica e alto tempo de endentulismo; avaliar a função mastigatória (FM) e a percepção subjetiva em pacientes com atrofia óssea mandibular severa em relação às alterações em seu padrão de mastigação e o tempo necessário para se identificar uma melhora nesses parâmetros quando se compara antes e após o tratamento com overdentures mandibulares retidas por dois implantes de diâmetro reduzido (2,9X10mm), durante o primeiro ano de tratamento; investigar a evolução dos parâmetros de FM, a satisfação e a qualidade de vida relacionada à saúde oral em pacientes com mandíbulas atróficas (PA) e não-atróficas (PNA) durante a transição de PTC para OM no primeiro ano após o carregamento.

2 ARTIGOS

2.1 ARTIGO: Predictability of mini-implants and narrow diameter implants used to anchor mandibular overdentures: A systematic review and meta-analysis

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(Anexo 2)

Running title: Mini-implants and Narrow diameter implants: Systematic review

Raissa Machado Marcello-Machado[1]; Fernanda Faot[2], Alessandra Julie Schuster[3]; Gustavo Giacomelli Nascimento[4]; Altair Antoninha Del Bel Cury[5]

[1] MSc, PhD student, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

[2] PhD, Professor, Department of Restorative Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil.

[3] PhD student, Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil

[4] PhD, Section of Periodontology, Department of Dentistry and Oral Health, Faculty of Health Sciences, Aarhus University

[5] PhD, Professor, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, Brazil.

SUMMARY

This study reviews the clinical and radiographic behavior of small-diameter dental implants, Mini-implants (MI) and Narrow Diameter Implants (NDI) as mandibular overdenture (MO) retainers, independently of loading protocol. Six databases were consulted for clinical studies evaluating implants with diameter ≤ 3.5 mm as MO retainers in edentulous patients. The studies presented data on the MI and NDI as predictors for peri-implant bone loss, success and survival rate. Subsequently, these data were submitted to meta-analysis. Thirty studies were included and divided into 2 groups, MI (n = 19) and NDI (n = 11). MI group was composed of 1 cross-sectional clinical study, 2 retrospectives longitudinal (RL) clinical studies, 9 prospective longitudinal (PL) clinical studies and 7 randomized clinical trials (RCT) with follow-up periods ranging from 1 day to 7 years. NDI group was composed of 3 RL clinical studies, 5 PL clinical studies and 3 RCT with follow-up ranging from 6 months to 10 years. The average survival rates of MI and NDI studies were 99% and 98%, respectively. The average success rates were 95% and 98% for MI and NDI studies, respectively. Peri-implant bone loss after 12, 24 and 36 months showed an average of 0.89, 1.18 and 1.02mm for MI and 0.18, 0.12 and 0.32mm for NDI. MI or NDI showed a good clinical behavior as overdenture retainers. NDI have a better long-term predictability with conventional loading.

Keywords: Narrow Dental implants; Mini-Implant; Systematic Review; Meta-analysis; Jaw, Edentulous; Overdenture.

INTRODUCTION

The life expectancy of the elderly population is increasing[1], and consequently the average degree of mandibular bone atrophy in completely edentulous patients rises. The resorption of the mandibular residual ridge is a chronic, progressive process and is directly linked to the duration of edentulism[2]. This common clinical condition is the main limitation for rehabilitation of complex cases with standard diameter implants (SDI).

Therefore, implants with a diameter less than 3.75 mm, termed mini-implants (MI) or narrow diameter implants (NDI) have become an attractive alternative for SDI[3–5]. The MI and NDI are comparable to other implants fabricated from biocompatible materials, except where the diameter is concerned. The diameter of MIs ranges from 1.8 mm to 2.9 mm, while the NDI diameters is 3-3.5 mm[4]. The MI have been used in orthodontic or prosthetic treatments, they have significantly lower costs than SDI[4], usually available in one piece and are used in prostheses with immediate loading in edentulous arches. Usually the MI are installed with flapless technique and are rarely used in combination with bone grafts. Most rehabilitations used more than 2 MI as mandibular overdenture retainers[4]. Conversely, the NDI have similar prices as other implants, and are used for definitive prosthetic treatment in the anterior region of the mandible and in the maxillary lateral incisor region. The NDI are usually available as 2-piece designs: the implant and the prosthetic abutment are connected separately. The NDI may receive immediate or delayed loading of the prosthesis and are sometimes used in combination with bone grafting and surgical flap[4]

MI and NDI are being extensively recommended to anchor overdentures, to increase retention and stability of mandibular dentures in cases of limited bone thickness. In such cases, poor bone availability is also often attributed to the surgical need of alveolar ridge regularization that may limit the height of the bone sites. Another direct benefit of this type of implants is the adoption of a simplified and less invasive surgical technique[6,7,3,8]. The latter results in shorter treatment times, shorter recovery times and

lower costs for the patients[6]. Furthermore, this technique enables the rehabilitation of patients who are unable to undergo more invasive and extensive surgical procedures with prolonged healing times[5].

Studies that evaluated patient satisfaction after treatment with NDI or MI implant-retained overdentures reported a direct positive impact on the patients' quality of life in terms of satisfaction, comfort and masticatory ability[9–12]. These improvements can already be perceived 3 months after conversion to implant-retained mandibular prosthesis[13]. The latter is mainly due to the increased comfort and high satisfaction with the prosthesis' retention and stability. Moreover, studies that assess the success and survival rates, peri-implant health and marginal bone loss of MI and NDI, reported similar results as studies performed with SDI[14–19].

Some reviews[20,5,21] already investigated the predictability of rehabilitation with MI or NDI. These reviews focused individually on survival rates, on surgical techniques, flap or flapless, or on the influence of implant length on the MI and NDI success and survival rates[20,5,21]. In addition, the reviews describe the success and survival rates irrespective of the prosthesis type used for the prosthetic rehabilitation. In this sense, the survival rates previously reported for implants with a diameter <3.5 mm were 90%[20]; 88%[5]; and 75%[21] for implants with a diameter <3.3 mm. Klein et al., 2014[5], performed a meta-analyses comparing the survival rate of NDI with SDI and no statistically significant difference in implant survival was demonstrated. Currently, there is little information in literature about the indication and prognosis of both MI and NDI systems. Therefore, it is essential to increase the understanding of the clinical performance indicators of these implants as overdentures mandibular retainers. The criteria for implant success have been defined as: (1) absence of clinical implant mobility, (2) no peri-implant continuous radiolucency, and (3) absence of signs and symptoms such as pain, infections, dysesthesia and marginal bone loss > 1.5 mm[22,23]. Implant survival is defined as remaining in situ, without having to satisfy the success criteria[24].. Despite the numerous encouraging results regarding the suitability of MI or NDI as mandibular overdenture

retainers[10,19,25,26], more data needs to be compiled about the success rates, survival rates, and their clinical, radiographic and biological behavior. These data will enable to determine which modality of small diameter implants (MI or NDI) can achieve stable results over time. Thus, this systematic review and meta-analysis aims to identify the predictability, clinical and radiographic behavior of MI and NDI as mandibular overdenture retainers.

MATERIAL AND METHODS

Search strategy

This review was conducted in accordance with the protocol for Systematic Reviews and Meta-analysis (PRISMA statement)[27]. The study aims to identify clinical trials evaluating implants with diameter ≤ 3.5 mm as mandibular overdenture retainers in mandibular edentulous patients. A literature search was conducted on 12 January 2016. The databases accessed were Medline (via PubMed), Scopus, Web of Science, Embase and Cochrane. In addition, a search on ClinicalTrials.gov was done to find ongoing studies on this subject. Subsequently, a complementary manual search was performed using the references used in the selected studies. The search string was a Boolean combination of the following MesH terms: "small diameter dental implants" OR "narrow diameter dental implants" OR "narrow dental implants" OR "small dental implants" OR "diameter dental implants" OR "mini-implants" AND Edentulous".

Eligibility criteria

1. Type of participants: edentulous patients who received implant-retained overdentures.
2. Type of intervention: MI or NDI installed in the anterior region of the mandible as overdenture retainers.
3. Comparison: show which minimal invasive surgical alternative, MI or NDI, would be safer/predictable for use by the clinician as mandibular overdenture retainers.
4. Main outcomes: success rate, survival rate and marginal bone loss.
5. Type of studies: cross-sectional, longitudinal and randomized clinical studies.

Inclusion criteria

1. Cross-sectional, longitudinal and randomized clinical studies performed with edentulous patients.

2. Clinical studies that evaluated implants with diameters ≤ 3.5 mm as mandibular overdenture retainers.
3. Outcomes contain at least one of the following variables: success rate; survival rate; evaluation of peri-implant health with bleeding on probing, probing depth or plaque index; marginal bone loss; masticatory function and patient satisfaction.
4. Study is written in English.

Exclusion criteria

1. Overdenture data not reported separately.
2. Maxillary overdentures only.
3. Sample consists of partially edentulous patients.
4. Case reports and case series.
5. In vitro and in silico studies.
6. Studies of implants with diameters > 3.5mm.
7. Animal studies.

Validity assessment and data extraction

The initial search and selection by title and abstract was carried out by a single evaluator (RMMM), based on the inclusion and exclusion criteria described above. After selection, the studies were read in full by two researchers (RMMM and FF), who subsequently identified the items that should be included in this review independently. Disagreements were resolved by mutual discussion.

The methodological quality and the risk of bias for each study were evaluated by two independent authors (RMMM) and (AJS). These authors used the checklist by Downs and Black, 1988[28], which evaluates the quality of the report, the internal validity, the power and external validity. If there is no agreement between the scores determined by each author, a third author (FF) served as an arbitrator. The checklist scores of Downs and Black, 1988[28] were calculated and grouped into four quality levels: ≥14 (poor), 15-

19 (fair), 20-25 (good) and 26-28 (excellent).

Statistical analysis

A total of 6 meta-analyses were performed separately to estimate the survival rate, success rate and bone loss for overdentures retained by MI and NDI over the years. The subgroup analyzes were conducted in accordance with the studies follow-up time. The MI studies were divided in two groups, with follow-up times ≤1 year (MIG1) and >1 year (MIG2). The NDI studies were divided in two groups with in follow-up time ≤4 years (NDIG1) and ≥5 years (NDIG2). The meta-analysis for peri-implant bone loss was performed by grouping the results according to the follow-up time: 0-12 months, 12-24 months and ≥36 months. The random effects model was used due to the heterogeneity of the data ($I^2 > 50\%$; $P < 0.05$). All analyzes were performed using Stata 13.1 (Stata Corp, College Station, TX, USA).

RESULTS

The search conducted in the six databases on January 2016 found 2119 studies: 280 on Medline (PubMed), 84 on clinical trials.gov, 52 on Scopus, 1303 on Web of Science, 2 on Cochrane and 398 on Embase. The 156 duplicates were subsequently deleted and the selection by title and abstract narrowed it further down to 105 studies, which were read in their entirety by two evaluators. Of these, 21 articles were selected for review. An additional 9 studies were added by manual search of references of these studies, bringing the total up to 30 studies. The selection process is summarized in a flow diagram (Figure 1). The following variables were extracted from these studies (Tables 1 and 2): author, year, country, type of study, sample, type of implant, type of loading, follow-up, outcomes, success, survival, marginal bone loss and main results.

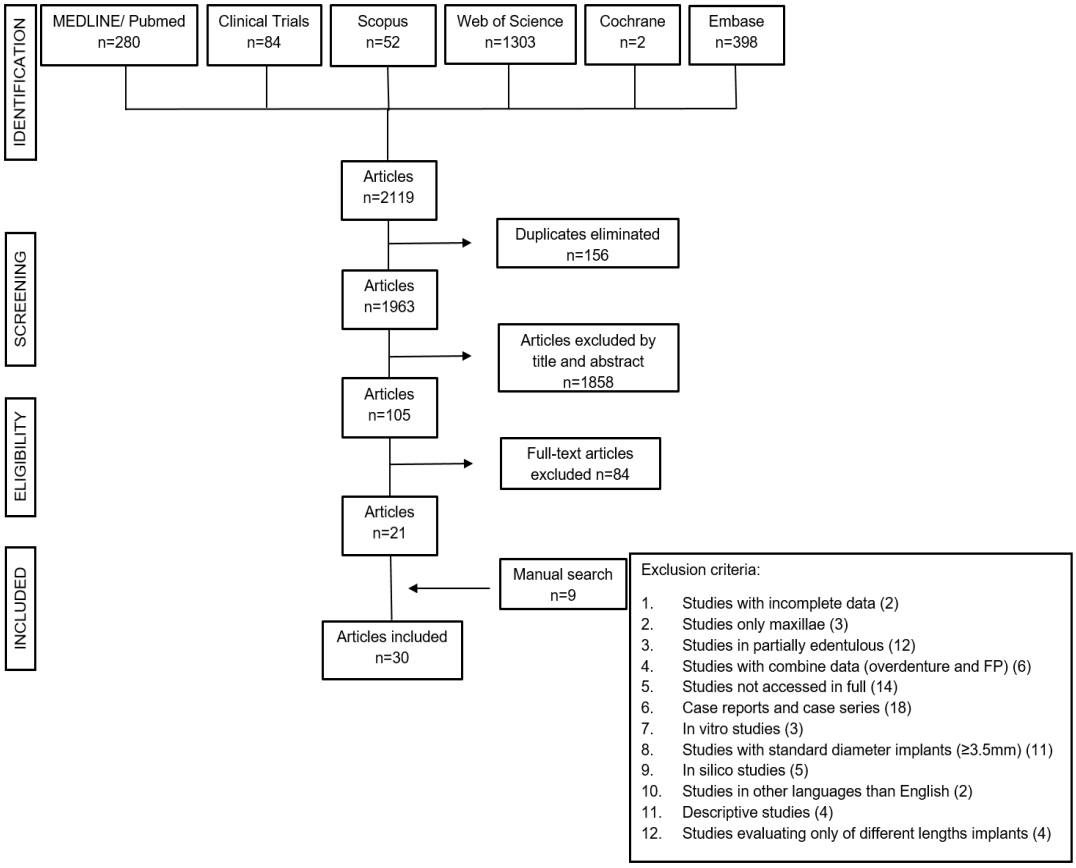

Figure 1. Flow diagram describing the search strategy.

General results of the studies

The selected studies were divided into two groups, one with studies using MI (n = 19) and another using NDI (n = 11). The MI group consists of 1 cross-sectional clinical study[29], 2 retrospectives longitudinal clinical studies[30,31], 9 prospective longitudinal clinical studies[9,15,18,32–37] and 7 randomized clinical trials[10,14,25,38–41]. The NDI group was composed of 3 retrospective longitudinal clinical studies[16,26,42], 5 prospective longitudinal clinical studies[6,11,12,43,44] and 3 randomized clinical trials[17,19,45]. The follow-up time of the MI studies varied from 1 day[29] to 7 years[36] while studies of NDI varied from 6 months[17] to 10 years[43]. In relation to the type of loading: in the MI studies 3 presented conventional loading[10,30,41], 13 immediate loading[9,14,15,25,31-33,35-40], 2 presented the two types of loading[18,29] and 1 study did not report the type of loading[34]; In the NDI studies 8 presented conventional loading[6,11,12,17,19,26,43,45], 1 presented immediate loading[42], 1 study the two types of loading[44] and 1 study did not report the type of loading[16].

The survival rate observed in the MI studies ranged from 89% to 100%, and 5 studies[14,29,37,38,41] did not presented results on survival. The survival rate of the NDI studies ranged from 85% to 100%. Only 1 study did not provide data on survival[26]. In the MI studies, a total of 1984 implants units were evaluated, 89 were lost. For the NDI studies 736 implants units were evaluated and 28 were lost. Studies evaluating the same sample at different times were counted only once[14,17,19,25,38,41,45].

The methodological quality of the studies was evaluated and classified separately, and the results are shown in Supplement 1. Of the 19 MI studies, 9 were classified as poor[9,15,18,29–33,39], 8 as fair[14,25,34–38,40] and 2 were classified as good[10,41]. Of the 11 NDI studies 3 were classified as poor[42–44], 5 were classified as fair[6,11,12,16,26] and 3 were classified as good[17,19,45]. The main problems found were the absence of information on i) distributions of major confounders in each group, ii) unplanned analyses and iii) adjustment for confounding factors in the analysis. The method for blinding patients and the main evaluations was not described in 90% of the studies, and the randomization

mode (occult or not) was not reported in 83.3% of the studies. Finally, the test's power to detect a clinically important effect was not described in 73.3 % of the studies.

Meta-analysis

This section reports the aggregated success and survival rates for the short term (G1) and long-term (G2) Mini Implant (MI) and Narrow Diameter Implant (NDI) groups. The associated 95% confidence interval is indicated between brackets. The MIG1 group showed a survival rate of 99% (98-100%). A similar survival rate of 99% (98 – 99%) was found in studies with higher follow-up times (MIG2). The compiled survival rate of the MI studies was 99% (99 - 100%; Figure 2a). The short-term NDI studies (NDIG1) yielded an average survival rate of 98% (95-100%), similar to the 98% (97-99%) survival rate of long-term NDIG2 studies. The compiled survival rate of the NDI studies was 98% (96-99%; Figure 2b).

The short-term MIG1 studies had a higher average success rate than the long-term MIG2 studies: 97% (95-99%) and 93% (84-100%), respectively. The compiled success rate of the MI studies was 95% (92-99%; Figure 2c). Similarly, the short-term success rate of the NDIG1 group at 99% (98-100%) was higher than the long-term success rate (NDIG2) of 95% (91-98%). The average success rate of all NDI studies was 98% (96-99%; Figure 2d).

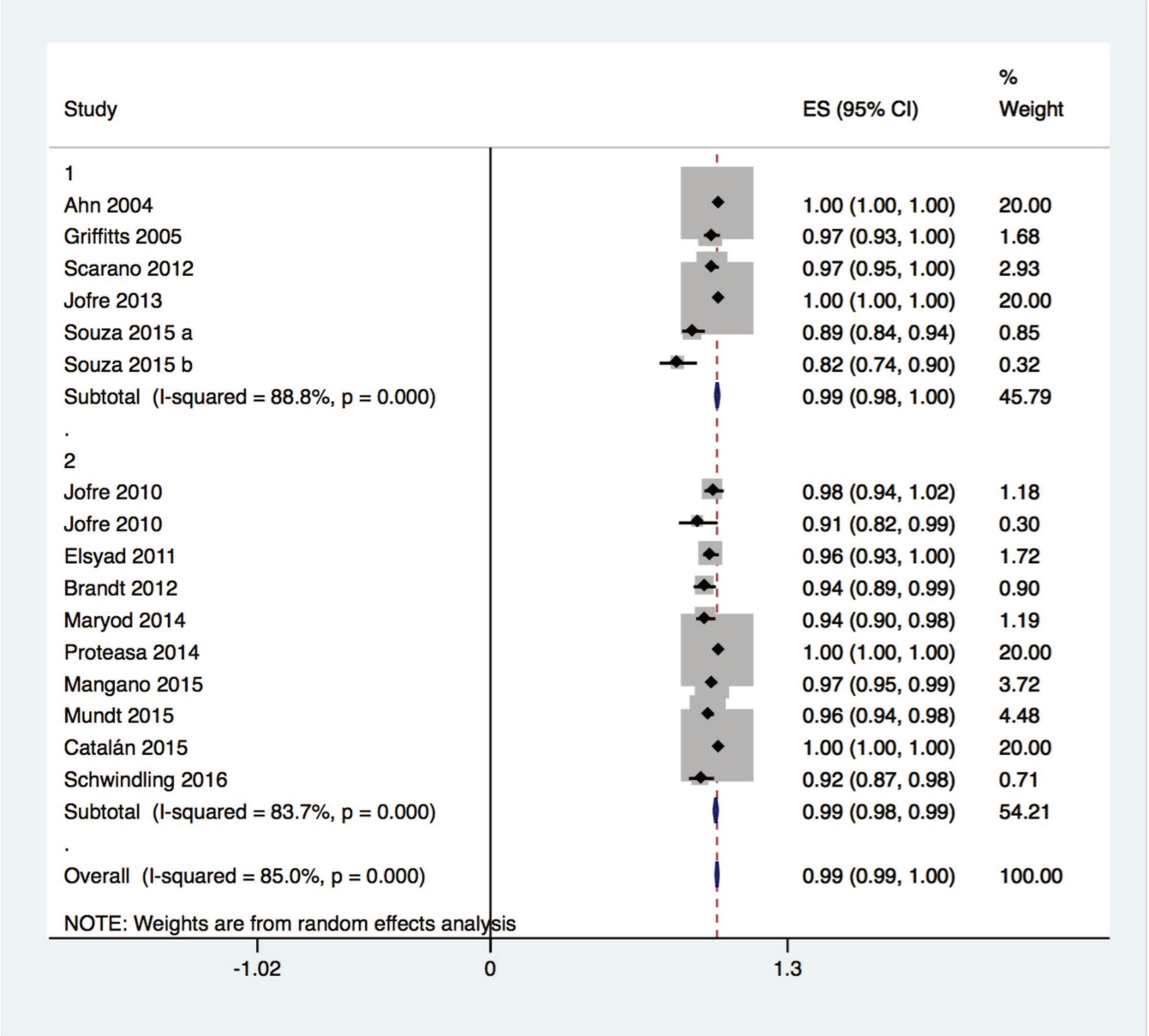

Figure 2.a) Survival rates of the MI studies. MIG1: ≤1 year follow-up; MIG2: >1 year follow-up.

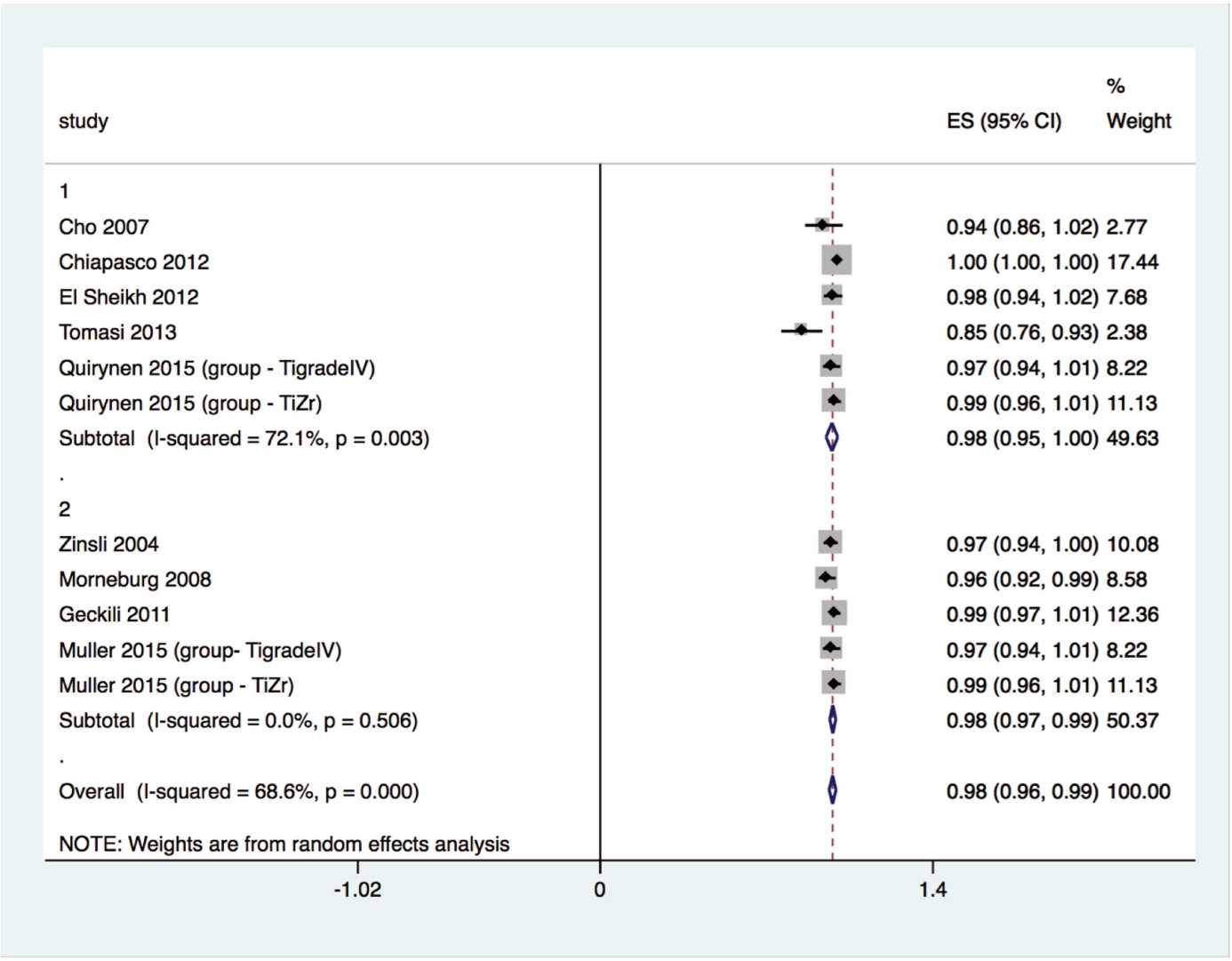

Figure 2.b) Survival rates of the NDI studies. NDIG1: ≤4 years follow-up; NDIG2: ≥5 years follow-up.

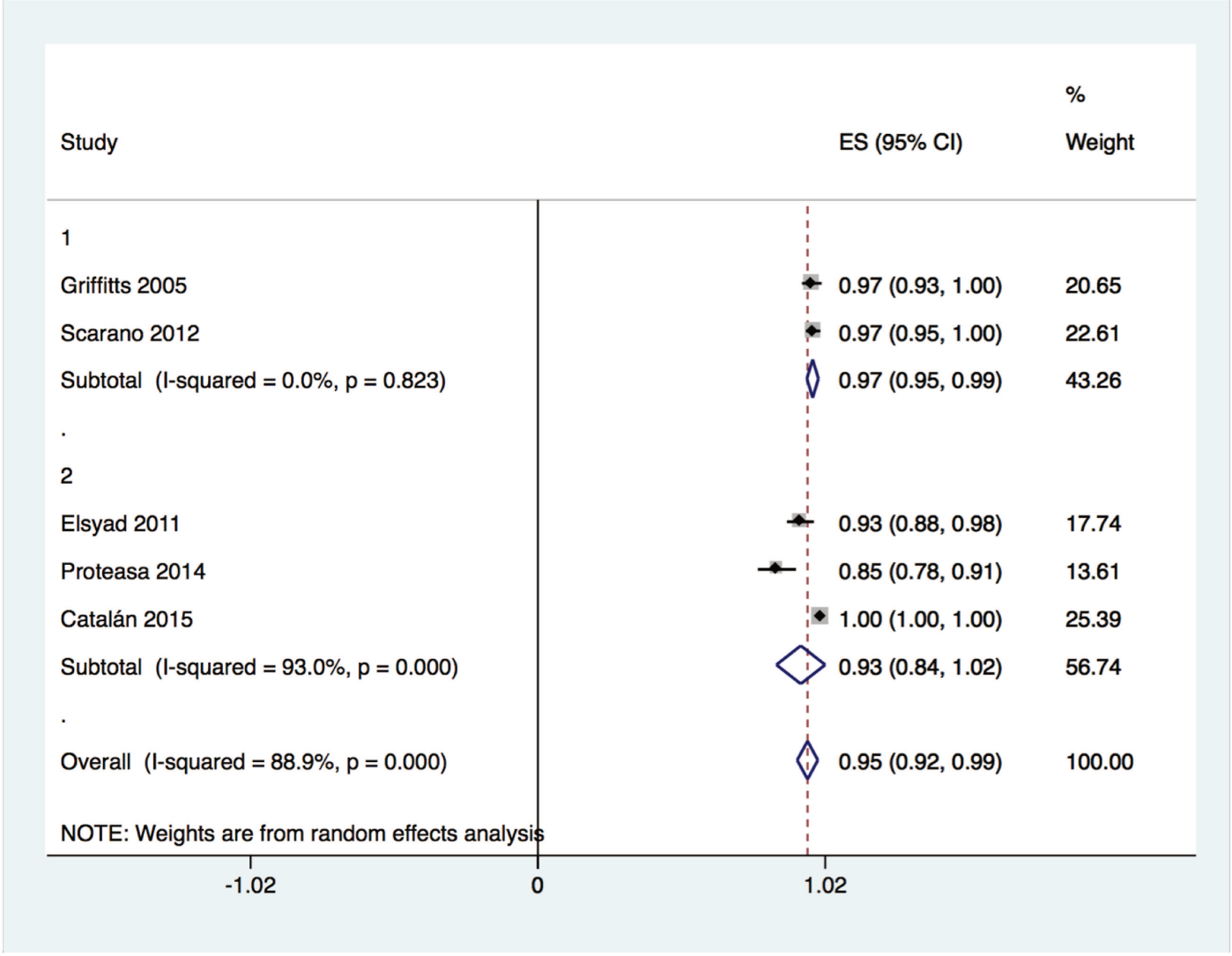

Figure 2.c) Success rates of the MI studies. MIG1: ≤1 year follow-up; MIG2: >1 year follow-up.

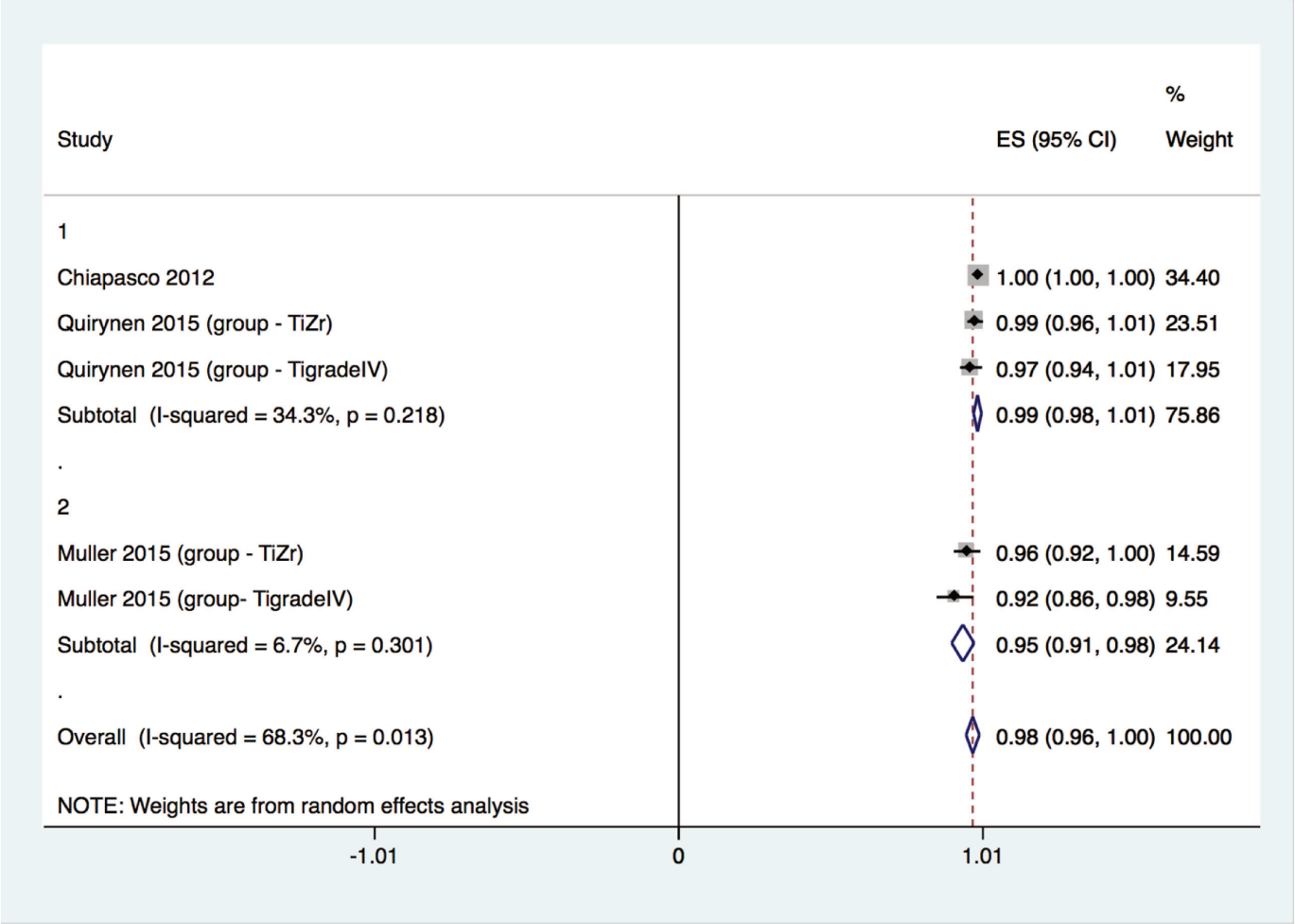

Figure 2.d) Success rates of the NDI studies. NDIG1: ≤4 years follow-up; NDIG2: ≥5 years follow-up.

To perform the meta-analysis of marginal bone loss of MI and NDI, the studies were grouped according to the follow-up period: ≤12 months, 12-24 months and ≥36 months (Figures 3 and 4). The MI studies with follow-up times up to 12 months showed an average marginal bone loss of 0.89 mm (0.55-1.24 mm; Figure 3a). The MI studies with 12 to 24-month follow-up times had an average marginal bone loss of 1.18 mm (1.04-1.33 mm; Figure 3b). The MI studies with follow-up times ≥36 months had an average marginal bone loss of 1.02 mm (0.62-1.42 mm; Figure 3c). The NDI studies with follow-up times up to 12 months showed an average marginal bone loss of 0.18 mm (0.20-0.57mm; Figure 4a). The NDI studies with follow-up times of 12 to 24 months showed a marginal bone loss average of 0.12 mm (0.36-0.60 mm; Figure 4b). The NDI studies with ≥36 months follow-up had an average marginal bone loss of -0.32 mm (-1.29 - 0.64 mm; Figure 4c).

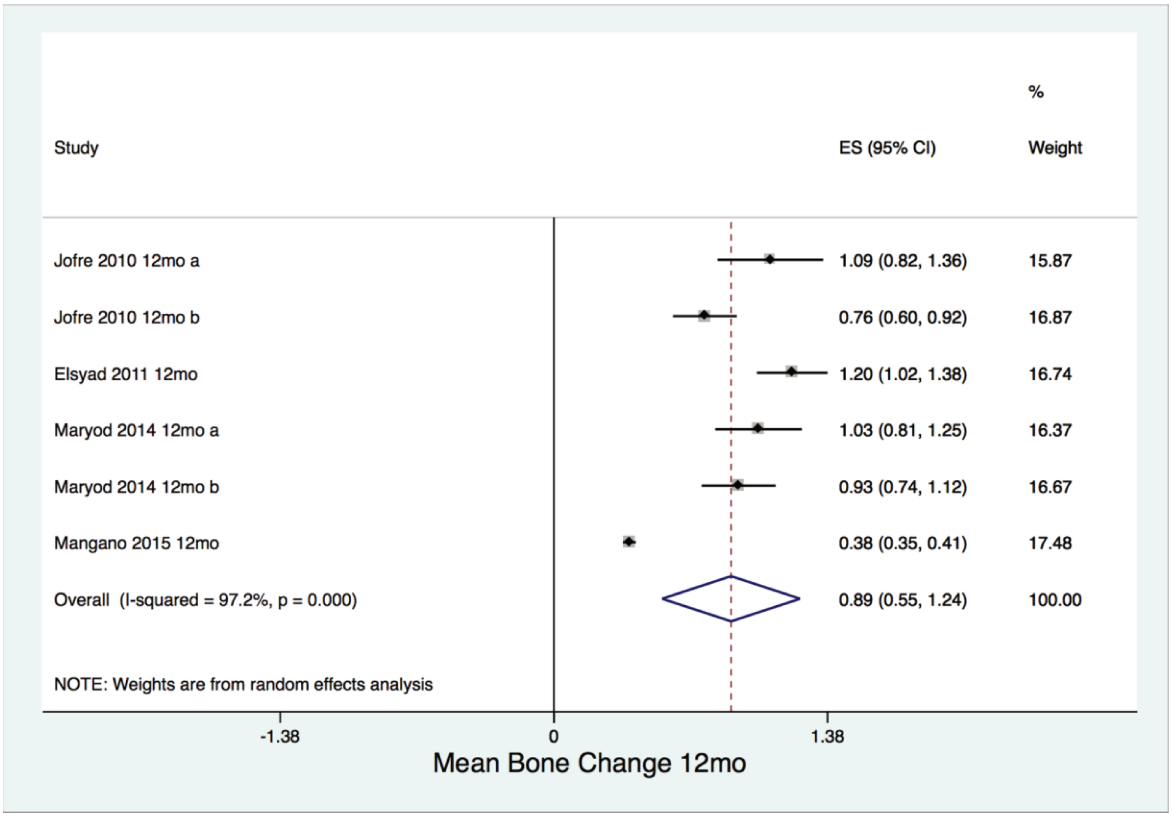

Figure 3. a) Marginal bone loss in MI studies until 1year follow-up.

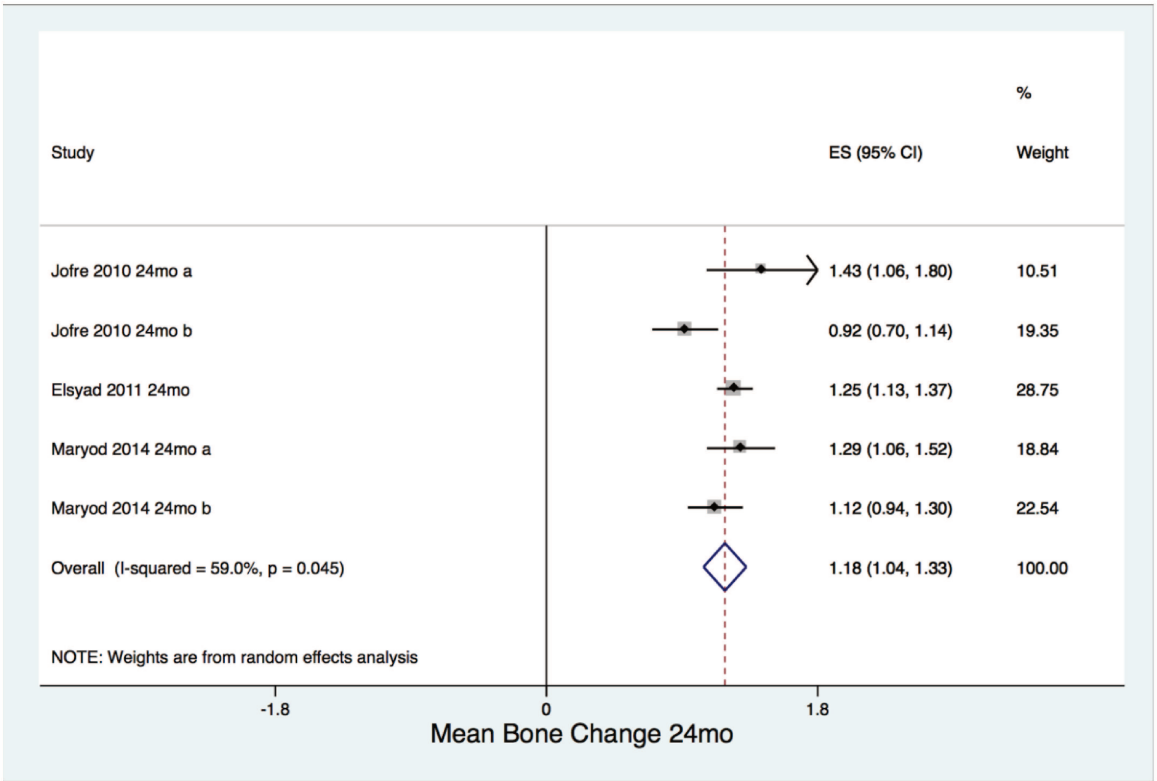

Figure 3.b) Marginal bone loss in MI studies until 2 years follow-up.

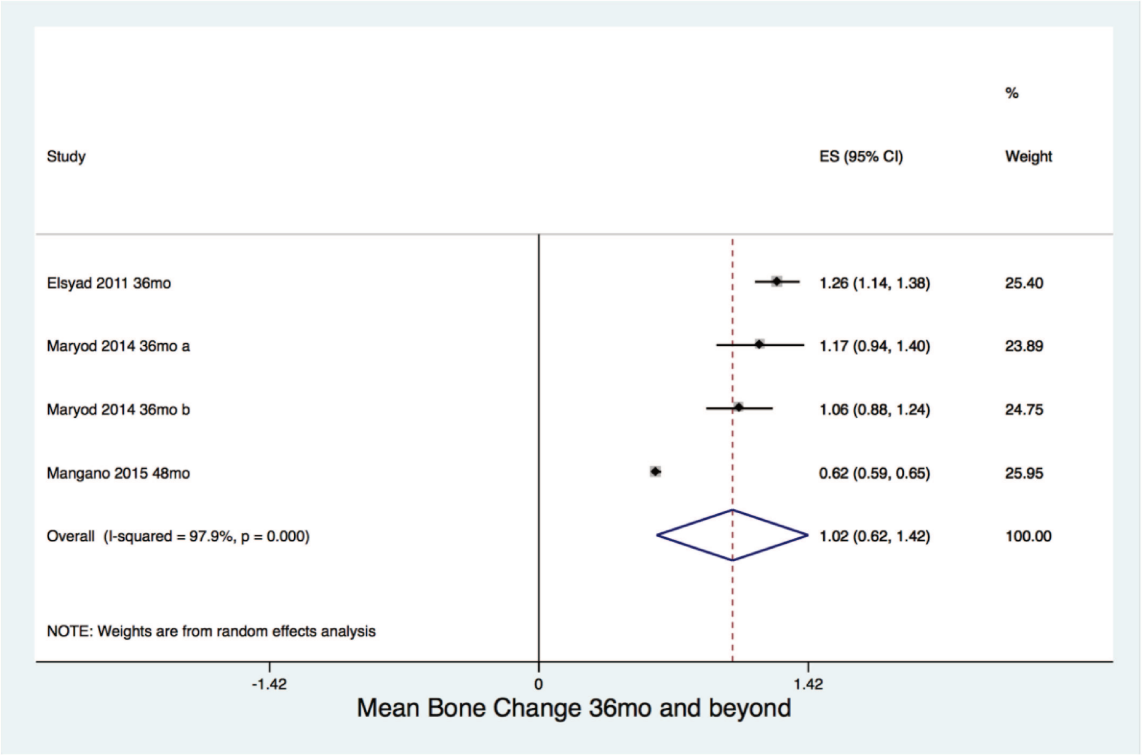

Figure 3.c) Marginal bone loss for MI studies after 3 years follow-up.

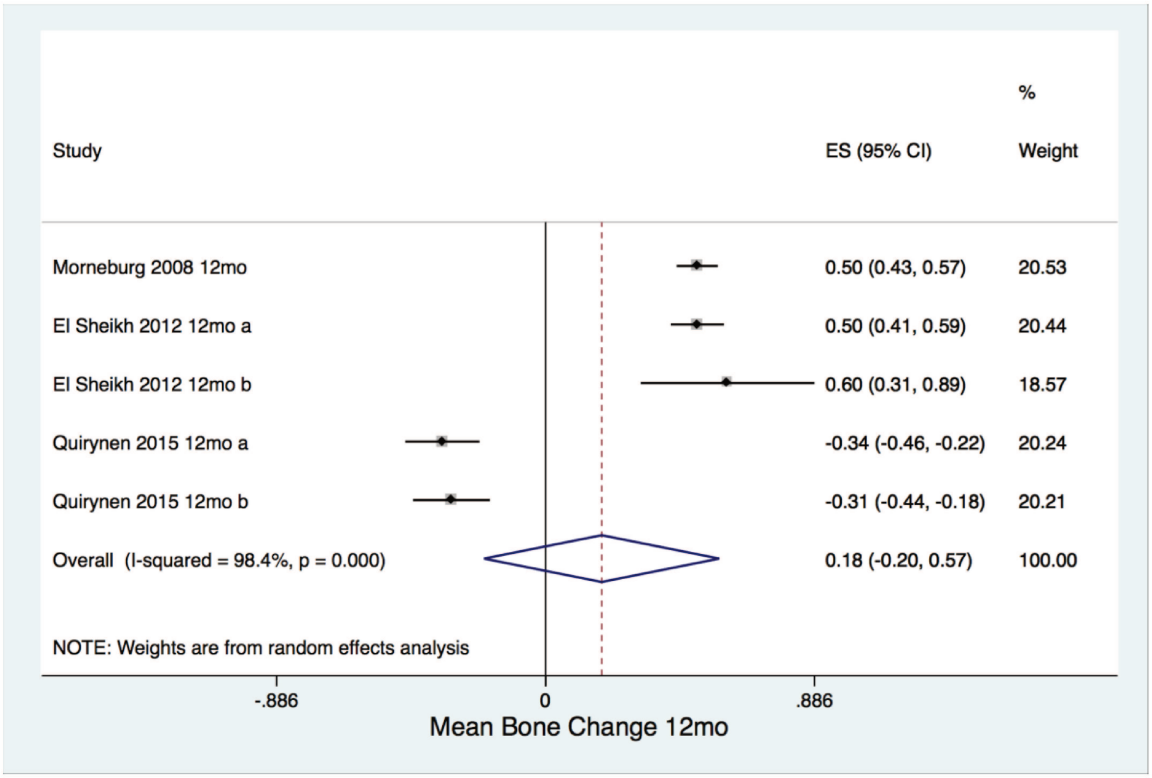

Figure 4.a) Marginal bone loss for NDI studies until 1year follow-up.

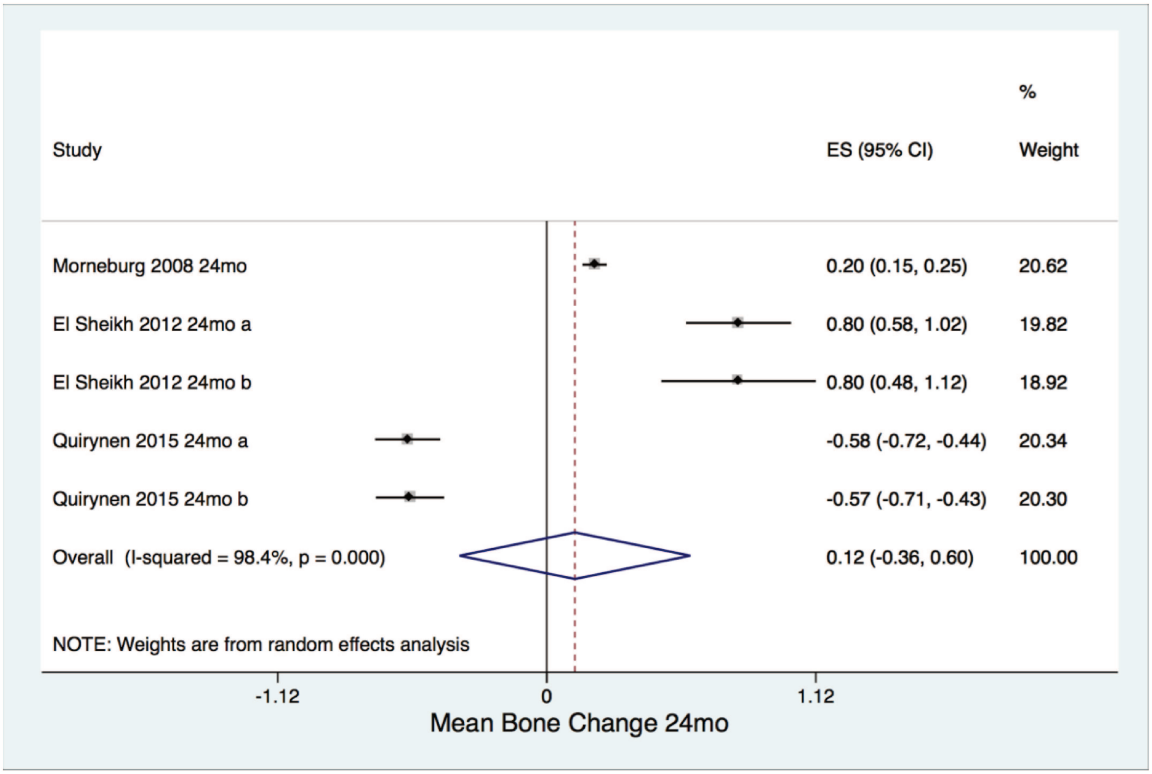

Figure 4.b) Marginal bone loss for NDI studies until 2 years follow-up.

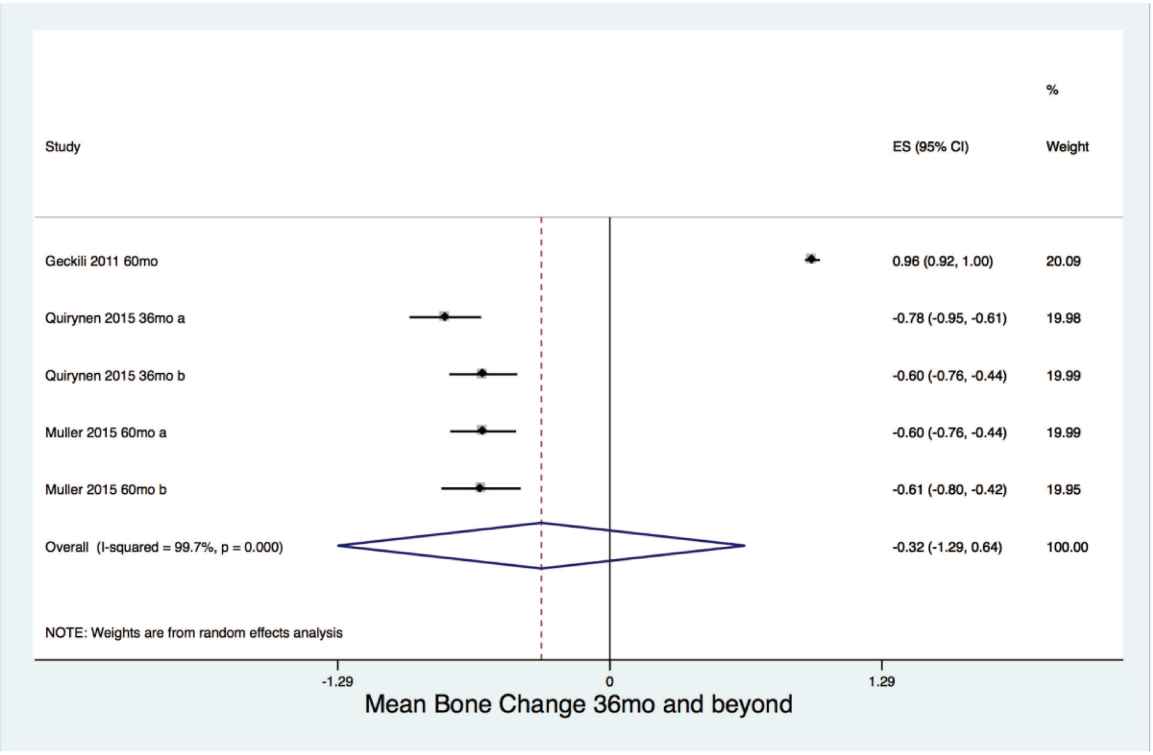

Figure 4.c) Marginal bone loss for NDI studies after 3 years follow-up.

DISCUSSION

This review was designed to meta-analyze studies that evaluated the clinical behavior of MI and NDI as mandibular overdenture retainers. It expands on previous reviews[20,5,21] by analyzing a specific population, and by describing the implant performance according to the prosthesis type (MI versus NDI). The previously reported outcomes are restricted to the predictability evaluated by the survival rate or their success compared to SDI. In this study, we also meta-analyze the peri-implant bone loss over time for MIs and NDIs, since this provides crucial information on the long-term clinical behavior. This aims to improve the clinical understanding of MI and NDI implants as mandibular overdenture retainers, to support the clinician in planning and selecting the implant type and the rehabilitation method.

Among the 19 MI studies included in this review, 14 report survival rates for follow-up times between 5 months and 7 years. Our meta-analysis found survival and success rates for MI similar to those of SDI[46,47]. This corroborates the results of de Souza et al., 2015[10], who stated that the MI can achieve at least similar results as SDI, while 4 MI as retainers can obtain a higher survival rate, probably due to biomechanical reasons. Factors such as the number of implants can thus also interfere in the implant performance. The downside of increasing the number of retaining implants is an increase in pain sensation, which is independent of the implant diameter[41]. Finally, the loading type may also influence the rehabilitation success. Therefore, Maryod et al., 2014[18] suggested that the conventional loading is preferred over immediate loading in these cases, due to most favorable peri-implant tissues responses during the healing time can be favored by the relining of the prostheses prior to loading[18]. We highlight that it was possible to observe from the studies included in this review that the majority of the studies using MI adopted the immediate loading while most of the studies reporting NDI results used conventional loading. Thus, from these meta-analyzes, we observed that the conventional loading is preferential due to the better performance of the NDI studies in

the success and marginal bone loss outcomes. The greater failure and fracture risk can also affect success and survival rates for MI and NDI. The latter is probably due to their smaller surface area in contact with the bone tissue and reduced mechanical stability thus increasing the risk of overload [48]. Because of these risks, MI and NDI are preferably used only in cases with space problems or in cases with reduced ridge thickness[6,7,43]. The meta-analysis of the NDI studies revealed an aggregated survival rate of 98%, similar to the equivalent for SDI studies: 96.7%[46] and 99%[10]. The NDI success percentages are well above the success criterion established by Albrektsson et al., 1986[22], which is 85% for follow-up periods up to 5 years and 80% for a follow-up period up to 10 years.

The aggregated survival rates of NDI studies with follow-up periods greater than five years was 3% higher than the success rate for the same follow-up period. Conversely, the NDI survival rate was 1% lower than the success rate for the studies with follow-up periods less than 5 years. In this way, we can observe that with the time passage the implants success rate tends to decrease. El-Sheikh et al., 2012[6], performed a study with overdentures retained by 2 or 3 NDI, with 2 years follow-up and found a survival rate of 98%. Thus, two NDI as mandibular overdenture retainers in the anterior region are sufficient to ensure predictable rehabilitation, also in patients with atrophic jaws[6]. The reduced discomfort and pain associated with MI and NDI is an additional benefit. However, it should be noted that this reduced pain perception may be more associated with the reduced surgical step, because bone grafting is not required for installation of NDI and MI[30].

The marginal bone loss over time is another important factor that influences the predictability. Recently, Assaf et al., 2015[49] suggested that the implants predictability is not only related to its diameter, but also to marginal bone loss and this should be within the same limits as those reported for SDI. The acceptable bone loss established in literature is 2 mm in first year after SDI loading, followed by a maximum of 0.2 mm per year[23,24]. From our meta-analysis, taking in account the longest period, we observe that

MI showed changes in marginal bone loss of approximately 1.03 mm (0.55-1.42 mm), while the NDI showed greater variability (-1.29 – 0.64 mm) with an average near zero (-0.007 mm). Due to the variability in marginal bone loss results, the precision of the pooled estimates was affected resulting in broad 95%CI what can be observed by the amplitude of the diamond. It was not noted in the MI meta-analysis with follow-up times of 24 months (Figure 3b) which presented a more homogeneous diamond. Zweers et al., 2015[26] also suggested that during the first 3 years after prostheses installation, the NDI show higher bone loss than the SDI. Differently, our findings could reveal that the greater marginal bone loss was observed from the third year of the prosthesis loading.

Most of the included MI studies (83.3%) provide little information to assess the risk of bias. The majority of MI studies (n=9)[9,15,18,29–33,39] were classified as poor due to inadequate details reporting such as randomization, blinding, sample size calculation, external validity and confounders. None were classified as excellent and only 5 out of 30[10,17,19,41,45] were classified as good. The NDI studies have been reported in more detail, so there was proportionately a greater number of studies classified as fair (n=5)[6,11,12,16,26] and good (n=3)[17,19,45].

CONCLUSIONS

Although the included studies were very heterogenic, meta-analysis could be performed regarding the survival and success rates, and marginal bone loss. MI or NDI showed a good clinical behavior as overdenture retainers. The NDI presented a better long-term predictability than the MI when conventional loading is applied.

Disclosure Statement

The authors declare no potential conflicts of interest with regard to the authorship and / or publication of this article.

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Table 1: Summary of the analyzed mini implant studies (n=19). Abbreviations: Average Age (AA), Complete Denture (CD), Calculus index (CI), Gingival index (GI), Marginal bone loss (MBL), Mini implants (MI), Mandibular Overdenture (MO), Narrow diameter implants (NDI), Probing depth (PD), Plaque index (PI), Sulcus Bleeding index (SBI), Standard Implant (SI), Conventional loading (CL), Immediate loading (IL), Prospective Longitudinal (PL), Retrospective Longitudinal (RL), Cross-sectional (CS), Retention (R), Chewing Ability (CA), Satisfaction (SA), Fixed prosthesis (FP).

Autors/ Year/ Country/ Type of study	**Sample (Average Age)**	**Type of implant (Total number / Brand / Dimensions /nº per prosthesis)**	**Loading Type**	**Follow-up (w, weeks; m, months; y, years)**	**Outcomes**	**Success rate**	**Survival rate**	**Marginal Bone Loss (MBL)**	**Main results**
Ahn et al. 2004[32] Republic of Korea PL	4/7 (AA=52.9)	25 IMTEC Sendax MDI System (IMTEC Corp., Oklahoma, USA) 1.8mm x 13 to 18mm 2 mini drive-lock implants (Intra-Lock International Inc., FL) - 2.0mm x 13 to 18mm 2 to 4 MI per prosthesis	IL	12 - 36 weeks Mean = 21 w	- SA Discomfort - Bone resorption	X	100%	X	Complete SA, no pain or discomfort No bone resorption
Griffitts et al. 2005[9] USA PL	24	120 IMTEC Sendax MDI System 1.8 x 10 to 18mm 4 MIs per prosthesis	IL	5 m	-Questionnaire: comfort, RE, CA and speaking ability) - Costs MI X SI - Survival rate	97.4%	97.4%	X	RE had greatest improvement, followed by comfort, CA and speaking ability Total costs MI=$262 X SI=924
Jofre et al. 2009[25] Chile RCT	23 GI- bar (AA=73) 22 GII- ball (AA=69)	90 IMTEC Sendax MDI System, - 1.8 x 15mm	IL	2 y		X	GI= 97.8% GII= 90.9%	X	2 patients were lost 1 implant failed (1/46) in GI 4 implants failed (4/44) in GII
Jofre et al. 2010[38] Chile RCT	22 GI- ball (AA=69) 23 GII- bar (AA=73)		IL	15 m, Intervals: baseline (b), 5 m, 7 m ,10 m and 15 m	- Maximal bite force (mBF) - MBL	X	X	GI: b=0.28±0.27 5 m=0.89±0.57 7 m=0.98±0.65 10 m=1.30±0.99 15 m=1.40±1.02 GII: b=0.24±0.17 5 m=0.50±0.53 7 m=0.65±0.56 10 m=0.80±0.63 15 m=0.84±0.66	mBF increase over time in both groups After 10 m a tendency towards stabilization MBL was higher in GI, and significant differences described only at 5 m

Jofre et al. 2010[14] Chile RCT	22 G-ball (AA=69) 23 G-bar (AA=73)	90 IMTEC Sendax MDI System 1.8 x 15mm	IL	2 y, Intervals: baseline (b), 5 m, 7 m ,10 m , 15 m and 20 m	- MBL - Bone Loss Morphology (BLM)	X	X	GI (ball): b=0.30±0.30 5 m=0.90±0.75 10 m=1.09±0.91 15 m=1.34±1.32 24 m=1.43±1.26 GII (bar): b=0.21±0.24 5 m=0.55±0.59 10 m=0.76±0.55 15 m=0.80±0.58 24 m=0.92±0.75	No differences in MBL, except at the 15m BLM showed difference between groups G-ball: 51% of the MI showed vertical BLM and 49% showed horizontal BLM bone loss G-bar: 29% of the MI vertical BLM and 71% showed horizontal BLM
Preoteasa et al. 2010[29] Romania CS	12/12 (AA= 61)	69 IMTEC Sendax MDI System 1.8 mm, 2.1 mm and 2.4 mm x 13 mm 4 or 6 4 MIs per prosthesis	IL/CL	-	- Alveolar mucosa status - Bone availability - MI characteristics - Insertion torque - Loading type	X	X	X	33 MI (55%) in the anterior region of the mandible Average bone's height=19.63mm MI's diameter= 1.8(5.26%), 2.1(42.1%), 2.4(52.64%) Frequent poorly ridge width (4.95 mm) Density (D): D4- 57.89%, D3- 5.7%, D2- 36.84% Insertion torque: D2=over 40Ncm, D3=30Ncm or 35 Ncm, D4= below 30Ncm. IL in 20.5% (24 MI)
Elsyad et al. 2011[15] Egypt PL	16/12 (AA=62.9)	112 Sandblasted acid-etched 1.8 x 12- to 18-mm length 4 MIs per prosthesis	IL	3 y, Intervals: baseline (T0), T1 - 6 m, T2 - 12 m, T3 - 24 m, T4 - 36 m	- PI, GI. PD - Implant stability: Periotest values (PTVs) - MBL: Vertical bone loos (VBLO); Horizontal bone loss (HBLO)	92.9%	96.4%	VBLO: T0=0 T1=0.71±1.0 T2=1.2±0.96 T3=1.25±0.64 T4=1.26±0.64 HBLO: T0=0 T1=0.46±0.35 T2=0.62±0.42 T3=0.64±0.49 T4=0.74±0.57	Improvement in RE, stability and CA PI and GI increased significantly between T0 -T1 and T0 -T2 Significant increase in PDs at T1 and T2 No significant differences in PTVs. MBL= 3.6 at T0 and -4.2 at T4 VBLO and HBLO significantly increased at T1 and T2 compared to T0, at T2, T3 and T4
Brandt et al. 2012[33] USA PL	24 Age range= 35 to 70	96 Acid-etched titanium grade MI (Intra-Lock International Inc, Boca Raton, Florida, USA) 2.0 x 10mm, 11.5mm, 13mm, 15mm, and 18mm 4 MIs per prosthesis	IL	24 m, Intervals: 3 m, 6 m, 12 m and 24 m	- SA questionnaire - Survival rate	X	93.75%	X	SA improvement after implants (baseline score = 3.8) 6 implants lost

Scarano et al. 2012[39] Italy RCT	38 (AA=69)	152 M.I.B. Mini-Implant Ball (Anthogyr, Sallanches, France) 2,6 x 10 to 13 mm 4 MIs per prosthesis	IL	5 m	- Questionnaire (comfort, RE, CA and speaking ability) - SA	97.4%	97.4%	X	RE, comfort CA and speaking ability improved Subjective measures: Highly levels of SA
Jofre et al. 2013[40] Chile RCT	BarG= 15 (AA=75.3) CDG= 15 (AA=75.5)	30 Sand-blasted treated surfaces - IMTEC Sendax MDI System - 1.8 x 15 mm 2 MIs per prosthesis	IL	12 m OHIP-EDENT: before and after 12m; Others outcomes: 24 hours, 7days, every 3 m and at 12 m	- OHIP-EDENT - Incidence of infection and implant failure - Presence of signs and symptoms of peri-implantitis and mucositis	X	100%	X	The OHIP-EDENT total score improved in the BarG showing differences between groups at 12m 1 patient reported slight soft tissue swelling
Maryod et al. 2014[18] Egypt PL	IL = 10/8 (AA=63.4) CL=10/8 (AA=64.8)	120 O-ring system (3M ESPE, St Paul, MN, USA) 1.8 x 15 mm 4 MIs per prosthesis	IL/CL	36 m, Intervals: 6 m, 12 m, 24 m and 36 m	- PI, SBI, PD - MBL	X	IL= 91.7% CL= 96.7% overall 94.2%	IL Group: T6=0.73±0.45 T12=1.03±0.61 T24=1.29±0.63 T36=1.17±0.65 CL Group: T6=0.37±0.18 T12=0.93±0.52 T24=1.12±0.51 T36=1.06±0.49	PI, SBI, and MBL increased over the time PD increased at 1 year and decreased thereafter IL had higher PI, BI, and PD than CL only at T6 and T12 MBL of IL higher than CL only at T6
Preoteasa et al. 2014[34] Romania PL	10/13 (AA= 62)	110 IMTEC Sendax MDI System (3M ESPE, Saint Paul, MN, USA): 74 in the mandible 1.8, 2.1, and 2.4 x 10, 13, 15, and 18 mm 4 to 6 MIs per prosthesis	x	3 y, Intervals: baseline, weekly during 1 m, 3 m, 6 m, 1 y, 2 y and 3 y	-Bone height, ridge width, bone density -Number, locations, length and diameter of MI -Insertion torque - Implant health, MBL Implant mobility, self-reported peri-implant bleeding, radiolucency at the apical part of the implant - Repair or maintenance of the CD - SA/dissatisfaction - Easy using of MI	85%	92.7% Mandible: 100%	X	11 MI satisfactory survival, 63 MI had success Complications: - MBL: 23 MI had 1-2 threads, 7 had a 2-3 threads, 4 had a >3 threads. 16 MI had apical radiolucency, 23 bleeding during brushing and 12 bleeding spontaneous Severe MBL more related to women, patients with decreased ridge width, sites with decreased bone density, implants with lower insertion torque values, MIs placed toward the midline General satisfaction: esthetics, RE, and functionality. Complaints: occasional pain, 6 patients reported difficulties related to use, MO removal was perceived by 16 patients being more difficult than MO insertion Cleaning of the MO described as easy

Mangano et al. 2015[35] Italy PL	38/24 (AA= 71.1)	231 Direct metal laser sintering (DMLS) 2.7 and 3.2 x 10, 11.5, and 13 mm 3 to 4 MIs per prosthesis	IL	2.7 y (Average time for patients)	- Implant failure - MBL - Complications	X	96.9%	G 2.7mm: 1y=0.45±0.31 4y=0.62±0.23 G 3.2mm: 1y=0.36±0.22 4y=0.62±0.19 3 implants OD: 1y= 0.44±0.32 4y= 0.64±0.24 4 implants OD: 1y=0.37±0.22 4y=0.61±0.22 Overall: 1y=0.38±0.25 4y=0.62±0.20	Bone level differences between 1-4 y No differences in crestal bone resorption according to diameter and different MO 6.1% biologic complications, 3.7% MOs cracked or fractured dentures, 9.3% loose or lost denture teeth Prosthetic maintenance required every 18m including relining of 11.1%
Mundt et al. 2015[30] Germany RL	54/79 (AA=71.2)	402 MDI (3M ESPE, Seefeld, Germany) 1.8 and 2.1 x 10, 13, 15 and 18 mm (O-ball attachment) 3, 4, 5 or 6 MIs in the mandible	CL	Mean observation: 29.4 ±13.1 m (range 7.2–61.6 m)	- Clinical examination - Questionnaires: OHIP-14 and QoL - Surgical complications - Prosthetic status and complications	X	95.7%	X	11 implants removed after insertion, 10 lost during first year. 2 implants fractured during insertion and 2 after placement, 9 implants replaced All original dentures remained functional RE rated as very high in 8 MO, fair in 84 MO and low in 3 MO 3 MO reinforced with a cast metal base 77 participants no prosthetic aftercare was required, only 3 prosthetic interventions Improvements for the participant ratings in all single questions for OHRQoL post-implant placement.
Ribeiro et al. 2015[41] Brazil RCT	39/81 (AA=59.5)	236 Mini-Drive Lock MDL (Intra- lock International)) 2.0x 10.0 mm 80 SI Morse-Lock Straight 4.0 (Intra-lock International) 4.0 x 10.0 mm GI 4 MI: 38 patients GII 2 MI: 42 patients GIII 2 SI: 40 patients	CL	7 days	-Questionnaire related to following criteria: pain, swelling, discomfort with chewing, speech and hygiene	X	X	X	At 6th day, GI felt higher pain than GII and GIII. GI reported more difficulty in performing oral hygiene practices than GIII during the 1st day No significant difference between groups for the other questions and periods

Souza et al. 2015[10] Brazil RCT	39/81 (AA=59.5)	236 Mini-Drive Lock MDL (Intra- lock International)) 2.0x 10.0 mm 80 SI Morse-Lock Straight 4.0 (Intra- lock International) 4.0 x 10.0 mm GI 4 MI: 38 patients GII 2 MI: 42 patients GIII 2 SI: 40 patients	CL	12 m, Intervals: 3 m, 6m and 12m	- OHIP-EDENT - SA - Implant survival - Complications - PD, SDI, PI and CI	X	GI= 89% GII= 82% GIII= 99%	X	Failed osseointegration (GI and II, n = 1), dissatisfaction (GII, n = 2; GIII, n = 3) Groups were different following treatment for OHRQoL with increased scores at 12 m OHIP-EDENT scores lower for GI and II SA and general CA ratings higher for treatment with 4 MI Tested treatment exerted a similar effect for speaking, comfort, and aesthetics MI were successfully replaced in 2 participants in GI and 7 participants in GII 4 MO fractured between 6 and 12m following insertion of matrices GI and II presented lower PI compared with GIII at the time of MO insertion and following 6 and 12m Peri-implant mucosal pain lower for GI at the 6m, as well as the number of substituted matrices after 12m Number of changed matrices in the GIII, nylon matrices used in GIII seem more severely worn than O-rings used for MI
Catalán et al. 2015[36] Chile PL	7	14 IMTEC Sendax MDI System (3M ESPE, Saint Paul, MN, USA) 1.8 x 13 or 15 mm 2 MIs per prosthesis	IL	7 y, Intervals: 1 m, 6 m, 2 y, 3 y, 5 y and 7 y	- RE, Stability, SA, CA - Presence of “clack” sounds - Presence of pain or/and check-biting - Limitations on diets - Presence of masticatory muscular fatigue - Difficulty in swallowing - Esthetic appearance - Social interactions and individual mood - Quality of life - Status of the peri-implant mucosa	100%	100%	X	Higher values of retention for MO. No differences between values post connection. SA level increased post-connection. Peri-implant mucosa showed no pathological changes for all patients

Elsyad et al. 2016[47] Egypt PL	16/12 (AA=62.9)	112 IMTEC Sendax MDI System (3M ESPE, Saint Paul, MN, USA) 1.8 x 12–18 mm 4 MIs per prosthesis	IL	5 y, Intervals: 6m, 1 y, 3 y, and 5 y	- SA (questionnaire and a visual analogue scale - VAS) - Complications	X	X	X	SA with eating, talking, appearance, comfort, healing process, socialization, stability/RE, ease of oral hygiene, and ease of handling the OM increased over the time After 5 y, the most common complication was wear/damage of O/rings, O/ring replacement, worn teeth, MO relines, detachment of the metal housings, and fracture of MO) Mucositis, soreness, and ulcer under MO occurred most often at 6m and decreased with time
Schwindling et al. 2016[31] Germany Luxembourg RL	17/8 (AA=72)	91 MDI (3M ESPE, Seefeld, Germany) 1.8, 2.1 and 2.4 x 10, 13, 15 and 18 mm	IL	7 y (mean observation time= 33 m)	- Implant survival - Complications and maintenance	X	92%	X	Complications: Relining=56%, Exchange of rings=20%, Denture base fracture= 24%, Resin tooth fracture=4% Repeated relining= 16%, multiple maintenance sessions=32% 8 MIs losses (mean time to implant exfoliation = 9.7 w)

Table 2: Summary of the analyzed narrow diameter implant studies (n=11). Abbreviations: Average Age (AA), Complete Denture (CD), Calculus index (CI), Gingival index (GI), Marginal bone loss (MBL), Mini implants (MI), Mandibular Overdenture (MO), Narrow diameter implants (NDI), Probing depth (PD), Plaque index (PI), Sulcus Bleeding index (SBI), Standard Implant (SI), Conventional loading (CL), Immediate loading (IL), Prospective Longitudinal (PL), Retrospective Longitudinal (RL), Retention (R), Chewing Ability (CA), Satisfaction (SA), Fixed prosthesis (FP).

Autor/ Year/ Country/ Type of study	Sample (Average Age)	Type of implant (Total number / Brand/ Dimensions / nº per MO)	Loading Type	Follow-up (w, weeks; m, months; y, years)	Outcomes	Success rate	Survivalrate	Marginal Bone Loss	Main results
Zinsli et al. 2004[43] Switzerland PL	50/104 (AA=62)	131 (Straumann, Waldenburg, Switzerland) 3.3 x 8 or 10 or 12 mm 2 NDI per MO	CL	10 y (annual recall)	- Successful osseointegration - Recurrent peri-implant infection with successful treatment - Implant failure related to untreatable infection Implant failure related to mobility or caused by fracture - Complications with implant components and anchorage structure - Repairs of fractured prostheses - Redesign of prostheses adjustments	X	96.6% (overall)	X	3 implants removed during the healing phase 3 implants failed during the healing phase 3 implants anchoring MO failed (peri-implant infection) at 7, 63 and 81m Redesign of 2 MO for esthetic reasons
Cho et al. 2007[42] USA RL	3/7 (AA=58.25)	34 (Dentatus Atlas*, NY, USA) 2.4mm, length not described 2 or 4 NDI per MO	IL	2004 - 2007 Mean time supporting MO = 22.8 m	- Subjective evaluation: Patient SA questionnaire (PSQ)	X	94.1%	X	MO improvements related to function, stability, comfort, fitness, occlusion, satisfaction, speech, social life compared to CD
Morneburg and Pröschel 2008[11] Germany PL	67 (AA=69)	134 (MicroPlant; Komet Brasseler Group, Lemgo, Germany) 2.5 x 9 or 12 or 15mm 2 NDI per MO	CL	9 y, Intervals: i) after surgery: 3 and 7 days; 3, and 8 w, 4 m ii) after uncovering implants: 14 days, 8 w, 6 m, and regularly every 6 m	- Periotest value - GI - Attachment level - MBL measured using panoramic radiographs - SA	X	95.5%	1 y = 0.5±0.4 2 y = 0.2±0.3	Mean GI=0.4±0.4, with a maximum score=2 2 patients with purulent inflammations or signs of peri-implantitis, who experienced implant loss after the 4 and 6 y Mean loss attachment height = 1mm within first 2 y SA and CA increased significantly after stabilization of the implants

Geckili et al. 2011[16] Turkey RL	30/41 (AA=52)	159 (mandible: 55 anterior, 33 posterior; 32 retaining MO) GA – 49 NDI 3.3mm (Straumann, Institute Straumann, Waldenburg, Switzerland). GB- 42 NDI 3.5mm, (Osseospeed, Astra Tech, Molndal, Sweden). GC- 37 NDI 3.45-mm (Silhouette LaserLok, Biolok International Inc, Deerfield Beach, Fla). GD- 32 NDI 3.4mm (Xive, Dentsply-Friadent, Mannheim, Germany) 3.4-mm Implants length and number of implants per MO not described	x	5 y after prosthetic loading	- Implant survival: absence of clinical mobility; absence of peri-implant radiolucency; absence of painful symptoms or paresthesia; absence of progressive MBL	X	98.7%	Anterior mandible: Distal= 1.00±0.19 Mesial= 0.96±0.17 Implant Brands GA Distal= 0.99±0.23 Mesial= 0.96±0.23 GB Distal= 0.94±0.21 Mesial= 0.93±0.20 GC Distal= 1.09±0.18 Mesial= 1.06±0.19 GD Distal= 1.01±0.19 Mesial= 0.99±0.16	No statistically significant relationship between MBL and gender Type of prosthesis (MO or FP) did not affect MBL rates No significant relationship between NDIs location and MBL (posterior mandible) No correlation between MBL and NDI length MBL around implant C higher than around implant B No significant relationship detected between MBL of other implant brands
Al-Nawas et al. 2012[17] Germany Italy Belgium Netherlands Switzerland RCT double-blind	89 (AA=65.8)	178 Bone level (Straumann AG, Basel, Switzerland) – 89 Roxolid ® (TiZr) x 89 Ti Grade IV (TiIV) 3.3X 8, 10, 12 and 14 mm 2 NDI per MO	CL	6m and 12 m	- MBL - PI - SBI - Survival rate - Success rate	TiZr: 96.6% Ti IV: 94.4%	TiZr: 98.9% Ti IV: 97.8%	12m TiZr= - 0,34±0.54 Ti IV= -0.31±0.56 The first 6m TiZr = -0.23±0.35 Ti IV= -0.23±0.40	Fair and poor hygiene: 9% of the group TiZr and 13.5% of the group Ti grade IV MBL 12m post-surgery was not significant different between the groups The most change in bone level occurred within the first 6m
Chiapasco et al. 2012[44] Italy PL	2/16 (AA= 58.5) 2 patients were rehabilitated with MO: both woman (AA=64.5)	51 Straumann Roxolid® (TL- Tissue Level and BL - Bone Level, Straumann AG, Basel, Switzerland) Mandible: 6 TL 2, 3.3 mm X 12mm 4, 3.3 mm X 8mm 2 or 4 NDI per MO	IL/CL	15 m for MO	- Successful implants - Survival rate - MBL - Implant-related complications - Prosthetic complications	100%	100%	X	0% of implant-related complications and prosthetic complications MBL values ranging from 0 to 1 mm at the end of the observation period

El Sheikh et al. 2012[6] Saudi Arabia PL	GA= 5/5 (AA=61.4) GB=6/4 (AA=58.9)	50 Bone level 3.3 X 10 to 14 mm GA=2 NDI GB=3 NDI	CL	2 y; Intervals: T0=baseline (b), T1= 6 m, T2= 12 m, T3= 24 m	- Implant lost number - PI, CI, GI, SBI, PD - MBL - Post insertion maintenance: any prosthodontic complications / interventions	X	98%	T0 - T1 GA=0.3±0.3 GB=0.4±0.3 T0 - T2 GA=0.5±0.2 GB=0.6±0.8 T0 - T3 GA=0.8±0.5 GB=0.8±0.9	No differences between means of the groups for the outcomes PI, CI, GI, BI and PD in the different periods No differences in MBL between both groups No differences for MBL between lateral and central implants in GB and no correlation between the radiographic findings and the peri-implant clinical parameters No loosening of the Locator attachments RE values increased after 12m in only 2 cases of GA One MO required relining in GA after 18 m
Tomasi et al. 2013[12] Sweden PL	9/12 (AA=71)	68 (Dentatus Atlas*) 4 NDI per MO (1 patient received 3 NDIs and 1 patient 2 NDIs)	CL	12 m, Intervals: baseline (b), 1 m and 12 m	- Degree of perceived SA (VAS) and yes/no questions) - PI, SBI, PD	X	85%	X	MO improved patients' perception of function and comfort All patients reported improved, chewing, and speaking comfort at the 1m Overall SA increased to 9.8 Significant improvement between baseline and 1m for all questions and VAS scale evaluations No significant changes were observed between 1m and 12 m examinations Clinical conditions of the implants at the 12 m revealed a subject PI mean of 20%, a SDI mean of 30% and a PD mean of 2.3 mm. All implants judged by clinical evaluation were stable
Quirynen et al. 2015[19] Belgium Germany Italy Netherlands Switzerland RCT double-blind	40/49 (AA=65.8) 75 patients completed 36-month follow-up	178 Bone Level (Straumann AG, Basel, Switzerland) 89 Roxolid® (TiZr) and 89 Ti Grade IV (Ti IV) 3.3x 8,10,12,14 mm 2 NDI per MO	CL	3 y, Intervals: 12 m, 24 m and 36 m	- MBL - PI, SBI - Survival rate - Success rate	TiZr: 98.7% Ti IV: 97.3%	TiZr: 98.7% Ti IV: 97.3%	12 m TiZr=-0.34±0.54 Ti IV=-0.31±0.56 24 m TiZr=-0.58± 0.60 Ti IV=-0.57±0.63 36 m Ti Zr=-0.78±0.75 Ti IV=-0.60± 0.71	3 patients dropped out before the 12m, 5 before 24m, and 8 before 36m 1 patient presented history of peri-implantitis for both implants at 12m and were considered unsuccessful, and at 24 m Ti–Zr implant continued to show peri-implantis. After 36m, no one implant in this patient showed detectable peri-implant infection with suppuration and most patients had a PI score of 0 or 1 and, SBI score of 0 9 cases of prosthesis fracture 5 cases presented minor inflammation during the healing process at the implant site

									5 cases with moderate peri-implant infection (5 5 cases presented tactile horizontal or vertical implant mobility 3 cases had loosening of a prosthetic component 3 cases needed prosthesis maintenance (repair of broken or lost matrix)
Muller et al. 2015[45] Belgium Germany Italy Netherlands Switzerland RCT double-blind	75 (at 60 months) 24/23 (AA=72)	150 - Bone Level Implants (Straumann AG, Basel, Switzerland), 75 Roxolid® (TiZr) and 75 Ti Grade IV (TiIV) 3.3x 8,10,12,14 mm 2 NDI per MO	CL	60 m, comparing results from 12 m, 24 m, 36 m	- Implant survival - Implant success - MBL - PI, SBI - Safety assessment: i) Adverse events (AEs) ii) Serious adverse events (SAEs)	TiZr: 95.8% Ti IV: 92.6%	TiZr: 98.9% Ti IV: 97.8%	60m TiZr=−0.60± 0.69 Ti IV=−0.61±0.83	MBL changes pronounced in the first years After 60m no significant differences in PI and SBI Most of the patients showed a PI score 0 or 1 and the same results were observed for the SBI 4 of the 49 patients (8.2 %) experienced AE during the observational period from 36m to 60m Implant success: 2 patients presented radiolucency around the implant and 1 patient had peri-implant infection, classified as AEs related to the study device 9 patients experienced an SAE between 36m and 60m after implant placement
Zweers et al. 2015[26] Netherlands RL	48/71(AA=69)	88 - SI 4.1 x 10, 12, 14 mm (Straumann) 150 - NDI 3.3 x 8,10,12, 14 mm (Straumann) 2 NDI per MO (64 - ball attachment and 55- locator)	CL	3 y (maintenance visits with radiographs taken at 1y and 3 y)	- Peri-implant conditions - PD - MBL - Prosthetic complications - Patient satisfaction	X	X	NDI - 3.3mm 1y=3.53±0.54 3y=3.84±0.49 MBL difference = 0.32±0.43 SI - 4.1mm 1y=3.59±0.55 3y=3.73±0.65 MBL difference = 0.14±0.50	No one implant was lost Prosthetic complication: healing abutment loosening (1%), loosening of the locator/ball attachment (0.4%) or wound healing (0.8%) Average PD decrease from 1 y to 3 y MBL was double in the NDI group Greater MBL difference observed at the distal aspect of both NDI and SI compared with the mesial side Patients with locator retention systems and NDIs showed increased MBL compared with the ball retention system SA with locator attachment was higher than with ball only in the first years

Supplement 1: Risk of bias for all included studies were analyzed using several signaling questions according to Downs & Black, 1998.

	Reporting										External validity				Internal validity – bias						Internal validity - confounding (selection bias)						Power	≤14; poor; 15–19, fair; 20 –25, good; 26 –28, excellent	
Autor/year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27		
Mini Implants																													
Ahn et al. 2004[32]	1	0	1	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	1	0	9	P
Griffitts et al. 2005[9]	1	1	1	1	0	1	1	1	0	0	0	0	0	0	0	0	1	0	1	1	0	1	0	0	0	1	0	12	P
Jofre et al. 2009[25]	1	1	1	1	0	1	1	1	1	0	0	1	1	0	0	0	1	1	1	1	1	1	1	0	0	1	0	18	F
Jofre et al. 2010[38]	1	1	1	1	0	1	0	0	1	1	0	1	1	0	0	0	1	1	1	1	1	1	1	0	0	1	0	17	F
Jofre et al. 2010[14]	1	1	1	1	0	1	0	1	1	1	0	1	1	0	0	0	1	1	1	1	1	1	1	0	0	1	0	18	F
Preoteasa et al. 2010[29]	1	1	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	9	P
Elsyad et al. 2011[15]	1	1	1	1	0	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	14	P
Brandt et al. 2012[33]	0	1	1	1	0	1	0	1	0	0	0	0	0	0	0	0	1	0	1	1	1	0	0	0	0	0	0	9	P
Scarano et al. 2012[39]	1	1	1	1	0	1	1	1	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1	0	12	P
Jofre et al. 2013[40]	1	1	1	1	0	1	1	1	1	0	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	1	0	16	F
Maryod et al. 2014[18]	1	1	1	1	0	1	0	1	1	1	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1	1	14	P
Preoteasa et al. 2014[34]	1	1	1	1	0	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0	1	0	16	F
Mangano et al. 2015[35]	1	1	1	1	0	1	1	1	1	1	0	1	0	0	0	0	0	1	1	1	1	0	0	0	0	1	0	15	F
Mundt et al. 2015[30]	1	1	1	1	0	1	1	1	1	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	1	0	13	P
Ribeiro et al. 2015[41]	1	1	1	1	0	1	1	1	1	1	0	1	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	20	G
Souza et al. 2015[10]	1	1	1	1	0	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	21	G
Catalán et al. 2015[36]	1	1	0	1	0	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1	1	0	0	0	1	0	16	F
Elsyad et al. 2016[37]	1	1	1	1	0	1	1	0	1	1	1	0	0	0	0	0	1	1	1	1	1	0	0	0	0	1	1	16	F
Schwindling et al. 2016[31]	1	1	1	1	0	1	1	1	1	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1	0	13	P

Narrow Implants																													
Zinsli et al. 2004[43]	1	1	1	1	0	1	1	1	0	0	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	1	0	13	P
Cho et al. 2007[42]	1	1	1	1	0	1	1	1	1	0	0	0	0	0	0	0	0	1	1	1	1	1	0	0	0	1	0	14	P
Morneburg and Pröschel 2008[11]	1	1	1	1	0	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0	1	0	15	F
Geckili et al. 2011[16]	1	1	1	1	0	1	1	1	1	1	0	1	0	0	0	0	1	1	1	1	1	1	0	0	0	1	0	17	F
Al-Nawas et al. 2012[17]	1	1	1	1	0	1	1	1	1	1	0	1	0	1	1	0	1	1	1	1	0	1	1	1	0	1	1	21	G
Chiapasco et al. 2012[44]	1	1	1	1	0	1	1	1	1	0	0	0	0	0	0	0	1	1	1	1	0	1	0	0	0	1	0	14	P
El Sheikh et al. 2012[6]	1	1	1	1	0	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	1	0	17	F
Tomasi et al. 2013[12]	1	1	1	1	0	1	1	1	1	1	0	1	0	0	0	0	1	1	1	1	0	0	0	0	0	1	1	16	F
Quirynen et al. 2015[19]	1	1	1	1	0	1	1	1	1	1	0	1	0	1	1	0	1	1	1	1	0	1	1	1	0	1	1	21	G
Muller et al. 2015[45]	1	1	1	1	0	1	1	1	1	1	0	1	0	1	1	0	1	1	1	1	0	1	1	1	0	1	1	21	G
Zweers et al. 2015[26]	1	1	1	1	0	1	1	1	1	1	0	1	0	0	0	0	1	1	1	1	0	1	0	0	0	1	0	16	F

2.2 ARTIGO: Narrow diameter implants connected to locking taper stud abutments as overdenture retainers: 1-year results with focus on clinical outcomes before and after occlusal loading

Submitted to Clinical Implants Dentistry and Related Research

(Anexo 3)

Running title: Narrow diameter implants as overdenture retainers

Raissa Micaella Marcello-Machado[1 *]; Fernanda Faot[2 *], Alessandra Julie Schuster[3]; Amália Machado Bielemann[3], Otacílio Luiz Chagas Júnior[4], Altair Antoninha Del Bel Cury[5]

[1] MSc, PhD student, Graduate Program in Clinical Dentistry, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

[2] PhD, Professor, Department of Restorative Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil.

[3] PhD student, Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil

[4] PhD, Professor, Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, School of Dentistry, Federal University of Pelotas, RS, Brazil.

[5] PhD, Professor, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, Brazil.

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Author Contribution Statement: Conceived and designed the experiments: RMMM, FF, AADBC. Data collection/analysis/interpretation: RMMM, FF, AJS, AMB, OLCJ. Drafting and critical revision of article: RMMM, FF, AJS, AMB, OLCJ, AADBC. Approval of article: RMMM, FF, AJS, AMB, OLCJ, AADBC.

Abstract

Background: Considering that narrow diameter implants (NDI) are being recommended to retain mandibular overdentures (OM), to increase retention and stability of dentures in cases of limited bone thickness. However, it is necessary to evaluate the clinical behavior of NDI as OM retainers, as well as, its predictability and maintenance problems.

Objectives: To evaluate the peri-implant tissue behavior around NDI and the performance of locking taper stud abutments as MO retainers.

Methodology: Sixty NDI implants were installed in 30 patients (average age=67.5 years). The implants were loaded after 12 weeks using Equator stud attachments. The plaque index (PI), calculus index (CI), gingival index (GI), probing depth (PD), bleeding on probing (BOP) and implant stability quotient (ISQ) were monitored during osseointegration at 0, 4, 8 and 12 weeks and post-loading at 24, 48 and 60 weeks. Marginal bone loss (MBL) and bone level changes (MBC) were determined by comparing panoramic radiographs at zero and 60 weeks. The data were analyzed with Wilcoxon's signed rank test, the McNemar test and Spearman correlations.

Results: The cumulative success rate was 83.3%. PI oscillated in the first 24 weeks, and decreased from 48 weeks onwards, while the CI score showed significantly higher values at week 8 (22%). The GI also peaked at week 8 (18.6%) and decreased from week 12 onwards. PD decreased gradually over time, but no significant differences were found between week 8 and 12 ($P > 0.05$). ISQ decreased significantly between 0 (55.95±4) and 12 (52.14±6.39) weeks. After MO loading, the ISQ values increased linearly and significantly between 12–24, 24–48, and 48–60 weeks, and reached values similar to the primary stability after 60 (55.6±4.87) weeks. No significant marginal bone loss was observed at 60 weeks, with average bone level changes of -0.06±0.64 mm.

Conclusion: NDI showed a stable clinical behavior, indicating that they are a safe option of treatment. Since they were clinically successful as MO retainers for edentulous patients with mandibular clinically atrophy.

Introduction

Alveolar ridge resorption is the primary adverse consequence of tooth loss, and this process is around four times faster in the edentulous mandible than in the maxilla[1]. The residual ridge resorption in edentulous patients is a physiologic and progressive process that results in bone volume reduction, modifying facial bone volume and facial appearance with direct consequences on the soft tissue profile[2,3]. Clinically, these alterations affect the retention and stability of conventional complete dentures (CD). Therefore, severe alveolar ridge resorption is the main factor responsible for problems related to difficulty of construction, adaptation and use of CD[4]. These conditions are substantially exacerbated with the patient's age[5], and the impact of edentulism on the patients' daily life is further aggravated when the masticatory function is not adequately reestablished by CD, resulting in chewing and nutritional problems[3,6–8].

Because of the substantial evidence that treatment with mandibular CD is often unsuccessful, the McGill consensus in 2002 and the York Statement in 2009 concluded that implant-retained mandibular overdentures (MO) should be the minimum treatment offered to edentulous patients [9,10]. The real benefits provided by MO are increased bite force, improved masticatory performance, improved satisfaction and oral health related quality of life [11], and improved neuromuscular control [12]. In addition, the presence of implants decreases the continuous bone resorption [13,14].

However, edentulous patients generally belong to the elderly population, often have prolonged edentulism time, and they are more susceptible to systemic chronic diseases[15]. These clinical limitations together with the continuous resorption of the alveolar ridge and significant decrease in bone volume may limit the utility of standard diameter implants in this population in the absence of additional surgical techniques for bone regeneration[16,17]. Different options have been proposed to overcome these limitations, such as narrow diameter implants (NDI) [17].

NDI have been indicated in cases with limited bone thickness where a less invasive and simplified surgical alternative for rehabilitation is required[18,19], and a high predictability was demonstrated for both anchorage modalities[20,21]. According to the aforementioned clinical findings, NDI are a safe treatment option for edentulous elderly patients with residual ridge atrophy. More invasive and extensive surgical procedures that would require prolonged healing time are unsuitable for the majority of these patients [22]. However, a factor that has not been discussed in these clinical situations is the option and selection of prosthetic attachments. The most widely studied of the available attachments are the O-ring type attachments. This system has some problems, such as a greater need of realigning over time and exchange of the retentive matrix (female part), requiring a greater number of maintenance sessions[23]. Stud attachment types are an alternative treatment option, and seem to promote greater comfort by generating greater retention and stability[24]..

In an attempt to overcome the current problems presented by edentulous patients, especially those with atrophic mandibles, a new NDI is being used by clinicians as an overdenture retainer. This implant system has a five-degree angled morse connection, is based on friction retention (Facility dental implant), and includes a screwless stud type attachment system (Equator abutment), and a 3.5 mm prosthetic seating diameter that is installed with the aid of a hammer. This type of abutment (Figure 1) has a similar retention mechanism as Locator systems, where retention arises from a dimensional misfit between the slightly oversized nylon male insert and the smaller diameter of the inner ring of the female abutment[25]. However, the behavior of this new implant system to anchor MO during the healing and functional loading, as well as, its predictability and inherent system maintenance problems have not yet been investigated. Therefore, the objective of this study was to investigate the clinical behavior of peri-implant tissues, survival and success rates and the presence of complications during treatment with MO anchored by two NDI with stud attachments installed a sample

population with atrophic mandibles and prolonged edentulism time. The trial included clinical data before and after installment of mandibular overdentures (MO), up to the first year after implant loading.

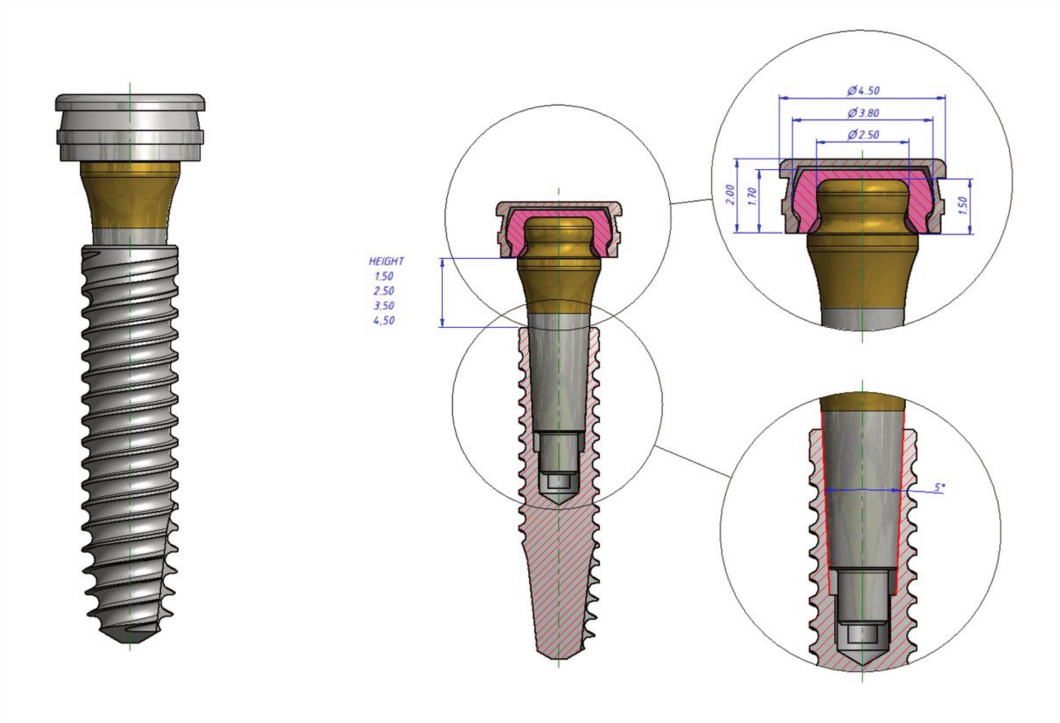


Figure 1. Illustration of the Facility-Equator System (2.9 x 10mm)(Neodent Company, Brazil) based on a pure friction connection showing the dimensions of the prosthetic components.

Methodology

Experimental Design

This is a longitudinal clinical study with a one year follow-up after implant loading, with periodic evaluations performed after the intervention. The study was conducted according to the Helsinki Declaration, 2008, following the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) protocol[26]. This study was approved by the Ethics Committee in Local Research (protocol number 1,267,086 / 2015) and included edentulous patients with atrophic mandibles who were rehabilitated with new CD and after being transformed into OM retained by NDI at the Dentistry School - UFPel. Patients were included if they had good general health or controlled diabetes/hypertension, smoked less than 11 cigarettes per day, and were wearing conventional CD for at least three months, while showing difficulty adapting to the mandibular prosthesis and poor mandibular denture-bearing tissue conditions[27]. The evaluation of denture-bearing tissue conditions was performed according to Kapur[27] criteria, which evaluated the based on the clinical evaluation of ridge shape, tissue resiliency and location of border tissue attachment.

The patients that fulfilled the inclusion criteria and agreed to the terms of the research were invited to sign a written informed consent form. Preoperative radiological evaluations were then performed for surgical planning and clinical verification of the patients' bone atrophy. An experienced surgeon performed the installation of the 2 NDI (2,9X10mm) and the healing abutments. After a 12-week osseointegration period, equator type retainers were installed and the MO were loaded.

The peri-implant health monitoring was performed by assessing the following indices: plaque index (PI), calculus, gingival index (GI), probing depth (PD), bleeding on probing (BOP); and implant stability quotient (ISQ). The marginal bone level (MBL) and marginal bone level change (MBC) were determined radiographically. Peri-implant

health assessments were performed in two post-surgical phases: i) osseointegration - 4, 8, and 12 weeks and ii) post-loading: 24, 48, and 60 weeks. The ISQ was also evaluated immediately after the NDI installation (baseline). The MBL and MBC were determined immediately after surgery and 1 year after MO loading (Figure 2). Complications and maintenance sessions were recorded for description (Table 5).

The sample calculation was based on a previous study by Tozum et al., 2007[28], with the implant stability quotient (ISQ) as primary outcome and using the following parameters: smallest expected difference between the means, standard deviation of difference between the means, beta error of 5% and alpha error of 5%. The sample size was increased by 20% to account for potential losses and refusals and 20% to consider implant losses. These calculations indicated that a minimum of 60 implants should be installed in this study.

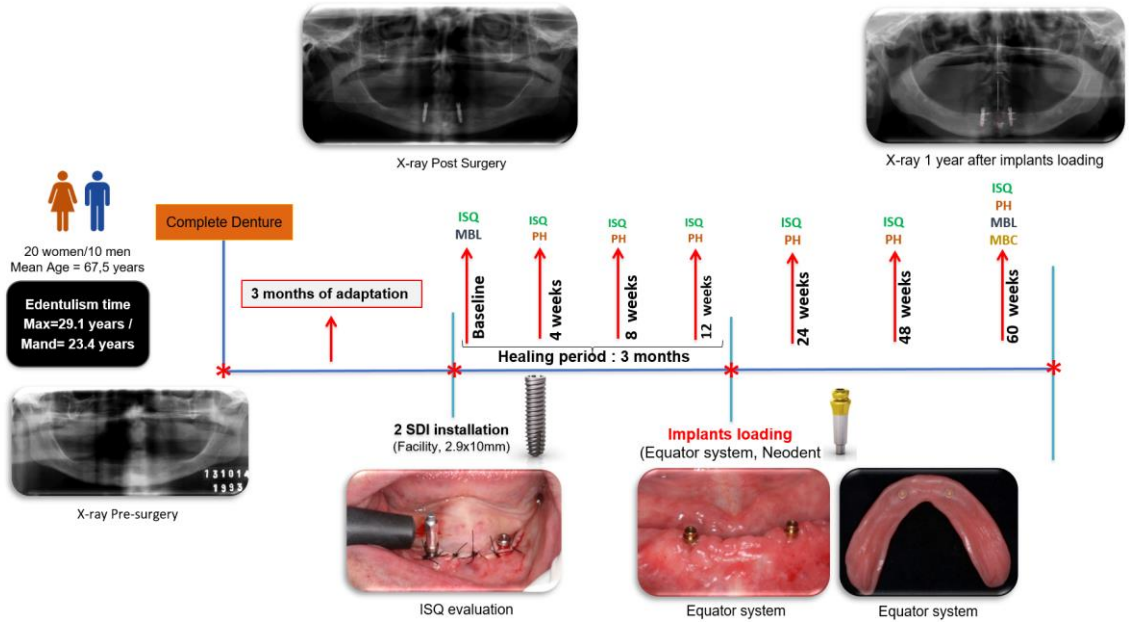


Figure 2: Flow diagram of experimental design.

Clinical evaluation of Peri-implant tissues

Measurements of peri-implant probing depth, calculus index, plaque index, bleeding on probing and gingival index were carried out during the clinical assessment. These

measurements were performed on the mesial, distal, buccal, and lingual side of the implants with the aid of a Goldman-Fox Williams probe [20,29,30].

The plaque index was classified as follows: 0 (no detection of plaque), 1 (plaque only recognized by running a probe across the smooth marginal surface of the implant), 2 (plaque can be seen by the naked eye), 3 (abundance of soft matter). The calculus index was scored as follows: 1 (presence) or 0 (absence). The gingival index was classified as follows: 0 (normal peri-implant mucosa), 1 (mild inflammation, slight change in color, slight edema), 2 (moderate inflammation, redness, edema, and glazing), 3 (severe inflammation, marked redness, edema, and ulceration). The bleeding on probing (BOP) index was classified as: 0 (no bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant), 1 (isolated bleeding spots visible), 2 (blood forms a confluent red line on margin), 3 (heavy or profuse bleeding). The probing depth was measured as the distance between the marginal border of the mucosa and the point of the probe that was inserted in the peri-implant sulcus[29,31].

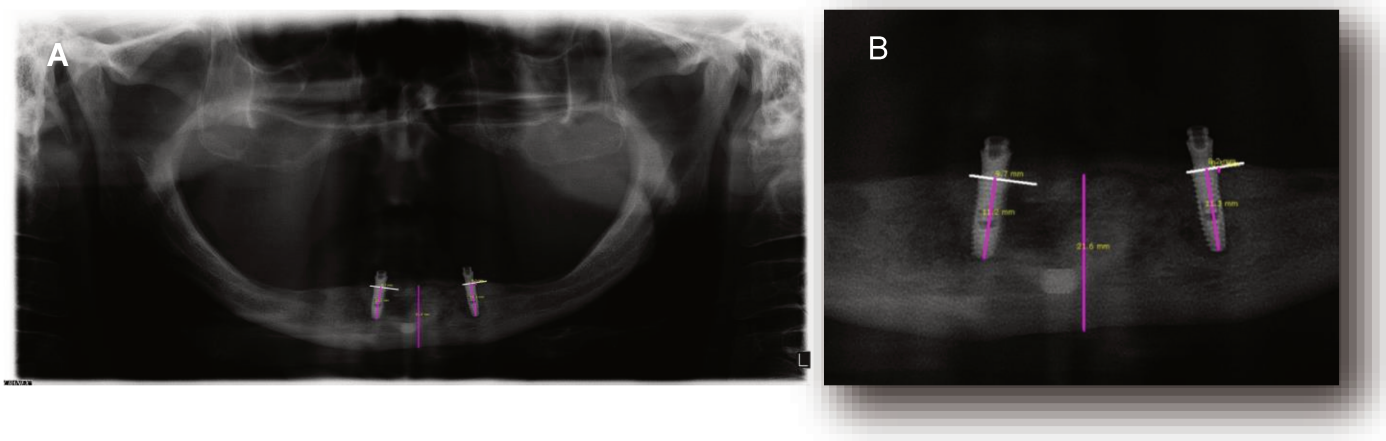
Evaluation of Implant Stability by Resonance Frequency Analysis

The primary and secondary implant stability was measured by the implant stability quotient (ISQ) obtained by Osstell® instrument (IntegrationDiagnostics AB, Gothenburg, Sweden). A single calibrated operator performed the measurements, following the instructions provided by the manufacturer. Measurements were performed in triplicate on the buccal-lingual and mesio-distal faces of each implant. The mean of these values was considered the ISQ of the evaluated implant[32].

Peri-implant bone level assessment

Standardized panoramic radiographs were performed immediately after surgery and 12 months after implant loading to measure the peri-implant bone level. The images were analyzed using DBSWin - VistaScan digital system the software for linear

measurements, and the external edge of the implant head was used as a reference point during evaluation of the peri-implant bone level (Figure 3) [20,29,30]. The measurements were performed in the mesial e distal faces, and the implant length was used for a control of the radiographic distortions.



Evaluation of implant success and survival

The success of the implants was evaluated according to the clinical criteria proposed by Albrektsson et al., 1986 and Papaspyridakos et al., 2012 [33,34]: Absence of clinical implant mobility, absence of peri-implant continuous radiolucency, and absence of signs and symptoms such as pain, infections, dysesthesia and marginal bone loss <1.5 mm [33,34]. Implants were categorized in the survival group when an implant remained in situ, but did not meet the criteria for success [35].

Statistical analysis

Data were submitted to descriptive analysis to evaluate the distribution of data and presence of asymmetries. The PI, calculus, GI and BOP indexes were dichotomized, the 0 and 1 score was determined as absence and the 2 and 3 scores was determined as presence. As the data presented a non-normal distribution, were used non-parametric tests. The McNemar test was used for the comparison of the dichotomized data as a function of time. The Wilcoxon's signed rank test was used for comparisons over time of

the continuous data. The Mann-Whitney test was used to compare possible differences between ISQ of the implants lost and the implants survived. The chi-square test was used to test for differences between the GI of lost and surviving implants. Spearman correlations were used to test for correlations between PD and ISQ, PD and MBL, PD and age, PD and edentulism time, and between MBL and MBC. The level of significance was set at 5%. All analyzes were performed using SPSS software 22 (IBM SPSS Statistics 22).

Results

The total sample consisted of 60 implants installed in the anterior region of the mandible of 30 patients (20 women and 10 men) with a mean age of 67.5 years (50–90 years) and average times of edentulism of 29.1 and 23.4 years in the maxilla and mandible, respectively. According to the radiographic evaluation performed during a previous study [35], our sample had an average height of 23.45 ± 3.78 mm in the anterior mandible region, an average height of 14.8 ± 3.46 mm in the posterior mandible region, and an average height of 3.56 ± 3.07 mm above the superior wall of the mental foramen.

Table 1 lists the means and standard deviations of the clinical parameters used to monitor peri-implant health over time and the differences between the evaluated time periods ($P < 0.05$). The PI oscillated in the first 24 weeks, and reached the highest percentage of presence at week 4 (63.3%) and at week 12 (55.4%). From week 48 onward, a significant decrease in the percentage of PI average was observed (26.0%), which was statistically different from weeks 4 and 12 ($P < 0.05$). The lowest percentage of PI presence was measured after week 60 (18.0%), only the week 48 score was statistically similar ($P > 0.05$). The calculus index peaked at week 8 (22.0%); this score was significantly higher than all other evaluation periods ($P < 0.05$). The gingival index also peaked at week 8 (18.6%), which was significantly higher than the GI recorded during all MO post-loading evaluation periods ($P < 0.05$).

Table 1: Descriptive statistics analyses of the evaluated clinical parameters (Plaque index – PI, Calculus, Gingival index – GI, Probing depth – PD, Bleeding on probing – BOP, Implant stability quotient – ISQ) in the first year (in weeks). Different capital letters indicate statistical differences between clinical parameters over time.

		Pre-loading			Post-loading		
Weeks	(0) Baseline	4	8	12	24	48	60
				% Presence			
PI		63.3A	42.4BC	55.4AB	42.0BC	26.0CD	18.0D
Calculus		0A	22.0B	7.1ª	4.0A	0A	0A
GI		13.3A	18.6A	14.3AC	0BD	4.2AD	2.0BCD
BOP		0A	0A	0A	0A	0A	0A
				Mean(SD)			
PD		3.25(1.03)A	2.83(0.87)B	2.77(0.82)B	2.21(0.69)C	1.92(0.52)D	1.7(0.74)E
ISQ	55.95 (4.0)A	52.56(7.95)BC	52.14(6.39)B	52.42(7.10)B	52.48(6.21)B	54.75(5.13)AC	55.6(4.87)A

Supplement 1: P-values for the comparisons of the clinical parameters (IPV, calculation, GI, IPS, ISG and ISQ) between different periods (Paired Wilcoxon test and McNemar test).

	PI	Calculus	GI	PD	ISQ
Baseline – 4	-	-	-	-	**<0.0001**
Baseline – 8	-	-	-	-	**<0.0001**
Baseline – 12	-	-	-	-	**<0.0001**
Baseline – 24	-	-	-	-	**0.001**
Baseline – 48	-	-	-	-	0.121
Baseline - 60	-	-	-	-	0.735
4 – 8	**0.015**	**<0.0001**	0.549	**0.001**	0.059
4 – 12	0.556	0.125	0.687	**<0.0001**	0.338
4 – 24	**0.027**	0.500	**0.008**	**<0.0001**	0.709
4 – 48	**<0.0001**	-	0.109	**<0.0001**	0.070
4 – 60	**<0.0001**	-	**0.016**	**<0.0001**	**0.005**
8 – 12	0.137	**0.004**	0.549	0.554	0.314
8 – 24	1	**0.013**	**0.004**	**<0.0001**	0.434
8 – 48	0.189	**<0.0001**	0.065	**<0.0001**	**0.004**
8 – 60	**0.013**	**<0.0001**	**0.021**	**<0.0001**	**<0.0001**
12 – 24	0.263	0.687	**0.031**	**<0.0001**	0.691
12 – 48	**0.014**	0.125	0.289	**<0.0001**	**0.014**
12 – 60	**<0.0001**	0.125	0.063	**<0.0001**	**<0.0001**
24 – 48	0.057	0.500	0.500	**0.008**	**<0.0001**
24 – 60	**0.008**	0.500	1	**<0.0001**	**<0.0001**
48 – 60	0.388	-	1	**0.016**	0.076

The PD progressively decreased during the successive evaluation periods; no statistical difference (P> 0.05) was observed only between week 8 (2.83±0.87) and 12 (2.77±0.82). No BOP was identified in any of the evaluated periods. The ISQ decreased significantly from baseline to week 12, and started to increasing from 48 weeks of loading, at weeks 48 remaining stable until 60 weeks, when the ISQ reached similar values to the registered primary stability values (P>0.05). The *P values* for all the comparisons of clinical parameters over time are included in Supplement 1. The Spearman correlation analysis between the PD and the ISQ showed no correlation between them in any of the evaluated periods (Table 2).. Negative correlation between age and PD at 60 weeks (R=-0.314, P=0.027) was observed while no correlation between edentulism time and PD was found. The dispersion diagram presented in the Figure 4a shows that with increase of the age the PD has a tendency to decrease.

Differently, in the Figure 4b, we observed that longer edentulism time showed a tendency to decrease in PD for both periods, however no significant correlation was found. At weeks 4 and 12, the ISQ values of the lost implants were significantly lower (P <0.05) than those of the surviving implants (Table 4). The GI did not show any significant difference between the lost implants and the surviving implants at any time point (P> 0.05).

Table 2: Spearman correlation between the clinical parameters, probing depth (PD) and implant stability quotient (ISQ).

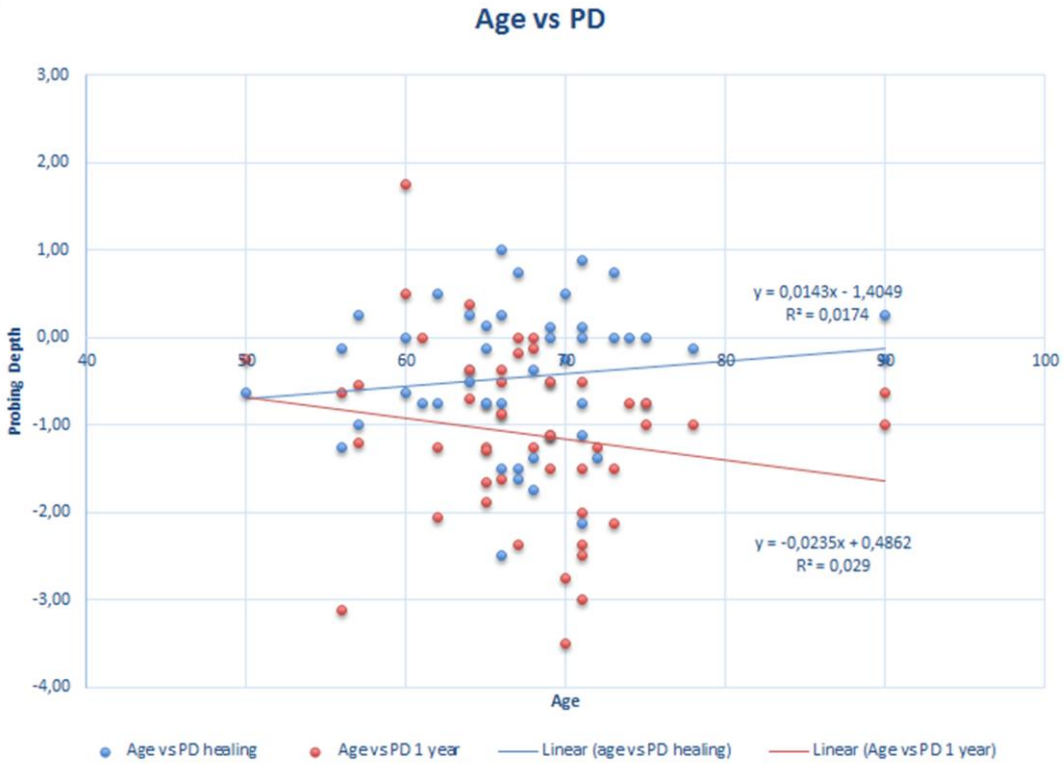
		ISQ					
		Before Loading			After loading		
IPS		4	8	12	24	48	60
2	R=	0.071					
	P=	0.592					
4	R=		0.148				
	P=		0.264				
8	R=			0.133			
	P=			0.330			
12	R=				-0.014		
	P=				0.925		
24	R=					-0.244	
	P=					0.087	
48	R=						-0.187
	P=						0.194

Table 3: Mean and standard deviation (SD) of ISQ values found in the lost and survived implants (Mann-Whitney Test).

	Lost		Survived		P-Value
Weeks	Implants (n)*	Mean/SD	Implants (n)	Mean/SD	
Baseline	10	51.93±9.36	50	55.95±4.0	0.311
4	10	41.55±16.3	50	52.56±7.95	0.02
8	9	39.25±21.84	50	52.14±6.39	0.094
12	6	33.96±16.69	50	52.42±7.10	0.001

* The n of implants lost corresponds to the implants that remained in situ in each evaluated period.

a



b

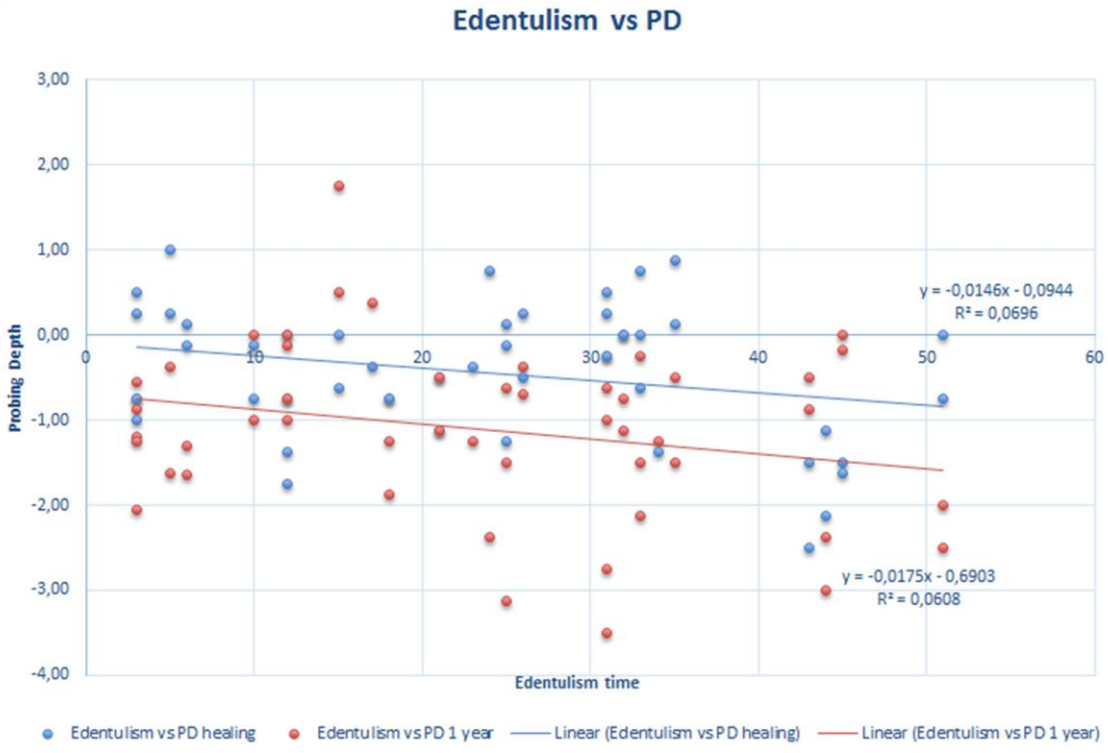


Figure 4: Dispersion diagrams showing the correlations between probing depth (PD) and Age (a) and between PD and edentulism time (b).

The MBL after 1 year of loading (-0.23 ± 0.5 mm) was similar (P>0.05) to the immediate bone loss (-0.13 ± 0.47 mm) and the MBC was negative, but not significantly different from zero (-0.06 ± 0.64 mm). The MBC showed a negative correlation with the immediate MBL (R=-0.634, P<0.0001) and positive correlation with MBL one year after loading. The MBL one year after loading was negatively correlated with the PD at week 60 (R=-0.317, P=0.025). The MBL was not correlated with ISQ. The observed cumulative success rate was 83.3%; the Kaplan-Meier survival curve is shown in figure 5. Ten implants were lost, being 6 in the osseointegration period. Three out of the 10 implants lost occurred in smokers.

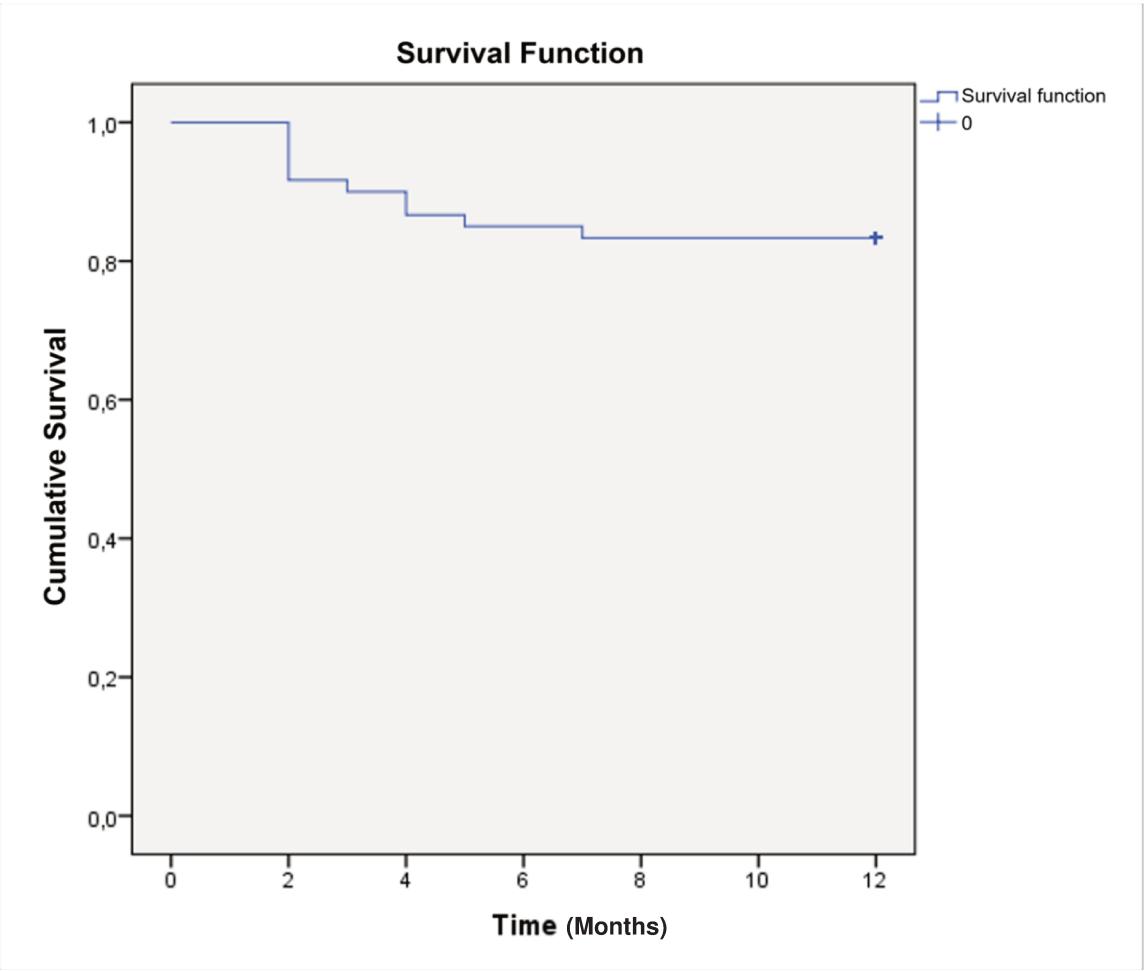


Figure 5: Kaplan Meier survival curve of the sixty narrow diameter implants during the 12 months of follow-up.

Table 4 lists the type and number of post-surgical and prosthetic complications occurred during the first year after MO loading. The most common complications were loosening of the stud attachments (28 events) and O-ring cylinder recapture (matrix; 19 events). The most necessary clinical maintenance was CD readjustment (30 events) and change of the O-ring rubber (nylon retention; 30 events).

Table 4: Type and number of complications and maintenances during the first year of occlusal loading.

Complications	Number of events
Loosening of the healing attachment	7
Loosening of the equator attachment	20
Loosening of the matrix (female)	1
CD fracture	5
Replacement of CD	5
Change of attachments (higher/lower)	6
Recapture of the matrix (female)	19
Tooth fracture	7
Change of the matrix (female)	8
Reopening for attachment replacement	11
Deepening of the buccal sulcus	1
Removal of peri-implant keratinized mucosa	10
Maintenance	**Number of events**
CD Adjustments	30
Change of the pink O-ring (nylon retention)	26
Relining	13

Discussion

Even with the benefits provided by the NDI, which allow installation in limited spaces and adopting less invasive surgical techniques [19], there is still little information about the clinical performance of these implants as overdenture retainers in edentulous patients with prolonged edentulism time and limited bone thickness. The clinical findings reported in the present study with success rate of 83.3% demonstrate the excellent predictability of NDI connected to locking taper stud abutments as MO retainers, especially in a sample population that can be considered at risk because they present clinical mandibular atrophy.

The evaluation of peri-implant health is fundamental to monitor the soft and hard tissues, as well as the implant stability over time, irrespective of the implant diameter, especially in a population known to be susceptible to general adversities [15]. The evaluation of the primary and secondary implant stability performed via the implant stability quotient only provides data regarding bone-implant contact as a means to predict the implant success or failure [37]. The soft tissues that support the implants may also interfere in the implant success, since these adjacent soft tissues are responsible for the biological sealing and function as a barrier protecting around the implant from external injuries. The inflammation of these tissues may lead to a marked marginal bone loss, peri-implantitis and consequent rehabilitation failure [38]. In view of the importance of these elements for the implants' survival and osseointegration, it is essential to implement routines to monitor the bone resorption process, peri-implant health and primary and secondary stability from the initial healing phase of the implants.

As the peri-implant tissues health evaluation becomes a routine for the clinician, the patient care with the new clinical condition is also improved by the frequent hygiene reinforcement, further increasing the chance of treatment success [39]. The evaluations of the PI, GI and the calculus in our study indicate that higher values for these indices occur during the osseointegration. We attribute this to the fact that these patients were edentulous for a long time and thus required a period of adaptation to the new clinical

condition. When we emphasized or reinforced the hygiene routines, those peri-implant health indices improved significantly over time. Quirynen et al., 2015 [20] also rehabilitate edentulous patients with OM retained by two implants, and reported that the majority of the patients had scores of 0 or 1 for PI. However, some studies showed a significant increase in peri-implant health indexes over time [19,40,41], which contrasts with our results. During their comparison of locator and magneto types attachment systems, Elsyad et al., 2016 [41] showed that the magneto attachment presented greater plaque accumulation after 1 year of follow-up.

It is well-known that all indices used for peri-implant health assessment are interdependent, since an increase in the PI or calculus leads to peri-implant soft tissue inflammation, possibly increasing PD levels, and BOP, and this may result in marginal bone loss [37,39]. During the PD and BOP measurements it is important to know that the new tissue formed around the implant presents some structural differences with the periodontal tissue; it probably originates from the oral epithelium and has a lower resistance to the probes than the tissues surrounding natural teeth [38]. This lower resistance is due to the parallel orientation of the collagen fibers in the peri-implant tissue [42]. According to Salvi et al., 2004 [39], successful implants allow a PD of up to 3 mm. The average PD decreased significantly over time, dropping from 3.25 mm to 2.8 mmm between 4 and 8 weeks, and remained stable between 8 and 12 weeks, giving an estimate of the period necessary for soft tissue healing in this type of patients. We can therefore affirm that we got a successful formation of a healthy peri-implant tissue around the NDI. The average PD continued to decrease gradually and significantly between 12 and 60 weeks, reaching an average of 1.7 mm at 12 months post-loading, and the PD was negative correlated with the MBL.

This post-healing period is interpreted as the tissue adapting to the overdentures; similar soft tissue recession has been observed earlier around implants in dentate sample populations [43]. Salvi et al., 2004 [39] shows that PD is an important diagnostic process for assessment of peri-implant tissues status, since the increase in PD is

pathognomonic for peri-implant disease. Our data shows that 47% of the population show large (≥ 1mm) reductions in probing depth, 14 out of 20 women and 6 out 10 men. Fortunately, neither the age nor the edentulism time is considered a risk factor for PD reduction over time (Figure 3). In the more extreme cases, leverage forces resulting from receding tissue may pose a risk for increased MBL, and eventually implant loss. Therefore, we recommend that clinicians stimulate edentulous OM wearers to attend long-term check-ups, especially those at high risk for major soft tissue recession. We also recommend to replace the Equator abutments when the PD decreases by more than 1 mm and when this is clinically observed. However, the PD decreases may also have occurred due to the formation of resistant keratinized mucosa around the prosthetic components.

The success of the NDI installation is also indicated by the decrease of peri-implant health indexes over time including PI, calculus, GI, and BOP [42]. The progressive healing of the peri-implant tissues is shown by the PD reduction and the formation of keratinized mucosa around the prosthetic attachment. Keratinized mucosa surrounding the implants is known to protect these tissues from inflammation caused by plaque accumulation. Therefore, the integrity and stability of keratinized mucosa is also correlated with the health of the peri-implant tissues [39]. In addition, it allows a greater resistance of the peri-implant soft tissue to the damages during the mastication and the frictional contact that occurs during the oral hygiene [42].

The primary and secondary implant stability measured by resonance frequency analysis is important for the early detection of implant failure, since this is a non-invasive, quantitative, reproducible and reliable method to verify bone-implant contact over time [37,44]. In the present study, the ISQ values decreased between the baseline and the first month after installation. The ISQ values subsequently remained stable until week 24, and from week 48 the ISQ values started to increase significantly, indicating the onset of secondary stability establishment, reaching values that are statistically identical to primary stability at 48 weeks. The reduction of implant stability was also reported by

Gokmenoglu et al. 2014 [45] and corresponds to the beginning of the osseointegration period and bone remodeling immediately after the implant installation, from eight week onwards the ISQ values increased. Furthermore, Boskey and Coleman et al., 2010 [46] illustrated that the composition of bone and its mechanical properties vary as a function of age. In addition, we highlight that our population has prolonged edentulism time, which may have slowed the osseointegration process. The ISQ values reached in our study can be also considered low, since these values has generally range from 60 to 84 [45,47], and the implants used in this study presented ISQ values between 45 and 67. The latter might be in part attributed to the connection between the smartpeg and the prosthetic attachment instead of direct connection to the implant[32]. In addition, lost implants had significantly lower ISQ values than the surviving implants. Finally, Monje et al., 2014 [48] cautioned that although ISQ is an excellent tool to determine the most appropriate moment for implant loading, it is not yet possible to determine cutoff values to diagnose early implant failure.

Some studies [19,20,30,49] conducted with NDI showed a high survival rate above 97% that is comparable to the performance of standard diameter implants [21,50]. However, Ortega-Oller et al., 2014 [17] found that NDI have a significantly lower survival rate than conventional diameter implants. The success rate found in the present study conducted in a high-risk population was 83.3% (n = 50/60). Six out of the ten lost implants were lost during the osseointegration period. This is considered the most risky period, probably because in this period occur the osteoinduction and osteoconduction, *de novo* bone formation and bone remodeling [51,52]. The relatively low success rate is probably related to mandibular atrophy condition. These patients had a higher proportion of cortical bone and a lower cancellous bone and consequently a lower blood supply, fewer mesenchymal cells and a worse biological response. Furthermore, our sample population had a high average edentulism time of these patients, and if the mandibular ridge does not receive mechanical stimuli for a long period, this can initiate changes in the bone microarchitecture, interfere in the blood supply and consequently influence the

quality and intensity of cellular responses [52]. Nevertheless, when these lost implants were replaced, the survival rate was 100%, suggesting that receiving new stimuli increased the bone's ability to regenerate. Another two facts may have contributed to the relatively low success rate of these implants, the type of alloy (Ti6Al4V) that NDI are made which is less biocompatible than cpTi, or the implant diameter being smaller and so the area of bone implant contact also be smaller[20,22].

The main factors that determine the implant success are the absence of clinical implant mobility, absence of peri-implant continuous radiolucency, and absence of signs and symptoms such as pain, infections, dysesthesia, along with the absence of marginal bone loss [33,34]. According to the criteria proposed by Albrektsson et al., 1986 [33], bone loss below 1.5 mm can be considered as a success. Ross et al., 1997 [35] and Papaspyridakos et al., 2012 [34], showed that a bone remodeling of 2 mm during the first year after implant loading, followed by a maximum of 0.2 mm per year is acceptable. The mean bone remodeling found in this study was -0.06 ± 0.64 mm, ranging from -1.1 to 1.2 mm, which is within acceptable limits. Al-Nawas et al., 2012 [30] found a bone remodeling of about -0.32 mm in the first year of MO loading using a Locator abutment similar to the one used in the present study. It is known that the attachment system based on a stud abutment has greater retention and stability than ball or magnet type systems. However, the results from Elsyad et al. (2016)[41] showed that a group rehabilitated with locator type stud abutments experienced 0.31 mm more vertical MBL than a group using magneto abutments after one year. Another study from Elsyad et al. (2014) [40] that compared the effects of the loading protocols when using locator type stud abutments found that immediate loading was associated with 0.18 mm more vertical MBL after one year. The negligible MBL values (-0.23±0.5mm) in our study population could thus be in part related to our adoption of the conventional loading protocol for the MO.

During the follow-up period, the observed events were recorded in order to determine the number of the return sessions required after installation, to list the main problems related to the maintenance of the MO with Equator type attachments, and to describe

the main complications that occurred. Our results highlight that, on average, only one return per patient was necessary to adjust the prosthesis after MO loading and to exchange the pink O-ring per patient. The latter are the most common reasons for clinical sessions during MO rehabilitation, mainly because the prosthesis can traumatize the mucosa during stabilization [53] and the pink O-ring can be damaged by the saliva and during the prosthesis insertion and removal. Kleis et al., 2010 [54] observed in their study that 75% of the cases of MO retention loss with the Locator system were due to the O-ring damage, by the prosthesis placement and removal, and thus suggest that annual follow-ups and adjustments are necessary with this system. Zinsli et al., 2004 [55] and Trakas et al., 2006 [56], showed that in the first year after MO loading, a greater number of clinical sessions are necessary, because of the adaptation phase.

The main complication during the first year was the expulsion of the prosthetic attachment, with 28 events in 11 patients. This dislodgment probably occurred due to the prominent soft tissue (wide and thick) around the implant, in most cases was quite keratinized and resistant. The dislodgment can also be related to the locking taper type connection between implant and prosthetic attachment. Another frequent complication was the need to recapture the MO this occurred more frequently in the first rehabilitated patients and can be explained by the first clinician's lack of experience with this system or due to the Equator system itself. Akça et al (2013) [23] observed that the female part of locator attachments had lower durability than ball-type attachments using in MO rehabilitation. Five prosthetic fractures occurred during the follow-up, and this is probably related to the reduced thickness of the prosthesis flange and to the larger diameter of the prosthesis's internal connector (matrix), which increase the fragility of the prosthesis. All of the complications were easily treatable, as reported by Zinsli et al., 2004 [55].

The limitations of present study include the lack of a control group in order to investigate different implant diameters or overdenture attachment systems. Furthermore, our evaluation of MBL and MBC was performed using digital panoramic radiographs due to the atrophic condition of the patients that did not allow us to properly insert the

radiographic film for a periapical radiography. The absence of surgical complications expected in this high-risk sample population can be justified by the surgeon experience. While the NDI provide a shorter surgical time with high predictability, their implementation is fairly recent and their clinical behavior and suitability is still heavily debated. However, our study presents interesting novelties regarding the peri-implant monitoring of a cohort of clinically atrophic patients rehabilitated with MO by NDI, especially regarding the progressive decrease in PD and its clinical implications. We can conclude that this method for rehabilitation of these high-risk patients can have a high success rate, proving that the planning is performed correctly.

Conclusion

The narrow diameter implants presented a stable clinical behavior after the osseointegration period, indicating that they are a safe option of treatment, but are quite sensitive to adequate patient care and health monitoring of peri-implant tissues. The new connection system demonstrates to be a safe treatment option, with maintenance periods expected for mandibular overdentures. The clinician should see to it that peri-implant soft tissues are fitted around the attachments so that does not expulsion of the prosthetic attachment. The PD continues to decrease, demonstrated the tissue sealing protection to the marginal bone. The NDI can thus be indicated as mandibular overdentures retainers for edentulous patients with mandibular atrophy and prolonged edentulism.

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2.3 ARTIGO: How fast can treatment with overdentures improve the masticatory function and OHRQoL of atrophic edentulous patients? A 1-year longitudinal clinical study

Submitted to Clinical Oral Implants Research

(Anexo 4)

Running head: Mastication improvements in atrophic patients after MO

Raissa Machado Marcello-Machado[1]; Fernanda Faot[2], Alessandra Julie Schuster[3]; Amália Machado Bielemann[3], Gustavo G. Nascimento[4]; Altair Antoninha Del Bel Cury[5]

[1] MSc, PhD student, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

[2] PhD, Professor, Department of Restorative Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil.

[3] PhD student, Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil

[4] PhD; Section of Periodontology, Department of Dentistry and Oral Health, Aarhus University, Aarhus, Denmark

[5] PhD, Professor, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, Brazil.

Key words: masticatory function; overdentures; edentulous, narrow dental implants; atrophic mandible

Abstract

Objectives: The aim of this prospective clinical study is to evaluate the masticatory function (MF) and subjective perception of patients with poor denture-bearing tissue in relation to change and the time required to identify an improvement in these parameters when compared before and after the rehabilitation with mandibular overdentures (MO) by 2 small diameter two-pieces-implants. **Material and methods:** Twenty-three edentulous patients were selected for MO installation. The masticatory function (MF) was evaluated with the masticatory performance (MP) and swallowing threshold (ST) tests. In the MP test, each volunteer was instructed to masticate a portion of Optocal (standardized artificial test food) for 40 masticatory cycles. During the swallowing threshold test, the patients were instructed to chew a new portion of Optocal cubes until they felt the desire to swallow. The MF tests were performed while complete denture (CD) wearers (baseline) and 1, 3, 6 and 12 months after MO loading. In addition, the subjective perception was assessed through the questionnaires Dental Impact on Daily Living (DIDL), Geriatric Oral Health Assessment Index (GOHAI) and Oral Health Impact Profile in Edentulous (OHIP- EDENT) at the baseline, 3, 6 and 12 months after MO loading. **Results:** A significant improvement in masticatory function ($P < 0.05$) was observed already in the first month of loading. Three months after MO loading, a significant improvement ($P < 0.05$) was found in the subjective perception of patients. The effect size indicates that the MO had the greatest impact on the domains related to function and comfort of all questionnaires and in relation to psychosocial domain of the GOHAI. The level of patient satisfaction increased significantly after the MO loading, and reached more than 90% satisfied patients at 12 months. **Conclusion:** The MO improved both the MF of the patient and their oral health related quality-of-life and satisfaction regarding the prosthesis in a short time period.

Introduction

Complete Denture wearers that switch to mandibular overdentures (MO) experience an improvement in masticatory function (MF) and satisfaction (Boven et al. 2015), increased bite force, and reduction of discomfort during function (Van Der Bilt et al. 2010; Mueller et al. 2013; Giannakopoulos et al. 2017). Several studies attributed these improvements mainly to the increased stability provided by MO (Bakke et al. 2002; A. Van Der Bilt et al. 2010; Giannakopoulos et al. 2017; Elsyad & Khairallah 2017). Narrow diameter implants were considered a promising option to support MO for mandibular edentulous patients with limited bone volume (Elsyad 2016). However, larger studies need to confirm a positive effect on the chewing efficiency (Enkling et al. 2017) as well as the time required to the patient to perceive objective and subjective improvements in the masticatory function.

Various aspects of the masticatory function can be measured by different parameters that each have their specific applicability domain and do not necessarily correlate, including masticatory performance, masticatory ability, maximum bite force and its muscular components, chewing rate, and swallowing threshold (Van Der Bilt et al., 2006; van der Bilt 2011; Elsyad et al. 2014; Elsyad & Khairallah 2017; Enkling et al. 2017). Several other factors can influence the masticatory performance, such as mandibular movement, occlusal contact area, occlusal force, and tongue and lip function (Koshino et al. 1997; Ikebe et al. 2011; Komagamine et al. 2011; Yamada et al. 2015).

Furthermore, some doubts remain about the improvements in masticatory function of MO wearers (Woda et al. 2011; Witter et al. 2013). Moreover, more studies are still needed to establish a parameter that allows to reliably assessing the performance of the patients' mastication. Witter et al. (2013) propose that mastication is satisfactory when the mean of the masticatory normative indicator (MNI) and the median

particle size (X50 value) for the Swallowing Threshold test does not exceed 3.68 mm. Healthy individual would perform this chewing with complete natural dentition as a standard, which decreases food particles to an average can size, forming a well-prepared bolus before swallowing. The mastication would be impaired when the urge to swallow occurs before reaching the average particle size.

However, few studies have focused on the mastication quality in edentulous patients (Woda et al. 2011; Witter et al. 2013), and no consensus on a clinical definition of an efficient masticatory parameter described for this population. Several studies (Fontijn-Tekamp et al. 2000; Fontijn-Tekamp et al. 2004; van Kampen et al. 2004; Van Der Bilt and Fontijn-Tekamp 2004) have validated methods for evaluating the mastication to determine the functional pattern or to compare the mastication between edentulous treated groups according to different types of prosthetic rehabilitation. Presently, only two paired studies reported results on chewing efficiency (Mueller et al. 2013; Enkling et al. 2017). A randomized clinical trial by Mueller et al. 2013 evaluated the satisfaction and functional, structural, nutritional and patient-centered aspects during the conversion from CD to MO in a target group that included extremely old and frail edentulous patients. Although MO treatment resulted in higher satisfaction levels, an increased oral health-related quality of life, and improvements in the maximum voluntary bite force, the chewing efficiency was not different from the control group (mandibular CD reline). A prospective clinical study by Enkling et al. 2016 investigated the evolution of chewing efficiency, maximum voluntary bite force, and oral health-related quality of life in edentulous patients treated with four narrow-diameter implants over 52 weeks. These authors observed an improvement in the oral function and oral health related quality of life, mainly in elderly patients aged of ≥65 years with limited bone support. However, an effect on chewing efficiency was not demonstrated.

The positive influence of MO rehabilitation on patient satisfaction and comfort due to the stabilizing function of the implants is well established (Bakke et al. 2002; Assunção

et al. 2009; Al-Omiri et al. 2011; Elsyad 2016). However, the magnitude and persistence of the changes that MO can provide in terms of objective and perceived masticatory function are unknown.

Thus, it is both interesting to compare the impact of MO treatment on patients' oral health and daily living, in combination with the assessment and determination of clinical and psychological status which is of great value whenever is necessary to perform a prosthetic rehabilitation and objectively measure if patients' expectations are being met in all activities of daily living. It is also important to observe if there is any relationship between objective and subjective masticatory function and how it impacts in quality of life of this population when they are evaluated by different questionnaires, such as: the Dental Impact on Daily Living (DIDL), the Oral Health Impact Profile Questionnaire (OHIP-EDENT) and the Geriatric Oral Health Assessment Index (GOHAI).

The aim of this study was to evaluate the masticatory function and subjective perception of patients with severe mandibular bone atrophy in relation to changes in your masticatory standard before and after treatment with mandibular overdentures supported by two small diameter implants, followed up over a one year period. The hypothesis to be tested is that both the masticatory function (measured by the sieving method using Optocal$_{TM}$ cubes) and the subjective perception of mastication ability (measured by DIDL, OHIP-EDENT and GOHAI) significantly improve quickly and persistently after MO rehabilitation, positively affecting the oral health related quality of life for edentulous patients with difficulties adapting to mandibular dentures. In addition, the interaction between masticatory function and the self-reported quality of life is assessed via regression analysis.

Materials and methods

Experimental Design

This is a longitudinal (1 year) clinical study with assessments while CD wearers (baseline) and after MO loading. The study was conducted following the Declaration of Helsinki, as seen in 2008, following the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (STROBE) (Bastuji-Garin et al. 2013). This study was approved by the Ethics Committee for Clinical Research of the Federal University of Pelotas – School of Dentistry (UFPel, Approval number: 69/2013) and included edentulous patients rehabilitated with new CD at Denture Clinic at the School of Dentistry / UFPel under treatment from February 2013 and April 2014. All patients were recruited consecutively and treated by two PhD students (RMM and AMB) that specialized in prosthodontics. A bilateral balanced occlusion scheme was adopted in which twenty teeth were replaced (Trilux, VIPI Produtos Odontológicos, Brazil). Patients were eligible if they had good general health or controlled diabetes/hypertension, smoked less than 11 cigarettes per day, and were wearing conventional CD for at least three months, while showing difficulty adapting to the mandibular prosthesis and poor mandibular denture-bearing tissue conditions, following the criteria from Kapur (1967).

A written informed consent form was obtained for the patients who fulfilled the inclusion criteria and agreed to the terms. Pre-surgery exams were subsequently performed for all patients, including panoramic radiograph, teleradiograph, blood exams, clinical exam and strict anamneses. Subsequently, the masticatory function tests (masticatory performance and swallowing threshold) and questionnaires regarding the oral health impact profile (OHIP-EDENT), self-perceived oral health (GOHAI) and impact on daily life (DIDL) were applied (CD wearers - baseline).

Subsequently, two small diameter implants (2.9 x 10 mm, Facility, Neodent, Curitiba, PR, Brazil) were installed in the interforaminal region of the jaw, healing

abutments were inserted and the lower denture was relined. After three months of osseointegration, stud abutments (Equator type, Neodent) were connected for MO loading. The masticatory performance and swallowing threshold were reassessed one, three, six and twelve months after the MO loading. In addition, the patients completed the OHIP-EDENT, GOHAI and DIDL questionnaires at three, six and twelve months after loading.

The sample size calculation was based on the masticatory performance outcome of Grover et al. (2014), using the following parameters: smallest expected difference between the means, standard deviations of the difference between the means, beta error of 10% and one-tailed alpha error of 5%. The sample size was increased by 20% to compensate for losses and refusals. These calculations indicated that 14 participants were needed for this longitudinal study.

Clinical evaluation of denture-bearing tissues

Clinical evaluation of denture-bearing tissues was performed according to the criteria described by Kapur (1967). Kapur's criteria are based on the ridge shape (flat, v-shaped, shaped between u & v or u-shaped), tissue resilience (flabby, resilient or firm) and location of border tissue attachment (high, low or medium). A final score below 7 indicates poor denture-bearing tissues and patients with these scores were eligible for the study.

Masticatory function evaluation (Masticatory performance and swallowing threshold)

The MF was evaluated using Optocal$_{TM}$ artificial food cubes, a mixture of condensation silicone and other materials (Pocztaruk et al. 2008). Standardized cubes with 5.6mm sides were produced following the procedures described in previous studies (Fontijn-Tekamp et al. 2000; De Lucena et al. 2011). Each volunteer was instructed to masticate 17 portions of Optocal for 40 masticatory cycles, counted by the operator.

Subsequently, the resulting triturated mass was expelled in a disposable paper filter, washed and dried. Afterwards, the particles were air-dried for at least 1 week, sieved in a stack of up to 10 sieves with square apertures between 5.6 mm and 0.5 mm. The masticatory performance (MPX_50) was calculated from the Rosin-Rammler equation: $Q_w^-(X) = 1-(2^{-x/x50})^b$. In this equation, the median particle size corresponds to the aperture of a theoretical sieve through which 50% of the particles can pass by weight (MP_X50). The B parameter (MPB) indicates the homogeneity of the chewing, with higher/lower values corresponding to more homogeneous distributions (Fontijn-Tekamp et al. 2000; De Lucena et al. 2011). The masticatory efficiency was evaluated by the weight of the material retained in 5.6 and 2.8 mm sieves (ME5.6 and ME2.8).

During the swallowing threshold test, the patients were instructed to chew a new portion of Optocal$_{TM}$ cubes until they felt the desire to swallow. At this point the total time and the number of chewing strokes were registered by the examiner. Finally, the STX50, STB, ME 5.6 and ME. 2.8 were calculated, following the methods described by Fontijn-Tekamp et al. (2004).

Oral Health Impact Profile Questionnaire (OHIP-EDENT)

The participants answered questions related to the use of CD and MO and their physical, functional, social and psychological effects. Each question has three possible answers: 'never', 'sometimes' or 'often', scored as 0, 1 and 2, respectively. Questions 1 to 20 were reproduced from the validated Brazilian version of the OHIP-EDENT questionnaire (Souza et al. 2007; de Souza et al. 2012), based on the original version from Allen & Locker (2002).

Geriatric Oral Health Assessment Index (GOHAI)

The validated Brazilian version of the GOHAI questionnaire from Atchison and Dolan (1990) was used to assess the self-reported oral health related quality of life of edentulous patients (da Silva & Fernandes 2001; de Souza et al. 2012). This index

summarizes twelve questions about oral problems that evaluate three dimensions: physical, psychosocial and pain / discomfort. Each question has three possible answers: always / often; sometimes / rarely; and never - receiving the scores 1, 2 and 3, respectively.

Dental Impact on Daily Living questionnaire (DIDL)

The DIDL questionnaire consists of 36 questions grouped into five domains: comfort, appearance, pain, general performance and eating/chewing. The questions have three possible answers: agree (1), disagree (-1) or neutral (0) and are averaged for each domain (Al-Omiri et al. 2011). The average scores for each domain are subsequently classified as dissatisfaction (<0); relatively satisfied (0 - 0.69) and satisfied (0.7 - 1) (Leao & Sheiham 1995).

Statistical analysis

Data were submitted to descriptive analysis in order to evaluate data distribution and skewness. Since the data presented a non-normal distribution, non-parametric tests were then employed. For comparisons of clinical and subjective aspects over time, the Wilcoxon matched-pairs signed-ranks test was used. Furthermore, multivariable multilevel mixed effects regression models were also performed in order to test the association between masticatory function outcomes and the quality of life adjusted by the time of the follow-up. This variable was included and maintained in the regression models, independently of its P-value. The stepwise backward approach was employed to select variables for regression. Variables with a P-value<0.20 were retained in the model as potential confounders. The significance level for all analyses was set at 5%. Additionally, the effect size was calculated according to the following formula. Based on the final score, the effect size can be classified as follows: small (ES≃0.2); moderate (ES≃0.5); and large (ES≃0.8). All analyses were performed using the software Stata 13.1 (StataCorp.; College Station, TX).

Results

The total sample consisted of 23 edentulous patients, 8 (34.8%) men and 15 (65.2%) women with a mean age of 65.95 years (57-77). The average time of edentulism was 29.1 years for the maxilla and 23.4 years for the mandible, respectively. Means and standard deviations of masticatory performance outcomes (MPX 50, MPB, ME 5.6 and ME 2.8) are shown in Table 1, while the outcomes of swallowing threshold test are summarized in Table 2. The comparison of the outcomes prior to intervention with MO and 3, 6 and 12 months after intervention, show statistically significant differences for all outcomes related to MF, showing that these improved significantly after 1 year. The average improvement of the masticatory performance was 18% (MPX 50), 52% (MPB), 45% (ME 5.6) and 50% (ME 2.8) (Table 1). The number of masticatory cycles decreased by 18% after the first month. This decrease remained similar within error afterwards (minus 13-22% compared to initial conditions; Table 2). The STB showed no statistically significant difference ($p > 0.05$) prior to MO instalment and 3 months after loading. The masticatory performance outcomes did not change significantly ($P > 0.05$) from the values obtained one month after MO loading.

Table 1. Means and standard deviations, P-value between the different periods for the masticatory performance (MP) outcomes (X50, B, masticatory efficiency-ME 5.6(%) and ME 2.8%) (Wilcoxon paired test). Different capital letters represent significant differences ($p<0.05$) between the periods.

	Baseline	1 month	3 months	6 months	12 months
PM_X50	5.29(1.15)A	3.17(1.37)B	4.38(1.37)B	4.44(1.20)B	4,31(1,21)B
PM_B	8.24(9.90)A	3.76(2.10)B	4.26(3.30)B	4.00(2.15)B	3,93(2,1)B
ME 5.6 (%)	51.82(29.20)A	26.17(26.68)B	30.03(28.22)B	31.04(24.14)B	27,15(22,97)B
ME 2.8 (%)	10.19(10.24)A	19.96(10.18)B	20.95(11.78)B	20.31(11.79)B	19,55(11,18)B

Table 2. Means and standard deviations, P-value between the different periods for thswallowing threshold (ST) (time, number of cycles, X50, B, masticatory efficiency-ME 5.6(%) and ME 2.8%) (Wilcoxon paired test). Different capital letters represent significant differences ($p<0.05$) between the periods.

	Baseline	1 month	3 months	6 months	12 months
Time	75.78(54.53)A	59.93(31.50)A	57.70(27.64)A	63.84(36.38)A	57.8(30.21)A
nº of cycles	75.83(54.72)A	63.43(35.06)A	65.78(34.97)A	67.84(37.43)A	59.17(24.51)A
ST_X50	4.88(1.22)A	3.71(1.19)B	3.95(1.03)B	4.06(1.39)B	3.86(1.26)B
ST_B	6.08(6.89)A	3.07(1.28)B	3.94(3.81)AB	3.52(1.74)B	3.34(1.6)B
ME 5.6(%)	40.87(29.56)A	17.90(20.15)B	22.10(16.42)B	25.77(25.49)B	20.85(23.5)B
ME 2.8 (%)	14.10(10.26)A	22.29(9.61)B	20.66(9.96)B	20.82(10.48)B	23.3(11.17)B

Table 3 shows the means, standard deviations, and effect size (ES) of the domains of the three questionnaires (OHIP-EDENT, GOHAI and DIDL) 3 months post-loading. Most of the domains recorded a statistically significant difference when comparing baseline and post-loading from 3 months onwards ($p> 0.05$), with the exception of psychological and social disability domains recorded in the OHIP-EDENT questionnaire. These two domains only reduced significantly after 6 months of loading. The global OHIP-EDENT score reached significantly lower scores after 3 months compared to the initial situation (2.96 ± 4.72 $p = 0.01$), with another moderate, but statistically significant improvement from 3 to 6 months, after which no significant differences were observed. The global OHIP-EDENT score records a second significant decrease between 3 and 6 months. This resulted in a high effect size of about 1.1 for the OHIP-EDENT score at 6-12 months post MO instalment. The effect size of the improvements in the physical pain (1.5) and physical disability (1.0) domains reached their peaks at 6 months compared to the baseline, and did not vary significantly afterwards. The functional limitation domain was associated with an effect size of around 1.0, which remained fairly constant between 3 and 12 months.

Table 3. Means and standard deviations, P-value between the different periods of the OHIP-EDENT, GOHAI and DIDL questionnaires (Wilcoxon paired test). Different capital letters represent significant differences ($p<0.05$) between the periods

	Baseline	3 months	6 months	12 months	Effect size 0 - 3	Effect size 0 - 6	Effect size 0 - 12	Effect size 3 - 6	Effect size 3 - 12	Effect size 6 - 12
OHIP-EDENT										
Global	11.48(7.8)A	4(5.62)B	2.26(2.43)C	2.96(4.72)BC	0.9	1.2	1.1	0.3	0.2	0.3
Functional Limitation	3.43(2.0)A	1.57(1.62)B	1.35(1.3)B	1.13(1.36)B	1.0	1.0	1.2	0	0.3	0.2
Physical pain	3.78(2.32)A	1.13(1.96)B	0.48(0.85)B	0.74(1.18)B	1.3	1.5	1.3	0.3	0.2	0.3
Psychological discomfort	0.78(1.24)A	0.17(0.49)B	0.09(0.29)B	0.22(0.67)B	0.6	0.6	0.5	0	0.1	0.5
Physical disability	1.78(1.62)A	0.52(1.08)B	0.22(0.52)B	0.39(1.08)B	0.9	1.0	0.9	0.2	0.1	0.3
Psychological disability	0.61(0.78)A	0.26(0.62)AB	0.13(0.46)B	0.17(0.49)B	0.4	0.5	0.6	0.2	0.1	0.1
Social disability	0.52(0.9)A	0.13(0.34)AB	0(0)B	0.09(0.29)B	0.5	0.6	0.5	0.3	0.1	-
Handicap	0.57(0.9)A	0.22(0.67)B	0(0)B	0.22(0.85)B	0.4	0.6	0.4	0.3	0	-
GOHAI										
Global	27.56(2.38)A	29.17(1.4)B	28.95(2.24)B	29.57(1.04)B	0.8	0.6	0.8	0.5	0.3	0.6
Physical	8.43(1.56)A	9.34(0.93)B	9.08(2.06)B	9.70(0.88)B	2.7	0.4	0.8	0.5	0.4	0.3
Psychosocial	11.52(1.44)A	12.86(0.45)B	12.91(2.06)B	12.83(0.49)B	3.0	1.0	0.9	0.2	0.1	0.2
Pain and discomfort	7.6(0.89)A	6.95(0.47)B	6.9(0.47)B	7.04(0.64)B	0.3	0.7	0.6	0.4	0.2	0.2
DIDL										
Appearance	0.65(0,55)A	0.96(0,21)B	0.96(0.21)B	1(0)B	0.6	0.6	0.6	0.4	0.2	-
Pain	0.61(0,41)A	0.91(0,21)B	0.96(0.14)B	0.85(0.24)B	0.8	0.9	0.6	0.2	0.3	0.8
Oral Comfort	0.14(0,4)A	0.76(0,27)B	0.89(0.19)C	0.81(0.29)BC	1.5	1.8	1.7	0.5	0.2	0.4
General performance	0.67(0,43)A	0.93(0,2)B	1(0)C	0.96(0.08)B	0.6	0.8	0.7	0.4	0.2	-
Eating and chewing	0.06(0,83)A	0.86(0,43)B	0.91(0.31)B	0.91(0.42)B	1.0	1.1	1	0.1	0.1	0

OHIP-EDENT (Oral Health Impact Profile Questionnaire), DIDL (Dental Impact on Daily Living) and GOHAI (Geriatric Oral Health Assessment Index)

The global GOHAI score increased significantly from baseline after 3 months, and peaked after 12 months of MO loading (29.57 ± 01.04, p =0.002), with an effect size 0.8. The highest effect sizes with respect to the baseline scores were observed in the psychosocial (3.0) and physical (2.7) domains, after 3 months.

The oral comfort domain in the DIDL questionnaire showed statistically significant improvements for all comparisons between baseline and post loading periods. The eating and chewing domain showed a large ES around 1.0 from 3 months onwards, and this did not vary significantly. Conversely, the oral comfort and general performance domains improved significantly after 6 months compared to the 3 months assessment. The general performance domain again decreased slightly, but significantly between 6 and 12 months. The effect sizes in the oral comfort domain with respect to the baseline scores are fairly high (1.5-1.8). The general performance domain has lower effect sizes, which increase gradually from 0.6 to 0.8 from 3 to 6 months, before dropping down slightly to 0.7 after 12 months.

The satisfaction rates obtained by the DIDL questionnaire (Figure 1) shows that the percentage of satisfaction increased after the MO loading across all domains. Three months MO post-loading, the lowest satisfaction percentage was observed in oral comfort domain 82.6%, while the highest percentage of satisfied patients was observed in the appearance domain with 95.7% satisfaction. Six months post loading, the lowest satisfaction rates were observed in the pain and oral comfort domains, both showed 91.3% of satisfied patients. Conversely, the highest percentage of satisfied patients was observed in the general performance domain, with a satisfaction rate of 100%. Twelve months post loading, the lowest satisfaction percentage was observed in the pain domain, with only 69.6% of satisfied patients, while the highest percentage of satisfied patients was observed in the appearance and general performance domain with 100% of satisfaction.

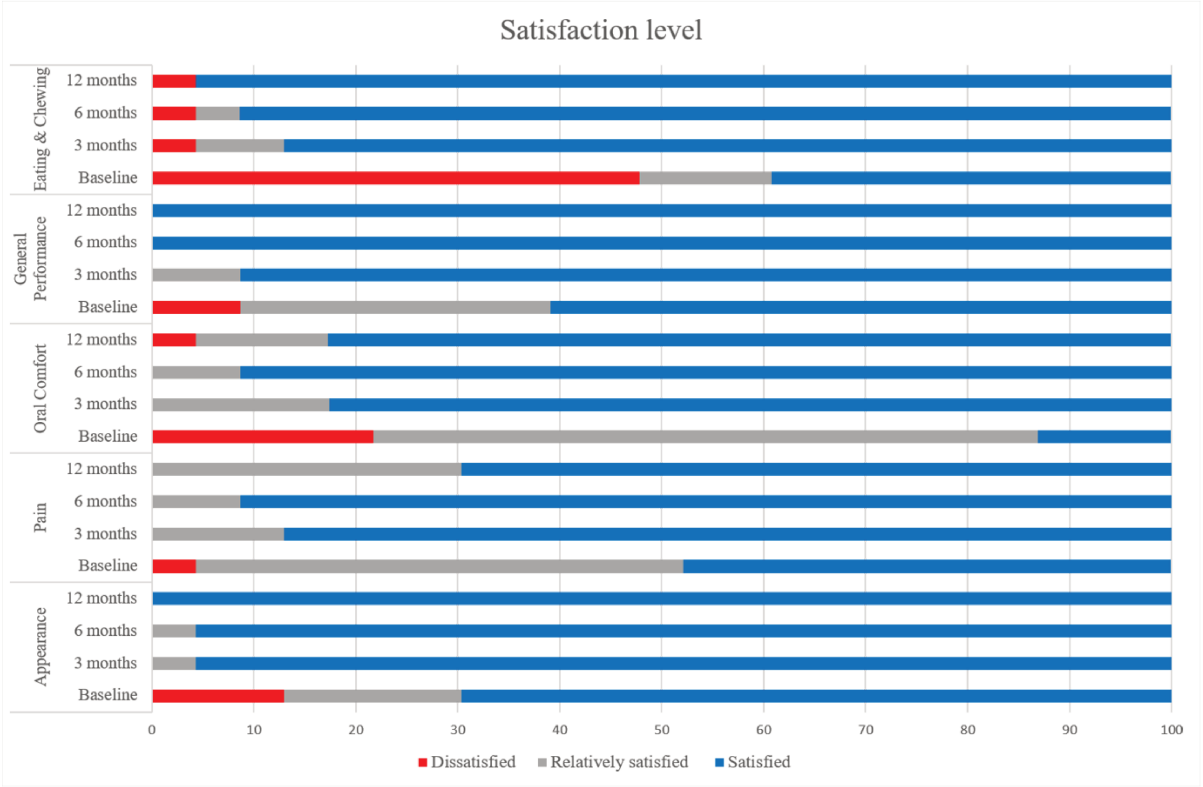

Figure 1. The graphic shows the patient's satisfaction level (Dental Impact on Daily Living - DIDL questionnaire) according to each domain over time.

The Tables 4 and 5 summarize the results of the regression model that investigates the association between the masticatory function outcomes (Masticatory performance, MP_X50, MPB, ME 5.6, ME 2.8, Swallowing threshold - Time, number of cycles, ST_X50, STB, ME 5.6, ME 2.8) and the domains of the three questionnaires. The paragraphs below focus on the positive and negative impacts of the objective masticatory parameters on the self-perceived determinants of the life quality observed in all questionnaires.

The masticatory performance outcomes over the 12 months of follow -up showed associations with the OHIP-EDENT questionnaire including 4 domains: i) MP_X50 had a positive impact on Functional limitation and Physical Pain domain; ii) MPB showed a positive impact on Functional limitation domain, and negative impact on Handicap domain.; iii) ME 5.6 had a positive impact on Functional limitation, Physical Pain and Social disability domains, while negative impact on the Handicap domain; iv) ME 2.8 had a negative impact on Functional

limitation, Physical pain and Handicap domain. The associations with DIDL questionnaire were observed in 3 main domains as follow: i) MP_X50 had a positive impact on Pain and Oral comfort; ii) MPB had a positive impact only on Oral comfort domain; iii) ME 5.6 had a positive impact on Appearance, Pain and Oral comfort domain; iv) ME 2.8 had a positive impact on Pain and Oral comfort domain. Regarding to GOHAI questionnaire, only the Psychosocial domain was positively associated with the masticatory outcomes MP_X50, ME 5.6 and ME 2.8.

The swallowing threshold outcomes over the 12 months of follow-up, the associations in the OHIP-EDENT questionnaire showed a positive impact on Global score related to ST_X50 and ME 5.6, and in were also found in 5 domains: i) ST_X50 had a positive impact on Physical pain domain, and negative impact on Handicap domain was noticeable; ii) STB had a positive impact on functional limitation domain while a negative impact on Psychological discomfort; iii) ME 5.6 had a positive impact on Physical pain domain and had a negative impact on Psychological discomfort domain; iv) ME 2.8 had a positive impact on Physical disability domain. The DIDL questionnaire revealed associations with all swallowing threshold outcomes in 3 main domains that indicates a clinical beneficial interaction: i) Time had a positive impact on Appearance and Pain domain; ii) Number of cycles had a positive impact on Pain domain; iii) ST_X50 had a positive impact on Oral comfort domain; iv) STB had a positive impact on Appearance and Oral comfort domain; v) ME 5.6 had a positive impact on Oral comfort domain; vi) ME 2.8 had a positive impact on Oral comfort domain. The GOHAI questionnaire showed only negative associations as follows: i) Time and number of cycles had a negative impact on Physical domain; ii) ST_X50 and ME 5.6 had a negative impact on Psychosocial domain.

Table 4. Summary of the significant associations related to Masticatory Performance from multivariable multilevel mixed effects regression models.[1] Abbreviations: OHIP-EDENT (Oral Health Impact Profile Questionnaire), DIDL (Dental Impact on Daily Living) and GOHAI (Geriatric Oral Health Assessment Index). Bold text indicates a clinically beneficial interaction while italic text indicates adverse clinically interaction.

	MP_X50		**MPB**		**ME 5.6**		**ME 2.8**	
	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value
OHIP - EDENT								
Functional Limitation	**0.16 (0.01;0.31)[1]**	**0.032**	**0.88 (0.01;1.76)[4]**	**0.048**	**0.13 (0.01;0.2)[6]**	**0.033**	*-0.05 (-0.1;-0.01)[6]*	*0.044*
Physical Pain	**0.22 (0.1;0.35)[1]**	**0.001**			**0.13 (0.03;0.2)[6]**	**0.009**	*-0.09 (-0.1;-0.05)[6]*	*0.001*
Social disability					**0.32 (0.02;0.6)[6]**	**0.039**		
Handicap			*-3.35 (-5.6;-1.1)[4]*	*0.034*	*-0.35 (-0.6;-0.1)[6]*	*0.009*	*0.15 (0.1;0.3)[6]*	*0.004*
DIDL								
Appearance					**-0.47 (-0.9;-0.1)[6]**	**0.038**		
Pain	**-0.88 (-1.5;-0.24)[2]**	**0.007**			**-0.84 (-1.4;-0.3)[6]**	**0.003**	**0.30 (0.05;0.5)[9]**	**0.019**
Oral Comfort	**-0.54 (-1.0;-0.1)[2]**	**0.014**	**-2.71 (-5.3;-0.1)[5]**	**0.041**	**-0.44 (-0.8;-0.1)[6]**	**0.020**	**0.21 (0.04;0.4)[9]**	**0.016**
GOHAI								
Psychosocial	**-0.33 (-0.6;-0.2)[3]**				**-0.40 (-0.5; -0.2)[7]**	**0.001**	**0.1 (0.04;0.2)[10]**	**0.002**

The domains that did not present significance (P <0.05) over time were not displayed in the table.

Legend: [1] Adjusted for variables retained in the model and Global Score; [2] Adjusted for variables retained in the model and Appearance; [3] Crude association; [4] Adjusted for variables retained in the model and Global Score and Psychological disability; [5] Adjusted for Physical Pain; [6] Adjusted for variables retained in the model; [7] Adjusted for pain; [8] Adjusted for physical inability; [9] Adjusted for variables retained in the model and chewing; [10] Adjusted for physical.

Table 5. Summary of the significant associations related to Swallowing Threshold from multivariable multilevel mixed effects regression models.[1] Abbreviations: OHIP-EDENT (Oral Health Impact Profile Questionnaire), DIDL (Dental Impact on Daily Living) and GOHAI (Geriatric Oral Health Assessment Index). Bold text indicates a clinically beneficial interaction while italic text indicates adverse clinically interaction.

	Time		**Number of cycles**		**ST_X50**		**STB**		**ME 5.6**		**ME 2.8**	
	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value	Coef. (95%CI)	P-value
OHIP												
Functional Limitation							**1.21 (0.7;1.7)[7]**	**<0.001**				
Physical Pain					**0.2 (0.04;0.3)[4]**	**0.007**			**0.1 (0.001;0.2)[7]**	**0.05**		
Psychological discomfort							*-1.5(-2.8;-0.3)[7]*	*0.014*	*-0.2 (-0.4;-0.1)[7]*	*0.04*		
Physical disability											**-0.1 (-0.2;-0.05)[2]**	**<0.001**
Handicap					*-0.4 (-0.7; -0.03)[4]*	*0.035*						
Global score					**0.1 (0.01;0.1)[4]**	**0.020**			**0.04 (0.001;0.07)[7]**	**0.05**		
DIDL												
Appearance	**-23.7 (-39.6;-7.8)[1]**	**0.003**					**-3.7 (-6.3;-1.0)[8]**	**0.006**				
Pain	**-24.8 (-43.4;-6.2)[1]**	**0.009**	**-28.4 (-50.0;-6.9)[3]**	**0.010**								
Oral Comfort					**-0.8 (-1.2;-0.3)[5]**	**0.001**	**-2.3 (-4.5;-0.1)[8]**	**0.04**	**-0.5 (-0.9;-0.2)[9]**	**0.004**	**0.21 (0.04;0.4)[9]**	**0.02**
GOHAI												
Physical	*-6.8 (-10.2;-3.3)[2]*	*0.001*	*-8.5 (-12.1;-4.9)[2]*	*0.001*								
Psychosocial					*-0.23 (-0.4,-0.1)[2]*	*0.001*			*-0.2 (-0.3;-0.02)[2]*	*0.046*		

The domains that did not present significance (P <0.05) over time were not displayed in the table.

Legend: [1] Adjusted for variables retained in the model and general performance; [2] Crude estimates; [3] Adjusted for appearance, general performance and chewing; [4] Adjusted for variables retained in the model and psychological discomfort; [5] Adjusted for pain; [6] Adjusted for variables retained in the model and social disability; [7] Adjusted for variables retained in the model; [8] Adjusted for variables retained in the model and chewing; [9] Adjusted for appearance and pain; [10] Adjusted for variables retained in the model and functional limitation, psychological discomfort and global score.

Discussion

The retention and stability of conventional dentures are determining factors in the comfort and successful rehabilitation (Jacobson & Krol 1983a; Abu Hantash et al. 2011). However, prolonged edentulism and progressive bone resorption results in difficulties to recover the masticatory function to a level that is satisfactory for the patient. Based on our 1-year follow up of the masticatory function via the masticatory performance, masticatory efficiency and swallowing threshold test and subjective perception through the OHIP- EDENT, GOHAI and DIDL questionnaires, we found that the MO significantly improved chewing, quality of life, self-perception of oral health and patient satisfaction within the first three months after loading.

The masticatory performance of patients improved significantly after MO loading, since the values of MPX50 and MPB were smaller and the amount retained on the 2.8 sieve was higher from 1 month onwards. Thus, we can state that the patients' mastication was more effective, leaving a more homogeneous food bolus. These values did not improve significantly afterwards. The latter can be attributed to the effective retention and stability of the mandibular complete dentures by the implants. Compared to MO wearers, patients rehabilitated with new CDs require a longer adaptation period to perform their masticatory functions, due to the initial difficulty in adapting with the mandibular CD (Marcello-Machado et al. 2017). Because of the progressive mandibular residual ridge resorption (RRR), the ridge becomes thinner and the mucosa more sensitive. The lack of retention and stability, subsequently causes ulcers and mucosal soreness (van Kampen et al. 2004; Polzer et al. 2010; Stellingsma et al. 2004). The MO wearers adapt faster to the new condition, due to the stability and retention that the implants provide to the mandibular prosthesis, illustrated by our results.

Based on our results, we believe that 1-month post loading is an excellent time to perform reliable MF tests, taking into account the different psychological profiles of the research volunteers and allowing sufficient time to adapt to the new condition. Previous

studies also found that MO wearers have better mastication and increased bite force, and these improvements are maintained over time (van der Bilt 2011; Fontijn-Tekamp et al. 2000; van Kampen et al. 2004). While these studies compared different groups of people, our clinical study evaluates the benefits provided by the MO in the same population over time, further validating their results. Van Kampen et al. (2004) found that MO wearers required 50% less chewing cycles than complete denture wearers to halve the size of food particles. In this sense, our study we observed that the largest decrease in number of cycles occurred at 12 months post MO loading.

Previous studies (Fontijn-Tekamp et al. 2004; van Kampen et al. 2004) comparing the swallowing threshold results between conventional CD wearers and MO wearers have described no significant differences between the number of cycles, the time of the swallowing threshold and the particle size to be swallowed. Our study also showed a limited effect of MO in terms of chewing cycles. No statistic differences were found between the number of masticatory cycles and chewing time at different time periods. The number of masticatory cycles only decreased by about 16% and 18%, respectively, after transforming the CD wearers in MO wearers. However, as indicated by the masticatory performance obtained for the swallowing threshold, a significant decrease in the size of the comminute particles was found. On average, STX50 decreased by about 20%, by about 43% the STB, by about 47% for the ME5.6, with a 38% increase in the amount of material retained in the ME 2.8.

So far, little has been discussed about what constitutes satisfactory chewing. Witter et al. (2013) define a healthy chewing function as one similar to a young, fully dentate patient. It is unknown whether patients rehabilitated with MO would really be able to get a well-prepared food bolus. In our study, we only observe an insignificant decrease in the number of cycles, with an average reduction by only 13 masticatory cycles after the MO loading, i.e., conventional denture wearers need 1.5 times more cycles. In this sense, our results are lower than those described in previous studies

(Geertman et al. 1994; Fontijn-Tekamp et al. 2000; van der Bilt 2011), which indicate that CD wearers need 2 to 4 times more masticatory cycles compared to MO wearers to form the food bolus. Still, with the intention to deepen the knowledge of how the MO improves the edentulous masticatory function and at what point they are efficient (Woda et al. 2011; Witter et al. 2013), conducted a study that proposed a X50 value as a delimiter between satisfactory and unsatisfactory mastication. Therefore, those who obtain one X50 below 4.0 or 3.7 in the swallowing threshold test, respectively, have achieved a satisfactory chewing. Taking this into consideration, we can say that on average our sample has achieved a satisfactory chewing in the evaluation periods after MO loading. It is also important to highlight that the B values of our patients almost halved, for both the masticatory performance and the swallowing threshold tests. This allows us to conclude that the MO provided a significant improvement in the food bolus homogenization.

While objectives benefits provided by MO are well established, it is not only in this context that its implementation makes difference to the patient. Often, the improvements treatment provides in their daily lives and in their in social interaction is the most important to them. In order to explore which factors have the greatest impact on patient's subjective perception, we chose to use three questionnaires (OHIP-EDENT, GOHAI and DIDL) that assess the Oral health related to quality of life (OHRQoL) in different ways. According to results from the OHIP-EDENT questionnaire, patients did not perceive a difference in their psychological and social life before the treatment 3 months post loading. However, after 6 months, all domains showed a statistically significant improvement. It is believed that this delay is related to the initial MO adaptation, in which the prosthesis can still move during use and consequently cause discomfort. This difficulty in adapting resembles the difficulties found in the CD use, which directly affect the social and psychological disability domains, so patients seek MO treatment (Assunção et al. 2009). We calculated decided to make the effect size for each

domain of the three questionnaires, so that we could determine which domains had the greatest improvement, as perceived by the patient. For OHIP-EDENT, the functional limitation, physical pain and physical disability domains were all associated with effect sizes, and strongly affecting the patients' perception at the third month. Therefore, we can say that comfort to eat and to use the prosthesis provided by the MO was what made the most difference for these patients. One study (Awad et al. 2014) that used the OHIP-EDENT questionnaire to compare people rehabilitated with conventional CD and MO in different regions of the world also noted better OHRQoL in the MO wearers. After effect size evaluation, the authors observed a greater impact of treatment in those rehabilitated with MO, in this case the population of South America, which has high effect sizes for the functional limitation (0.85), physical pain (0.88), psychological disability (0.87), physical disability (0.83) and psychological discomfort (0.85) domains.

The GOHAI is a simple and effective questionnaire to assess the self-perception of patients on the new prosthetic treatments (Madhuri et al. 2014). The positive impact of MO loading in the patients' OHRQoL was immediately apparent, showing that this tool was very sensitive to detect improvements in all domains already at 3 months. Some studies also report this improvement in OHRQoL after performing of a new treatment, either with CD (Madhuri et al. 2014; Veyrune et al. 2005) or with mplant retained prosthesis (Fillion et al. 2013; Veyrune et al. 2013). Moreover, the greatest impact caused by the treatment was perceived in the physical (speaking, eating and swallowing) and psychosocial (appearance, worry and discomfort in interpersonal relationships). However, when we analyse the effect size of all questionnaires together, we can say that the lack of CD's stability and retention difficult to the function, and after the MO loading, the prosthesis' stability and retention increased, providing a considerable improvement in the function. These facts can be easily perceived by high effect size values in the domains related to function and comfort and by the significant improvement in objective evaluation of masticatory function.

The impact on daily living questionnaire (DIDL) is an instrument that evaluates the impact and importance of each domain in the patient's satisfaction and daily activities in relation to the treatment performed (Al-Omiri et al. 2011). When analysing the results obtained from the DIDL questionnaire, all domains had significant difference when comparing the assessment with conventional CD and post loading, but the appearance and general performance domains showed a moderate effect size while the other domains had a high effect size. These data indicate that rehabilitation with MO positive impact on patient OHRQoL, and more intensely in comfort with the prosthesis and its subjective perception of the quality of mastication after loading. Abu Hantash et al. (2011), also reported that the comfort and safety in the use of the prosthesis during daily activities is the aspect that generates more concern to patients, however, the function and appearance of the prosthesis is not always the most important to them.

After analysing the results of satisfaction resulted from DIDL questionnaire, the majority of patients in this study was already satisfied in the third month after loading in relation to all domains, and only one patient was dissatisfied in the first evaluation about the eating/chewing domain and this patient was the only one that remained with the same perception at 6 and 12 months. Differently, one study (Abu Hantash et al. 2011) that also evaluated the satisfaction, but only for CD wearers, observed that the most of the patients were dissatisfied with their CD in relation to the pain, oral comfort and general performance domains. That way, when analysing the results of this study together with the results of Abu Hantash et al. (2011), we can say that the increasing in the retention and stability of the mandibular prosthesis promoted by implants can provide greater comfort and self-confidence for the patient to perform their activities of daily living, consequently improving OHRQoL.

Regarding the associations between MF parameters from MP and ST tests and self-perception quality of life some interesting points can be raised. Fist, GOHAI questionnaire was not able to show any association between the specific domain related

to the MF and the objective parameters related to the MF, only the Physical domain showed a negative association with the time and number of cycles to complete the ST Test. Second, in the OHIP-Edent and DIDL questionnaire, MP tests were able to present higher number of associations related to masticatory outcomes compared to ST tests. Functional Limitation Domain from the OHIP-Edent showed strong associations with all masticatory outcomes in MP tests, however when the ST test was taking into account only the ST_B values were able to be captured/felt by the self-perception of the patient. Physical Pain domain showed also significant associations in MP and ST tests, however without any perceived effect in the B parameter. Finally according to DIDL questionnaire, the oral comfort domain shows the greatest capacity to detect associations with MF improvement during the MP and ST tests, while the association between MF parameters and Pain domain was observed only during the MP test evidencing that when the patients are allowed to performed the number of cycles to swallow they are not able to report pain. This study was able to reliably demonstrate the real and perceived benefits that the MO provided, and highlights the differences between the functional domains and the patients perceptions related to the masticatory improvements and its relationship with the quality of life determinants.

The oral comfort domain of the DIDL shows the greatest capacity to detect associations with MF improvement. This study was able to reliably demonstrate the real and perceived benefits that the MO provided, and highlights the differences between the functional domains. The objective outcome of homogenizing the food bolus (MPB, STB), achieved an improvement of about 50% compared to baseline conditions. Subjectively, the MO provide greater safety for patients, and considerably improve their self-confidence in the execution of activities. Though some limitations can be identified, such as not having assessed the maximum bite force, which is directly linked to the masticatory function and salivary flow that helps the homogenization of food bolus for a better swallowing. Further studies should be conducted in order to identify the dynamic

and metabolic factors involved in masticatory function of this population and thus investigate the treatment process with MO in more detail.

Conclusion

Implant-retained overdentures considerably improved both the objective masticatory function as well as the OHRQoL and patients' satisfaction about the treatment. This improvement was already noticeable after 1 month for functional parameters and 3 months for subjective perception.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Compliance with Ethical Standards

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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2.4 ARTIGO: How does mandibular bone atrophy influence the masticatory function, OHRQoL and satisfaction in overdenture wearers? Clinical results until 1 year post-loading

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(Anexo 5)

Running head: Mandibular bone atrophy and overdenture wearers

Raissa Micaella Marcello-Machado[1]; Fernanda Faot[2], Alessandra Julie Schuster[3]; Amália Machado Bielemann[3], Otacílio Luiz Chagas Júnior[4], Altair Antoninha Del Bel Cury[5]

[1] MSc, PhD student, Graduate Program in Clinical Dentistry, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

[2] PhD, Professor, Department of Restorative Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil.

[3] PhD student, Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, RS, Brazil

[4] PhD, Professor, Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, School of Dentistry, Federal University of Pelotas, RS, Brazil.

[5] PhD, Professor, Department of Prosthodontics and Periodontology, Piracicaba Dental School, State University of Campinas, Piracicaba, Brazil.

*Corresponding author:

Prof. Altair Antoninha Del Bel Cury, PhD, Department of Prosthodontics and Periodontology, Piracicaba Dental School, University of Campinas, Avenida Limeira 901, 13414-903 Piracicaba - São Paulo – Brazil, e-mail: altair@unicamp.br

Summary

This longitudinal clinical study investigated the differences in the masticatory function (MF), satisfaction and oral health related quality of life (OHRQoL) between atrophic patients (AP) and non-atrophic patients (NAP) before and after rehabilitation with mandibular overdenture (MO). Twenty-six complete denture (CD) wearers were categorized into two groups, according to the mandibular bone atrophy (MBA) degree. MF was evaluated before and after 1, 3, 6 and 12 months of the MO loading via 2 standardized tests: i) MP, masticatory performance (MP_X50, MPB, ME 5.6, ME 2.8) and ii) ST, swallowing threshold (time, number of cycles, ST_X50, STB, ME 5.6, ME 2.8). The Dental Impact on Daily Living (DIDL) questionnaire measured changes in the satisfaction level and OHRQoL. MP comparisons showed significant difference only for ME 5.6 12 months after MO loading (AP=33.79±23.6; NAP=17.58±20.1). ST presented significant differences before MO loading for: ST_X50 (AP=5.48±0.83;NAP=4.31±1.44), ME 5.6 (AP=53.17±24.71; NAP=29.83±31.45) and ME 2.8 (AP=8.76±6.91; NAP=18.61±10.71). One month after MO loading, NAP performed the ST test 21% faster than AP. After 3 months significant improvements in STB (AP=4.93±4.82; NAP=2.73±1.27) and ME 2.8 (AP=17.15±10.00; NAP=24.69±7.82) also were observed. DIDL evaluation showed significant differences in the oral comfort domain after 3 months (AP=0.66±0.29; NAP=0.87±0.16) and after 6 months (AP=0.79±0.22; NAP=0.98±0.08), with lower satisfaction levels in the AP. MBA negatively affects the MF mainly the ST. After 6 months, differences between AP and NAP disappeared and ST results were equalized. AP initially have lower satisfaction levels reaching similar levels of satisfaction as NAP after 1 year.

Key-words: atrophy, bone resorption, mandible, mastication, overdenture, patient satisfaction,

Introduction

Residual ridge resorption (RRR) is one of the major oral diseases, which occurs in a progressive, chronic, uncontrollable and irreversible way[1]. Progressive RRR in edentulous patients leads to increasingly severe levels of atrophy, negatively influencing the selection of the rehabilitation type, predictability and patient expectation. From an anatomical point of view, a thin and flat ridge leads to superficial muscular insertions, and resorption of the superior wall of the mental foramen results in superficiality of the alveolar nerve. These factors contribute to an unfavorable prognosis of the treatment[2]. Consequently, the patient's major complaint has been attributed to a lack of comfort, retention and stability, and especially to a painful sensation during the use of the complete denture (CD)[3].

Oral sequelae of edentulism have a direct relationship with impaired mastication, unhealthy diet and poor quality of life, and an association between edentulous patients' poor chewing and depression was also reported[4,5]. The masticatory function (MF) of CD users is also limited by the usage time of the prostheses, poor retention and stability, and pain in the denture-bearing tissues, especially in the mandible[3,6].

Implant-supported mandibular overdentures (MO) are currently the most accepted reference treatment for rehabilitation of edentulous patients, especially for patients with a long edentulism time and limited bone availability[6,7]. The rehabilitation with MO supported by only two implants has shown favorable results[8] and a significant impact on the MF improvement of edentulous patients, since it is able to increase bite force, decrease the number of masticatory cycles and reduce the size of the chewed particles for swallowing[6,8,9]. Improvements in satisfaction rates have also been reported. However, Boven et al., (2015)[8] state that the effects on the quality of life after treatment with MO is still uncertain. In addition to the functional and psychosocial benefits generated by the increased MO retention and stability, prospective longitudinal clinical

studies have shown that this prosthetic modality is able to reduce the RRR rate in the mandible by about 57.7%, compared to the RRR rate in CD wearers[10].

Nevertheless, the relationship between MF and mandibular bone atrophy is still controversial, especially when these patients are adapting to the transition between CD and MO[11]. Furthermore, the effect of MO on the quality of life of these patients is uncertain[8]. Thus, the objective of this study was to investigate the evolution of MF parameters, satisfaction and oral health related quality of life in atrophic patients (AP) and non-atrophic patients (NAP) during the transition from CD to MO in the first year after loading.

Material & Methods

Experimental Design experimental

This is a longitudinal clinical study, conducted in accordance with the Helsinki Declaration, 2008, following the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (STROBE)[12]. The study was performed in the Complete Denture Clinic at the UFPel's School of Dentistry and approved by the Ethics Committee in Local Search (69/2013). Patients wearing a new CD for at least three months, who did not present uncontrolled diabetes or hypertension, bleeding disorders, serious systemic diseases, compromised immune system, a history of radiotherapy in the head or neck region and were available to attend the school of dentistry on the evaluation days were invited to participate in the research. All patients were rehabilitated with prostheses made with heat-*polymerized acrylic resin (VIPICRIL plus* - VIPI® - Pirassununga, SP, Brazil), acrylic resin artificial teeth (Trilux – VIPI® - Pirassununga, SP, Brazil) and implants system were consisted of Ti Grade V (NeoPoros surface - Neodent® - Curitiba, PR, Brazil).

All selected patients subsequently signed the written informed consent file. The patients' mandibular bone atrophy was subsequently evaluated with panoramic radiographs, according to the criteria of Cawood & Howell[13]. To be allocated to the AP group, patients should present both a bone height in the anterior region below 25 mm and a bone height in the posterior region below 16 mm. For the NAP group, patients should present bone heights equal or higher than 25 and 16 mm in the anterior and posterior region, respectively (Figure 1a and 1b). Patients that met only one of the criteria were excluded from the study.

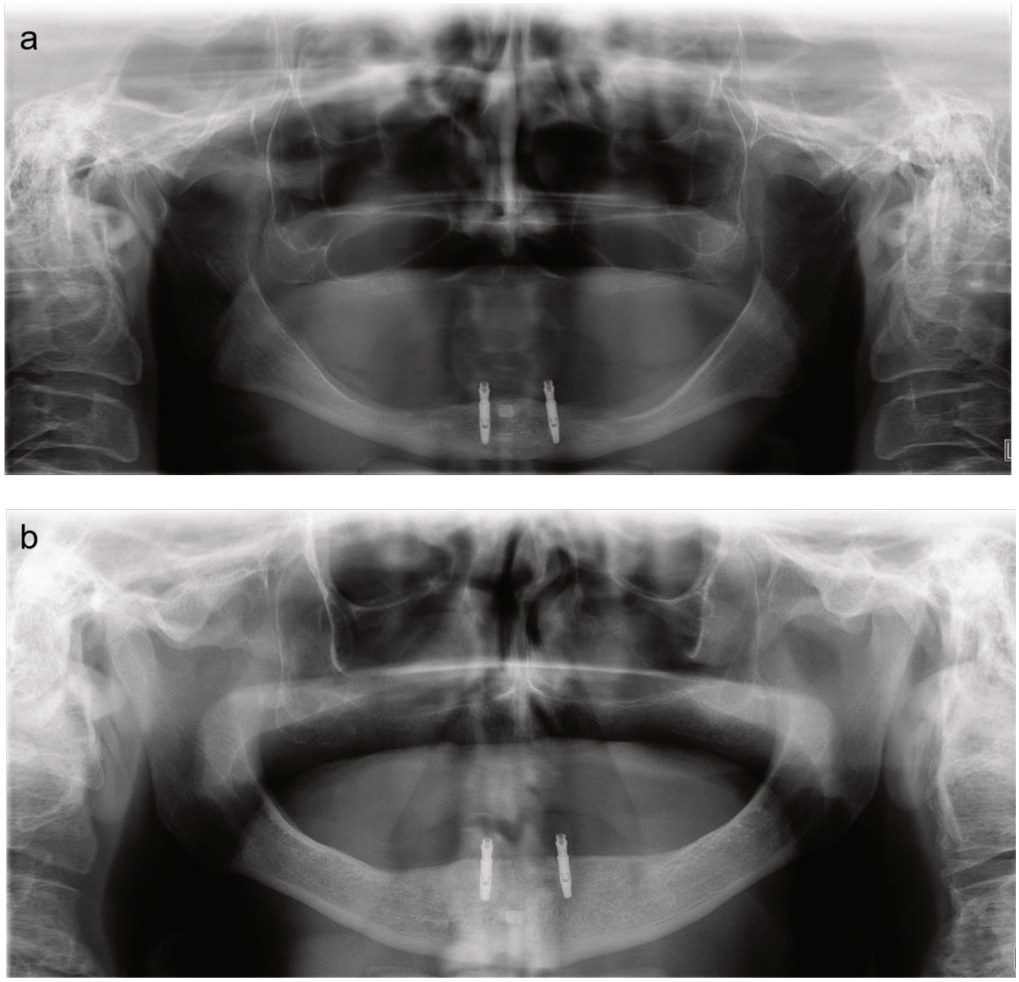

Figure 1. Panoramic radiograph after MO installation: a.) atrophic patient; b) non-atrophic patient.

The dental impact on daily living (DIDL) questionnaire and MF tests were performed before and after the installation of two narrow dental implants (Facility NeoPoros, 2.9X10mm – Neodent® - Curitiba, PR, Brazil) in interforaminal region of the mandible. The DIDL questionnaire evaluates how oral health is perceived by individuals and determines the impact of oral interventions in daily life in relation to each domain, and the total index score can be used as a proxy for patient satisfaction[14–16]. Masticatory performance (MP) tests were performed according to the methodology previously described for this population[3]. In addition, the Swallowing Threshold test (ST) was also performed by the patient that was instructed to chew the “Optocal” portion until they felt the desire to swallow. For the ST test, the time of mastication and the number of

masticatory cycles were also registered[17].The MF (MP_X50, ST_X50) was then calculated using the median particle size, which corresponds to the aperture of a theoretical sieve through which 50% of the particles weight can pass. The B outcome variable (MPB, STB) is a measure for the homogeneity of the chewed particle size distribution6. The masticatory efficiency was evaluated by the weight of the material retained in 5.6 and 2.8 mm sieves (ME5.6 and ME2.8).

After 3 months of osseointegration, the stud attachments (Equator type, Neodent) were installed for the MO loading. The MF tests were applied again, 1, 3, 6 and 12 months after the MO loading, and the DIDL questionnaire was completed 3, 6 and 12 months after loading.

The sample size calculation was based on the MF outcome of a previous study[18], using the following parameters: smallest expected difference between means, standard deviations of the difference between means, beta error of 10% and one-tailed alpha error of 5%. The sample size was increased by 20% to account for potential losses and refusals. These calculations determined that 12 participants were required for this longitudinal clinical study.

Statistical analysis

The data were submitted to descriptive analysis to evaluate the distribution and asymmetry of the data. The clinical and radiograph parameters presented normal distribution and were analyzed using T-test. Non-parametric tests were used for analysis of non-normally distributed data (MF and DIDL outcomes). The Mann-Whitney test was used for comparisons of the clinical and subjective aspects between the groups at each time. The Wilcoxon matched-pairs signed-ranks test was used to compare the clinical and subjective aspects at different evaluation times. For the paired comparisons, we used a correction of the P-value. The p-value of 0.05 was divided by the number of follow-ups, and then a P-value ≤0.01 was considered as being significant. In addition, the effect sizes (ES) were calculated as the difference in the mean DIDL scores, divided by the

standard deviation of the DIDL score at the previous time. The effect sizes were classified as follows: small (≤0.2), moderate (0.2-0.5) and large (≥0.5). All analyses were performed using SPSS software 22 (IBM SPSS Statistics 22). The level of significance was set at 5% for all analyses.

Results

The sample population consisted of 26 patients divided in two groups of 13. The AP group consists of 2 men and 11 women with a mean age of 68.4 years. The non-atrophic patient (NAP) group consists of 7 men and 6 women with a mean age of 66.2 years. The maxillary and mandibular edentulism time was significantly different between both groups (p=0.03 and p=0.001, respectively). The height in the anterior region, in the posterior region and the superior height of the mental foramen in the NAP group were significantly higher than the AP group (P<0.0001), only the mandibular length was not significantly different between the groups (p=0.192). Table 1 describes the MP outcomes for each group, and the intragroup differences at the evaluated periods. None of the MP outcomes presented a statistically significant difference (p>0.05) between the groups at any evaluation period, except ME 5.6. The lowest EM5.6 value found in the NAP group of 17.32% was found after 1 month, and this value rises slightly between 1 and 3 months towards 23.57%, (p>0.05). The percentage of non-reduced food particles in the EM5.6 mesh was significantly higher for the AP group (33.8) than for the NAP group (17.6; p=0.039) at 12 months post MO loading. When comparing the post-loading evaluation periods in the AP group, the MP_X50 outcome showed a small but significant increase of around 4% between 1 and 3 months, and the MPX_50 value remained 2.2% smaller than baseline after 6 months.

Table 1. Comparisons between the means and standard deviations of the Masticatory Performance outcomes (MPX50, MPB, ME 5.6 and ME 2.8) intragroup (Wilcoxon Test, $p<0.05$) and intergroup (Mann-Whitney Test, $p<0.05$), atrophic (n=13) and non-atrophic (n=13), at different evaluation periods.

	Baseline		**1 month**		**3 months**		**6 months**		**12 months**	
	Atrophic	**Non-atrophic**	**Atrophic**	**Non-atrophic**	**Atrophic**	**Non-atrophic**	**Atrophic**	**Non-atrophic**	**Atrophic**	**Non-atrophic**
MP X50	5.72±1.13a	5.03±1.25a	4.55±1.33b	3.69±1.22b	4.76±1.32ac	3.99±1.35b	4.65±1.04c	4.21±1.32b	4.66±1.15bc	3.85± 1.10b
MPB	8.34±4.93a	8.99±13.86a	4.34±2.41b	2.92±0.98a	4.55±2.79ab	4.17±4.39a	3.78±1.45b	3.98±2.38a	4.25±2.06b	3.31±1.52ac
ME 5.6(%)	62.95±28.96a	47.37±31.42a	32.68±28.34ac	17.32±21.03b	36.51±28.84ac	23.57±27.79b	32.03±20.74bc	29.02±26.34b	**33.79± 23.6*bc**	**17.58± 20.1*b**
ME 2.8(%)	7.01±8.19a	13.28±11.48a	17.97±12.23b	23.51±7.15b	18.94±12.75b	23.57±11.04ab	19.83± 10.83b	21.44±12.21b	18.63±12.29b	23.44±9.84b

* The asterisk shows the differences between the groups (Atrophic and Non-atrophic) at each evaluation period. The letters show the differences between the intragroup comparisons.

Comparisons between the baseline ST outcomes of the AP and NAP groups (Table 2) indicate significant statistical differences ($p<0.05$) for the variables ST_X50 (AP=5.48; NAP=4.32; p=0.022), ME5.6 (AP=53.17; NAP=29.83; p=0.029) and EM 2.8 (AP=8.76; NAP=18.61; p=0.015). One month post MO loading, the NAP group performed the test 20% faster than the AP group (AP=65.95 sec; NAP=52.13 sec; p=0.043). After 3 months of MO loading, the STB outcome indicated significantly more homogeneous ST size distributions for the NAP group (AP=4.92; NAP=2.72; p=0.021), paired with a significantly larger fraction of reduced particles in ME2.8 (AP=17.15; NAP=24.69; p=0.038).

Table 2. Comparisons between the means and standard deviations of the Swallowing Threshold outcomes (Time, number of cycles, STX50,STB, ME 5.6 and ME 2.8) intragroup (Wilcoxon Test, $p<0.05$) and intergroup (Mann-Whitney Test, $p<0.05$), atrophic (n=13) and non-atrophic (n=13), at different evaluation periods.

	Baseline		**1 month**		**3 months**		**6 months**		**12 months**	
	Atrophic	**Non-atrophic**	**Atrophic**	**Non-atrophic**	**Atrophic**	**Non-atrophic**	**Atrophic**	**Non-atrophic**	**Atrophic**	**Non-atrophic**
Time(s)	82.22±56.2a	70.57±49.14a	65.95±24.13a	52.13±25.32*a	66.80±30.44a	50.02±20,04a	68.35±38.74a	52.51±19.93a	60.2± 33.1a	52.58± 16.74a
N° of cycles	73.31±58.85a	71.54±40.38a	66.0±24.1a	52.13±25.32a	73.38±36.22a	60.31±31.09a	70.15±39.05a	58.23±19.91a	58.5± 27.9a	55.62± 14.91a
ST X 50	**5.48±0.83*a**	**4.31±1.44*a**	3.88±1.36b	3.54±1.08a	4.25±1.16b	3.64±0.88a	3.92±1.16b	4.01±1.47a	4.20±1.32b	3.54±1.29b
STB	7.05±7.15a	5.13±6.00ab	3.49±2.22c	2.94±0.84ab	**4.93±4.82*ab**	**2.73±1.27*a**	3.41±1.76b	3.57±1.79b	3.78± 2.07ab	3.29±2.03ab
ME 5.6(%)	**53.17±24.7*1a**	**29.83±31.45*a**	21.99±23.96b	14.58±17.95ab	26.68±21.38b	18.20±12.31ab	20.71±20.18b	25.01±26.89ab	26.0± 25.3b	17.16± 25.61b
ME 2.8(%)	**8.76±6.91*a**	**18.61±10.71*a**	19.99±10.65bc	22.45±10.74a	**17.15±10.0*b**	**24.69±7.82*a**	22.74±9.72c	20.48±11.48a	23.2± 12.9bc	23.2±9.32a

* The asterisk shows the differences between the groups (Atrophic and Non-atrophic) at each evaluation period. The letters show the differences between the intragroup comparisons.

Table 3 presents the intragroup and between group comparisons for each DIDL domain. The oral comfort domain scores of the AP and the NAP group were significantly different ($p<0.05$) after 3 months (AP=0.66, NAP=0.87, p=0.035) and after 6 months (AP=0.8, NAP=0.98, p=0.011). The DIDL score effect sizes (ES) are presented in Table 4. The largest effect sizes compared to the baseline scores were found in the AP group. The greatest effect of treatment was observed after 3 months in the pain domain (ES 1.3), after 6 and 12 months in the oral comfort domain (ES 2.3), and after 12 months in the eating/chewing domain (ES 1.7). The largest ES in the NAP group were found in the oral comfort domain, with ES of 1.5, 1.7 and 1.4 after 3, 6 and 12 months, respectively. The satisfaction levels obtained by the DIDL questionnaire presented in (Figure 2a and 2b) show that the percentage of satisfaction increased after the MO loading across all domains in both patient groups.

Table 3. Comparisons between the means and standard deviations of the DIDL domains intragroup (Wilcoxon Test, p<0,05) and intergroup (Mann-Whitney Test, p<0.05), atrophic (n=13) and non-atrophic (n=13), at different evaluation periods.

	Baseline		3 months		6 months		12 months	
	Atrophic	Non-atrophic	Atrophic	Non-atrophic	Atrophic	Non-atrophic	Atrophic	Non-atrophic
Appearance	0.58±0.56a	0.52±0.71a	0.92±0.27a	1±0a	1±0a	0.92±0.27a	1±0a	1±0a
Pain	0.56±0.31a	0.67±0.47a	0.96±0.14b	0.88±0.29a	0.86±0.36ab	0.96±0.14a	0.87±0.22b	0.85±0.24a
Oral Comfort	0.11±0.30a	0.05±0.56a	**0.66±0.29*b**	**0.87±0.16*b**	**0.79±0.22*b**	**0.98±0.08*b**	0.78±0.31b	0.82±0.32b
General Performance	0.58±0.46a	0.66±0.36a	0.90±0.26b	0.98±0.05b	1±0c	1±0b	0.98±0.07bc	0.97±0.08b
Eating/Chewing	-0.14±0.67a	0.23±0.91a	0.89±0.21b	0.83±0.55a	0.95±0.19b	0.89±0.37a	1±0b	0.85±0.55ab

* The asterisk shows the differences between the groups (Atrophic and Non-atrophic) at each evaluation period. The letters show the differences between the intragroup comparisons.

Table 4. Effect sizes in the different DIDL domains as a function of time (in months) within the atrophic (n=13) and non-atrophic (n=13) groups.

	Effect-size 0-3	Effect-size 0-6	Effect-size 0-12	Effect-size 3-6	Effect-size 3-12	Effect-size 6-12
ATROPHIC (n=13)						
Appearance	0.6	0.8	0.7	0.2	0.3	0
Pain	1.3	1	1	0.7	0.7	0
Oral Comfort	1.8	2.3	2.3	0.5	0.4	0.1
General Performance	0.7	0.9	0.9	0.4	0.3	0
Eating/ Chewing	1.5	1.6	1.7	0.2	0.5	0.3
NON ATROPHIC (n=13)						
Appearance	0.7	0.6	0.7	0	0	0.3
Pain	0.4	0.6	0.4	0.3	0.1	0.8
Oral Comfort	1.5	1.7	1.4	0.7	0.3	1.9
General Performance	0.9	0.9	0.8	0.4	0.2	0
Eating/ Chewing	0.7	0.7	0.7	0.1	0	0.1

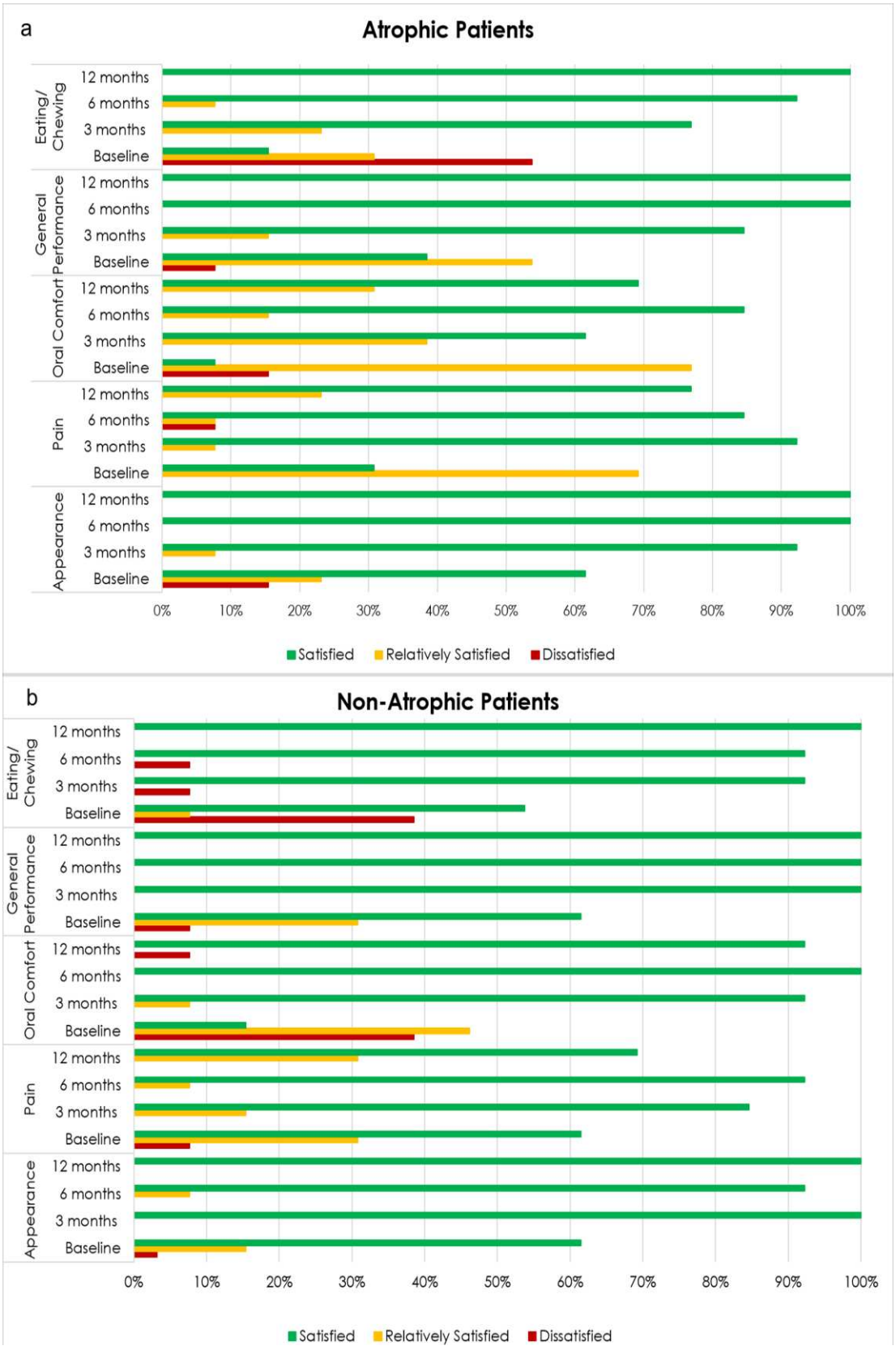

Figure 2. Representative graphic of patients' satisfaction level (DIDL questionnaire) according to each domain over time: a.) atrophic patient; b) non-atrophic patient.

Discussion

Previous clinical studies[6,9] along with a systematic review[8] described the improvement of the MF and highlighted the positive impact of the MO on various aspects of edentulous patients oral health. The present study expands on these previous results by providing data from a controlled clinical study with frequent follow-ups over 1 year for a sample categorized according to well-established Cawood & Howell mandibular bone atrophy criteria. The influence of mandibular bone atrophy on MF and OHRQoL of the edentulous patients has not been investigated with details in the literature. By measuring the objective MF modifications and combining this with the patients' subjective perception, this setup allows to determine the effective and acute adaptation period during the transition from CD to MO in AP and NAP, which has not previously been reported.

The objective MF evaluations in our clinical study showed that the mandibular bone atrophy interferes in the MF only when patients are wearing CD. Conventional denture-wearing AP obtained a worse MF, mostly determined by ST test, characterized by a greater number of masticatory cycles and impairment mastication compared to CD-wearing NAP. This changed after transition to MO, since 6 months after MO loading the AP group achieved similar chewing abilities as the NAP group. Regarding the satisfaction and quality of life, we can affirm that the mandibular atrophy does not interfere in these parameters. However, our results indicate that the AP group requires a longer time to adapt to MO mainly observed when the oral comfort domain is evaluated over time.

The MP is measured by the mean particle size that the patient can masticate the test food after a fixed number of masticatory cycles[19,20]. The masticatory outcomes from this test showed that there was no difference between the NAP and AP groups until 12 months after MO installation. After 12 months, the percentage of particles in the ME5.6 mesh for the AP group was twice as high as in the NAP group, evidencing that NAP have a better capacity to masticate the test food. The absence of a detected significant

difference in the finer sieve fractions is attributed to the smaller mass fractions in these sieves, reducing the reliability with which differences can be detected. However our study following patients during the transition period from CD into MO during 1-year showed significantly improved most MP parameters for both the AP and NAP groups. The MPB outcome for the NAP group remained identical to the baseline value, indicating that the particle homogeneity did not change significantly.

The ST test showed that CD-wearing NAP chewed about 14% faster than CD-wearing AP, and the number of cycles in the NAP group was only 2% lower than in the AP group, with no statistically significant difference. After the transition from CD to MO, these differences were amplified. This difference is less pronounced than the one reported by Fontijn-Tekamp et al.[6]. One month after MO loading, the NAP group finished the ST significantly faster than the AP group. However, no significant differences were found after 12 months, although the NAP group chewed on average about 21% faster than the AP group and performed about 13% less cycles than the AP group. It is known that the bite force of edentulous patients after MO installation have an improvement of only 20%[11].

Based on our results and based on the outcomes from previous study[21], we can state that MO rehabilitation is more impactful in the objective outcomes of MF when measured by ST, and the improvements are more clear for AP than for NAP. Similar results were found in the study of Kimoto et al., 2003[21], who declare that the MO considered is the most effective treatment when an advanced RRR process is observed[21]. The CD-wearing AP probably have more difficulties to masticate food due to lack of support from the CD, thus requiring a greater number of masticatory cycles to fragment the food before swallowing the food bolus in an effective and comfortable manner. This decrease in the MF of the AP can only be detected by the ST test, because each volunteer chews the test food until they felt the desire to swallow. Consequently,

only the ST illustrates the real functional scenario related to the adaptation of the masticatory system and the committed chewing for edentulous patients[6,17].

Although the treatment of edentulous patients with MO clearly improves patient satisfaction, a systematic review[8] about the MO performance concluded that high levels of satisfaction are not always accompanied by a proportional increase of the quality of life related to oral and general health. In this sense, based on an evaluation of the patient's perception, our study showed that residual ridge atrophy does not affect patients' perceived satisfaction, since both AP and NAP reported similar satisfaction levels, although the MF of the AP group is objectively worse. However, after the transition to MO, the satisfaction regarding the DIDL questionnaire's oral comfort domain at 3 and 6 months was affected by mandibular ridge atrophy, with AP group reporting lower values for this domain.

In this way, we can affirm that AP need a longer time to adapt to the new clinical condition imposed by the MO treatment. A possible explanation for this is related to the time required for the reestablishment of oral comfort of the mandibular CD, since this was directly related to a greater number of prosthetic adjustments. The number of prosthetic adjustments post-installation in AP are proportional to the severity of the anatomical and morphological changes. In cases of severe atrophy, the musculature commonly becomes superficial, the surrounding mobile tissues invade the prosthesis edge and the alveolar nerve becomes exposed, resulting in a greater sensitivity during the first months of MO loading[1,22]. In addition, the support area for MO in AP is lower and consequently the CD design is more bulky and has a larger flange, because it needs to account for the resorbed bone tissue and the patient's vertical occlusion distance[6]. Although the intragroup comparisons in our study indicate that MO affect the satisfaction and quality of life for both groups in an equally positive way, but in the AP group the treatment with MO is perceived as a larger improvement. In accordance with our results, Kimoto et al., 2005 and Pan et al., 2010[23,24], also evidenced that regardless of the

residual ridge height, the perception of patients' satisfaction with prosthetic treatment is improved.

Finally, we should note that we have not investigated some aspects that may interfere with the masticatory process, such as bite force, salivary flow and mapping of mandibular kinematics. Another limitation of our study was that we did not consider the possible interferences of the material used to manufacture the overdentures, including the type of attachments, type of tooth, type of acrylic resin. At this moment, it is not fully understood how these factors could influence the results. What is known is that the difference between the rehabilitating materials can affect the comfort of the patient and the difference in the occlusal table of different types of artificial teeth can affect the masticatory function. In relation to tooth type, several studies have shown that teeth with cusp angles between 30° and 33° simulate a physiologic occlusion[25–27]. These studies indicated that these types should preferred for patient's rehabilitation, because they allow a better penetration of the food, thus providing a better masticatory efficiency. In addition, the attachment type may have influenced some variables that affect chewing, such as retention, stability, and comfort. The most widely studied of the available attachments are the O-ring type attachments. This system has some problems, such as a greater need of realignment and exchange of the retentive matrix, requiring a greater number of maintenance sessions[28]. Stud attachment types are an alternative treatment option, and seem to promote greater comfort by generating greater retention and stability[29].

Nonetheless, our study brought new results that illustrate the differences in the MF development in AP and NAP during the transition from CD to MO in the first year of MF. Based on our results and those of previous studies, we indicate that the clinician makes a prior evaluation of the patient's degree of atrophy. This will enable the clinician to raise the patient's awareness that their RRR condition will influence the duration of the adaptation phase from CD to the new mandibular rehabilitation by MO.

CONCLUSION

We observed that mandibular bone atrophy negatively affects the MF of completely edentulous patients. However, after six months of MO treatment, the masticatory outcomes of all patients improve and atrophic patients achieve similar MF outcomes as non-atrophic patients. Regarding the satisfaction and quality of life, we observed that AP need a longer adaptation time than NAP, because the former more dissatisfied with oral comfort domain until six months MO post-loading. Clinicians should keep this in mind when informing and preparing their patients for the objective and perceived improvements that they can expect.

Disclosure

The authors declare no potential conflicts of interest with regard to the authorship and / or publication of this article.

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3 DISCUSSÃO

O uso de implantes de diâmetro reduzido (IDR) vem sendo extensamente recomendados para reabilitação oral em virtude de sua versatilidade e melhorias relacionadas a macrogeometria e resistência mecânica provenientes do desenvolvimento das ligas de titânio. Entretanto, diante de restrições para indicação de IDR e de poucas evidências científicas a respeito do prognóstico destes sistemas de implantes em longo prazo, torna-se de extrema importância aprofundar-se na compreensão de indicadores do desempenho clínico dos mesmos, principalmente como retentores de overdentures mandibulares (OM), indicação para qual estes tem sido amplamente adotada. Para tanto, os índices de sucesso e sobrevivência, além de perda óssea marginal após carregamento funcional destes 2 tipos de implantes foram levantados na literatura e sistematicamente organizados no capítulo 2.1. Esta revisão sistemática, embora existam revisões a respeito deste tipo de implantes (Sohrabi et al., 2012; Ortega-Oller et al., 2014; Klein et al., 2014), analisou dados clínicos de uma população específica baseando-se no desempenho individual de MI e IDR de acordo com o tipo de prótese. Desfechos já relatados em revisões previas são restritos a previsibilidade desses implantes avaliados apenas através das taxas de sobrevivência e ou sucesso comparando-os aos implantes de diâmetro convencional (IDC).

Ao estimar a previsibilidade de ambos os tipos de implantes, nossa revisão se destaca por agrupar dados que ilustram o desempenho clinico de índices de sucesso, sobrevivência e perda óssea peri-implantar ao longo dos anos por meio de meta-análises. Estes resultados evidenciaram que MI e IDR apresentam taxas de sobrevivência (MI=99%; IDR=98%) e sucesso (MI=95%; IDR=98%) semelhante aos já descritos para IDC, 96.7% (Buser et al., 1997) e 99% (de Souza et al., 2015). Entretanto, alguns fatores como número de implantes e o tipo de carga, também podem interferir nos resultados de desempenho obtidos. Souza et al., 2015 afirma que os MI podem alcançar resultados no mínimo parecidos com os IDR, sendo que overdentures retidas por 4 MI podem obter uma maior taxa de sobrevivência, provavelmente devido a biomecânica. Além disso, o tipo de carga pode influenciar no sucesso da

reabilitação. Portanto, a carga convencional nestes casos, torna-se preferencial em relação à carga imediata (Maryod et al., 2014). Por fim, risco maior de falha e fratura pode ser apresentado tanto pelos MI quanto pelos IDR, provavelmente devido à sua menor área de superfície em contato com o tecido ósseo e por apresentarem menor resistência aos esforços mastigatórios quando comparados a IDC. Assim, recomenda-se que MI e IDR sejam utilizados apenas em pequenos espaços ou rebordos com espessura reduzida (Zinsli & Mericske 2004; Allum et al., 2008; El-Sheikh et al., 2012). El-Sheikh et al., 2012, realizou um estudo com OM retidas por 2 ou 3 IDR, com acompanhamento de 2 anos e encontrou alta taxa de sobrevivência de 98%. Assim é possível concluir que dois IDR instalados na região anterior de mandíbula como retentores de OM são suficientes para garantir a previsibilidade deste tipo de reabilitação, especialmente em pacientes com mandíbula atrófica (El-Sheikh et al., 2012).

Outro fator bastante importante para determinar a previsibilidade desses implantes é a perda óssea marginal. Sabe-se que uma remodelação óssea de 2 mm no primeiro ano pós carregamento dos IDC, seguido de no máximo 0,2 mm por ano é aceitável (Roos et al., 1997; Papaspyridakos et al., 2012). Assaf et al., 2015 sugeriram que a previsibilidade dos implantes não está relacionada somente ao seu diâmetro, mas também à perda óssea marginal e se essa está dentro dos limites relatados para os IDC. A partir da nossa meta-análise, observamos que os MI apresentaram perda óssea marginal de 0.89 mm no primeiro ano, de 1.18 mm no segundo ano e de 1.02 no terceiro ano. Já os IDR apresentaram uma perda óssea menor, sendo de 0.18 mm no primeiro ano, 0.12 mm no segundo ano e de -0.32 mm no terceiro. Zweers et al., 2015 também sugeriram que durante os primeiros 3 anos pós instalação das próteses, os IDR apresentam maior perda óssea quando comparado com os IDC.

Mesmo diante dos benefícios, das indicações e das considerações observadas através da revisão sistemática e metanálise realizada, ainda são escassas as informações sobre a performance clinica destes implantes como retentores de OM em pacientes desdentados totais com alto tempo de edentulismo e limitada espessura óssea. Neste sentido, o estudo clínico longitudinal relatado no capítulo 2.2, determinou a previsibilidade e o

comportamento clínico dos IDR como retentores de OM em uma população considerada de risco por apresentarem alto tempo de edentulismo e clinicamente atrofia mandibular. Durante o primeiro ano em função, os dados clínicos de 30 pacientes evidenciaram que durante a fase de osseointegração dos IDR, os índices IPV, GI e o cálculo apresentaram maiores valores. Atribuímos isto ao fato destes pacientes serem desdentados totais por um longo tempo, e assim necessitaram de um período de adaptação à nova condição clínica. Os índices utilizados para avaliação da saúde peri-implantar são interdependentes, uma vez que um aumento no acúmulo de placa ou cálculo leva à inflamação dos tecidos moles peri-implantares possivelmente aumentando os níveis de profundidade de sondagem, sangramento gengival podendo resultar em perda óssea marginal (Salvi & Lang 2004; Baltayan et al., 2016). Assim, acredita-se que a excelente higienização com consequente bem-sucedida cicatrização dos tecidos moles peri-implantares foi responsável pela diminuição gradativa da profundidade de sondagem ao longo dos tempos avaliados, sendo maior no período pós carregamento. Sugere-se que quando esta diminuição for maior ou igual a 1mm avalie-se clinicamente a necessidade de troca do componente protético devido à exposição do transmucoso em excesso. Entretanto, a diminuição da profundidade de sondagem também pode ter ocorrido pela formação de mucosa queratinizada resistente ao redor dos componentes protéticos, a qual funciona como uma proteção dos tecidos frente a inflamação dos tecidos moles que pode ser causada pelo acúmulo de placa. Sendo assim, pode-se afirmar que a mucosa queratinizada está diretamente relacionada à saúde dos tecidos peri-implantares(Salvi et al., 2004; Bouri et al., 2008).

Ainda neste estudo observou-se queda nos valores de ISQ durante o primeiro mês pós-instalação, os quais se mantiveram estáveis, e a partir da semana 48 tornaram a subir significativamente chegando à valores semelhantes à estabilidade primária (baseline). Esta redução da estabilidade dos implantes corresponde ao início do período de osseointegração e de remodelação óssea que ocorre logo após a instalação dos implantes (Gokmenoglu et al., 2014). Além disso, isso pode estar vinculado ao alto tempo de edentulismo da nossa população, que pode ter tornado o processo de osseointegração mais lento. Outro fato bastante interessante, foi observarmos diferença significativa no ISQ de implantes perdidos, sendo que estes apresentaram valores mais baixos do

que os implantes sobreviventes. Neste sentido, Monje et al., 2014 (Monje et al., 2014) afirmam que apesar do ISQ ser uma excelente ferramenta para determinar o momento mais adequado para o carregamento dos implantes, ainda não é possível, determinar valores de cut off para diagnosticar falha precoce do implante.

Adicionalmente, a taxa de sucesso e sobrevivência encontrada em nossa amostra foi de 83,3% e considerada mais baixa provavelmente pela condição de atrofia do rebordo mandibular. Em geral, este perfil de paciente apresenta maior proporção de osso cortical e menor proporção medular e, consequentemente um menor suprimento sanguíneo com menor número de células mesenquimais atuando na fase inicial do reparo ósseo resultando em uma resposta biológica comprometida/piorada. Além disso, com o alto tempo de edentulismo apresentado por estes pacientes, e o rebordo mandibular não receber estímulos mecânicos por um período prolongado, podem desencadear alterações na microarquitetura óssea, interferência no suprimento sanguíneo e consequentemente influenciar a qualidade e intensidade das respostas celulares (Davies, 2003). Entretanto, quando esses implantes perdidos foram substituídos a taxa de sucesso e sobrevivência foi de 100%, isso confirma a hipótese de que após receber novos estímulos o osso teve uma maior capacidade de regeneração. Em relação ao processo de remodelação óssea peri-implantar, Roos et al., 1997 e Papaspyridakos et al., 2012, afirmam que uma remodelação de 2 mm no primeiro ano pós carregamento dos implantes, seguido de no máximo 0,2 mm por ano é aceitável. Em nossa amostra encontramos uma média de -0.06±0.64, variando de -1.1 a 1.2 mm, sendo esta dentro dos parâmetros aceitáveis na literatura. Além disso, podemos destacar que toda nossa amostra recebeu carga convencional, e provavelmente por isso apresentou uma perda óssea marginal baixa.

Dentre as intercorrências observadas destacamos que em média foi necessário um retorno por paciente para ajuste da prótese após o carregamento da OM, como também, uma troca de o'rings rosa por paciente. Em casos de reabilitação com OM esses são os atendimentos podem ser mais frequentes, principalmente porque a prótese torna-se estável e pode traumatizar a mucosa (Albrektsson et al., 1987) e o oring pode se desgastar com a ação da saliva, e com a inserção e remoção da prótese ao longo do tempo. Kleis et al., 2010

sugerem que acompanhamentos e adequações anuais são necessárias com o sistema Locator devido à perda de retenção das OM em decorrência do desgaste da borracha. A principal complicação que ocorreu durante o primeiro ano foi a expulsão do componente protético, que provavelmente ocorreu devido a quantidade de mucosa ao redor do implante, na maioria dos casos, ser bastante queratinizada e resistente, e ainda também pode ser devido ao tipo de conexão entre implante e componente protético que é do tipo locking taper juntamente ao movimento de remoção da prótese (junção cone morse pura instalada com auxílio de martelete). Outra complicação frequente foi a necessidade de recaptura da OM. Akca et al., 2013 observaram que componentes do tipo locator tiveram menor durabilidade da fêmea em relação à componentes do tipo bola em reabilitações com OM. Durante nosso follow-up ocorreram 5 fraturas de prótese, e isto se deve provavelmente a espessura reduzida da flange da prótese e ao maior diâmetro do conector interno da prótese resultando em uma maior fragilidade da prótese.

Do ponto de vista funcional, o estudo do capítulo 2.3 descreveu os benefícios funcionais promovidos pela estabilização de PT mandibulares por dois IDR nesta população com atrofia óssea e longo tempo de edentulismo. Sabe-se que as OM ao aumentar retenção e estabilidade das próteses é um fator determinante no conforto e no sucesso da reabilitação (Boven et al., 2015). Em nossa população, após a transformação das PTs em OM, observamos que os pacientes foram capazes de triturar, cerca de 20%, melhor o alimento teste deixando o bolo alimentar, cerca de 50%, mais homogêneo e após atingir esta condição, observada já após 1 mês de conversão da prótese, ela se manteve inalterada ao longo de 1 ano, sem qualquer mudança significativa entre os tempos pós carregamento. De fato, esta melhora na condição mastigatória ocorreu devido ao aumento da retenção e estabilidade das próteses mandibulares proporcionada pela ancoragem sobre implantes osseointegráveis e efetivamente relatada e percebida pelo paciente especialmente quando avaliamos o impacto nos indicadores positivos obtidos por domínios relacionados ao conforto durante o uso.

Alguns estudos (Van Der Bilt et al., 2010, van Kampen et al., 2004; Fontijn-Tekamp et al., 2000) encontraram resultados semelhantes, no qual usuários de OM apresentam melhor função mastigatória (FM) e força de mordida

que são mantidas ao longo do tempo. Entretanto, estes estudos prévios compararam diferentes grupos de pessoas, enquanto nosso estudo clinico avalia os benefícios proporcionados pela OM em uma mesma população ao longo do tempo. Diferentemente, van Kampen et al., 2004 encontrou que o grupo de usuários de OM necessitaram de 50% menos ciclos mastigatórios que o grupo de PT para quebrar a partícula a metade do seu tamanho. Já nosso estudo clínico pareado observou que a maior diminuição no número de ciclos mastigatórios ocorreu aos 12 meses pós instalação das OM, cerca de 22%. Dois estudos clínicos (Fontijn-Tekamp et al., 2004; van Kampen et al., 2004) assim como o nosso também evidenciaram um efeito limitado das OM no limiar de deglutição (LD) de desdentados totais, pois não houve diferença significativa entre o número de ciclos e no tempo. Entretanto diferentemente desses estudos (Fontijn-Tekamp et al., 2004; van Kampen et al., 2004) nós observamos uma diminuição significativa, cerca de 20%, no tamanho das partículas trituradas.

Até o momento pouco tem se discutido a respeito de como seria classificada uma mastigação satisfatória-saudável. Para Witter et al., 2013 uma mastigação saudável é aquela semelhante à de um paciente jovem completamente dentado, porém não se sabe se os pacientes reabilitados com OM seriam realmente capazes de alcançar essa adequada formação do bolo alimentar. Ainda, com a intenção de aprofundar os conhecimentos do quanto as OM melhoram a FM de desdentados totais e em que ponto elas são eficientes, Woda et al., 2010 e Witter et al., 2013, realizaram um estudo em que propuseram um valor de X50 como delimitador entre uma mastigação satisfatória e insatisfatória. Sendo assim, aqueles que obtivessem um X50 abaixo de 4.0 ou 3.7 no teste de LD, respectivamente, conseguiram atingir uma mastigação satisfatória. Levando isto em consideração, é possível afirmar que em média a nossa amostra conseguiu atingir uma mastigação satisfatória nos períodos de avaliação pós carregamento das OM, além da mesma diminuir os valores de B, tanto no teste de performance mastigatória (PM) quanto LD, em quase a metade dos valores iniciais, nos permitindo concluir que as OM proporcionaram uma importante melhora significativa na homogeneização da formação bolo alimentar.

Os benefícios objetivos proporcionados pelas OM são inúmeros, porém não é só neste âmbito que sua implementação faz diferença para o paciente, muitas vezes o que o tratamento proporciona na sua vida diária e no seu convívio em social é o mais evidente. Ao explorarmos o impacto da OM através da percepção subjetiva do paciente optamos por utilizar três questionários (OHIP-EDENT, GOHAI e DIDL) que avaliam a qualidade de vida relacionada à saúde oral (OHRQoL) de maneiras diferentes. Através do OHIP-EDENT observamos que os domínios Limitação funcional, dor física e incapacidade física obtiveram um alto efeito clínico evidenciando que o conforto para comer e utilizar a prótese, proporcionados pela OM, é o que mais impacta e também é rapidamente percebido. Diferentemente, durante a utilização da PT são os domínios incapacidade social e psicológica os mais afetados , por isso os pacientes procuram o tratamento com OM (Assunção et al., 2009). Através da interpretação do GOHAI também observamos um maior impacto do tratamento nos domínios funcionais e relacionados ao conforto, assim é evidente que a falta de estabilidade e retenção das PTs dificultam a função do paciente. Por fim, o DIDL indicou que a reabilitação com OM impacta positivamente na OHRQoL do paciente, e de forma mais intensa no também no conforto em relação à prótese e na sua percepção subjetiva em relação à qualidade da mastigação após o carregamento. Abu Hantash et al., 2011 em seu estudo também relatou que o conforto e a segurança na utilização da prótese durante as atividades diárias é o aspecto que mais gera preocupação aos pacientes. Em relação à satisfação observou-se que já no terceiro mês pós carregamento a grande maioria dos pacientes ficou satisfeito, em relação a todos os domínios.

Diante da grande confiabilidade os benefícios reais e perceptíveis que as OM proporcionaram, com ênfase nos domínios funcionais, dúvidas ainda persistem quanto a influência da atrofia óssea mandibular na FM e na OHRQoL dos desdentados totais. E ainda o impacto de OM não tem sido investigado com detalhes na literatura, especialmente durante o período de transição entre PT e OM em uma amostra pareada de pacientes. Neste sentido, o estudo clínico relatado no capítulo 2.4 investigou o comportamento da FM, a satisfação e a qualidade de vida relacionada à saúde oral em pacientes com atrofia óssea mandibular (PA) e pacientes sem atrofia óssea mandibular (PNA) quando

reabilitados com PT e após a transição para OM. A partir de avaliações objetivas em uma amostra similar de 13 PA e PNA, observamos que a atrofia óssea mandibular interfere na FM somente enquanto usuários de PT, pois os PA obtiveram pior FM uma vez que além de executarem um número maior de ciclos mastigatórios, ainda assim não conseguem triturar o alimento como os PNA no teste de LD para os desfechos LD_X50, EM5.6 e EM2.8. Além disso, somente após 6 meses de transformação da PT em OM os PA conseguiram atingir uma mastigação semelhante à dos PNA. Em relação a satisfação e qualidade de vida, podemos afirmar que a atrofia por si só não interfere nestes parâmetros, no entanto os PA necessitam de um maior tempo para acostumar-se com o modelo de mastigação mais estável proporcionado pelo uso de OM.

Através do teste de LD observamos que os PNA, enquanto usuários de PT, mastigaram cerca de 14% mais rápido que os PA e o número de ciclos foi apenas 2% menor que o dos PA. Após a transformação das PT em OM houve um aumento nessas diferenças, os PNA, ao longo dos 12 meses, mastigaram em média cerca de 21% mais rápido que os PA e executaram cerca 13% menos ciclos que os PA, entretanto somente 1 mês após o carregamento houve diferença estatística significativa para o tempo. Diferentemente do nosso estudo, Fontijn-Tekamp et al., 2000 relataram que PNA usuários de PT necessitaram de 50% menos ciclos mastigatórios que os PA usuários de PT para trituração do alimento. Ao avaliarmos o LD de cada grupo, separadamente, foi possível perceber que PA apresentam mais resultados significativos na melhora dos desfechos mastigatórios após 12 meses do tratamento com OM ($p<0,05$ para LDX50, LDB, EM 5.6 e EM 2.8 entre baseline e 12 meses) do que PNA, pois, após 1 ano somente o LDX50 e EM 5.6 tiveram diferenças significativas no grupo de PNA.

A partir da avaliação da percepção subjetiva do paciente, observamos que a atrofia do rebordo residual não afeta a satisfação do paciente enquanto usuário de PT. Entretanto, após a transformação em OM, a satisfação em relação ao domínio conforto oral do DIDL, aos 3 e 6 meses, foi afetada pela atrofia do rebordo alveolar. Desta forma, podemos afirmar que os PA necessitam de um maior tempo para adaptarem-se à nova condição clínica. Uma possível explicação para isso está ligada ao tempo requerido para o reestabelecimento

do conforto oral da prótese mandibular, diretamente relacionado ao maior número de consultas para ajuste protético observado neste tipo de paciente que são proporcionais a severidade das mudanças anatômicas e morfológicas, existentes a um longo período de tempo, causadas pela RRR. Nestas situações é comum observar-se que a musculatura torna-se superficializada, os tecidos móveis circundantes invadem a borda da prótese e o nervo alveolar torna-se exposto resultando em uma maior sensibilidade durante os primeiros meses de instalação das OM (Atwood & Coy, 1971; Atwood, 2001). Além disso, a área de suporte para OM nos PA é menor e consequentemente a PT apresenta um desenho com flange maior e mais volumosa, pois ela necessita restaurar além do tecido ósseo reabsorvido, a dimensão vertical de oclusão do paciente (Fontijn-Tekamp et al., 2000). Ainda observamos que para os PA o tratamento com OM apresentou um maior efeito, visto que houveram valores elevados de ES nos domínios dor, conforto oral e mastigatório em todos os tempos quando comparados ao baseline. Kimoto & Garrett, 2005; Pan et al., 2010, assim como no presente estudo, também evidenciaram que independente da altura do rebordo residual a percepção de satisfação dos pacientes frente ao tratamento protético é melhorada.

Em adição estudos como van der Bilt, 2011 e Marcello-Machado et al., 2016 também afirmam que a percepção subjetiva da habilidade mastigatória do paciente desdentado total tende a ser mais otimista do que de fato ocorre quando estes são avaliados objetivamente. Nosso estudo, também complementa estes achados clínicos prévios pois diferenças significantes na satisfação entre PA e PNA antes da instalação das OM não foram encontradas enquanto que na avaliação do LD se observou diferença entre os grupos no baseline. Em complementação, mesmo que objetivamente as OM não apresentaram tanto impacto nos aspectos funcionais relacionados a FM em PNA, a percepção subjetiva de qualidade de vida e satisfação após a instalação de OM mostraram melhora significativa em ambos os grupos.

Desta maneira, acreditamos que com esta tese conseguimos apresentar uma compilação de informações para fornecer subsídios para o clínico no planejamento, na escolha do tipo de implante e do tipo de reabilitação, e desta forma auxiliar na determinação de um prognóstico seguro para o tratamento de pacientes que requeiram overdentures implanto-retidas por MI ou

IDR. Ainda, elencamos os muitos benefícios que a estabilização das PT por dois implantes de diâmetro reduzido trouxe a esta população com pobres condições de suporte para PT e alto tempo de edentulismo. Outro fato importante de salientarmos é que dois pacientes da nossa amostra eram ex-fumantes e três eram fumantes. Entretanto, isto não influenciou no sucesso e sobrevivência dos implantes, pois dos dez implantes perdidos apenas três foram em fumantes. Portanto, podemos salientar que este novo sistema (Facility e Equator - Neodent®) é uma alternativa segura e menos invasiva para ancoragem de overdentures em pacientes com limitada disponibilidade óssea. Destacamos que a técnica cirúrgica e a experiência do cirurgião foram muito importantes para o sucesso da instalação dos IDR, para a cicatrização e acomodação das estruturas anatômicas que suportam a prótese total. Entretanto, nossos resultados são todos baseados em apenas um ano de acompanhamento do comportamento clínico peri-implantar e do desempenho das overdentures e suas complicações/manutenções.

4 CONCLUSÃO

- Os MI e IDR mostraram ter um bom desempenho clínico como retentores de OM, evidenciado através das meta-análises. Sendo, que a previsibilidade dos IDR é melhor quando carregados convencionalmente.

- Os IDR e o novo sistema de conexão Facility apresentaram comportamento clínico estável após o período de osseointegração, indicando que são uma opção segura de tratamento para pacientes edêntulos com atrofia mandibular e edentulismo prolongado. Entretanto, são bastante sensíveis ao cuidado do paciente, ao monitoramento da saúde dos tecidos peri-implantes e apresentaram períodos de manutenção esperados para OM. O IPS sofre diminuição contínua, demonstrando a proteção e o selamento dos tecido ao osso marginal.

- As OM retidas por implantes melhoraram consideravelmente a função mastigatória objetiva, bem como a satisfação dos pacientes e a QVRSO. Essa melhora já foi notada após 1 mês para parâmetros funcionais e 3 meses para percepção subjetiva.

- A atrofia óssea mandibular afeta negativamente a função mastigatória de pacientes completamente edêntulos. No entanto, após seis meses de tratamento com OM, os pacientes com mandíbula atrófica alcançaram resultados semelhantes aos pacientes com madíbula não atrófica.

- Em relação a satisfação e qualidade de vida, observamos que os pacientes com mandíbula atrófica precisam de um tempo de adaptação mais longo com as OM do que os pacientes com mandíbulas não atróficas.

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ANEXOS

ANEXO 1 - CERTIFICADO DO COMITÊ DE ÉTICA – PARECER FINAL

FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFEITO DE OVERDENTURES MANDIBULARES NA EVOLUÇÃO DA FUNÇÃO MASTIGATÓRIA DE DESDENTADOS TOTAIS COM ATROFIA ÓSSEA

Pesquisador: Fernanda Faot

Área Temática:

Versão: 2

CAAE: 47353215.4.0000.5318

Instituição Proponente: Faculdade de Odontologia da Universidade Federal de Pelotas/ FO-UFPel

Patrocinador Principal: MINISTERIO DA CIENCIA, TECNOLOGIA E INOVACAO

DADOS DO PARECER

Número do Parecer: 1.267.086

Apresentação do Projeto:

Em virtude do aumento da expectativa de vida das populações em envelhecimento dos países em desenvolvimento, tem resultado no aumento da necessidade e substituição de próteses totais. O principal problema que acomete esta população é o processo de reabsorção óssea fisiológica, mais severa na mandíbula, resultando em problemas cada vez mais frequentes de retenção e estabilidade das próteses totais. Neste sentido, as "overdentures" implantosuportadas proporcionam um grande benefício a esses pacientes, aumentando a estabilidade e retenção e surtindo efeitos diretos na "performance" mastigatória, controle neuromuscular, e na qualidade de vida. Porém o custo efetivo desta intervenção bem como a severidade da atrofia óssea decorrente do tempo de edentulismo tem dificultado o acesso dos pacientes a esta modalidade de tratamento.

Objetivo da Pesquisa:

o objetivo deste estudo é avaliar a evolução da função mastigatória de pacientes com atrofia óssea mandibular severa antes e após a reabilitação com "overdentures" implantosuportadas, ancoradas em implantes de pequeno diâmetro.

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

Avaliação dos Riscos e Benefícios:

Riscos e desconfortos mínimos. Benefícios incluem propor intervenções clínicas reabilitadoras que auxiliam na prevenção do processo de reabsorção óssea.

Comentários e Considerações sobre a Pesquisa:

Os pesquisadores atenderam todas as solicitações do parecer anterior de forma satisfatória.

Considerações sobre os Termos de apresentação obrigatória:

Todos os termos foram apresentados de forma adequada.

Recomendações:

Nenhuma

Conclusões ou Pendências e Lista de Inadequações:

Nenhuma pendência

Considerações Finais a critério do CEP:

APÓS ANALISE DA RESPOSTA E ESCLARECIMENTO AO PARECER NO1.201.436, O PROTOCOLO REAPRESENTADO FOI APROVADO.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_512188.pdf	30/09/2015 14:00:45		Aceito
Outros	resposta_parecer.pdf	30/09/2015 13:59:50	Fernanda Faot	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Resposta.pdf	30/09/2015 13:56:21	Fernanda Faot	Aceito
Outros	Proposta de emenda.pdf	17/07/2015 17:50:29		Aceito
Folha de Rosto	folhaDeRosto final.pdf	03/07/2015 09:03:16		Aceito
Projeto Detalhado / Brochura Investigador	Projeto Final-Emenda CEP 2015.pdf	03/07/2015 09:01:31		Aceito
Outros	carta deresponsabilidade.pdf	03/07/2015 08:59:43		Aceito
Outros	carta de apresentação.pdf	03/07/2015 08:59:27		Aceito
Parecer Anterior	aprovação comitê de ética.jpg	13/05/2015		Aceito

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

Parecer Anterior	aprovação comitê de ética.jpg	10:49:01		Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PELOTAS, 07 de Outubro de 2015

Assinado por:
Renato Waldemarin
(Coordenador)

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

ANEXO 2 – COMPROVANTE DE SUBMISSÃO DO ARTIGO 1

Submission Confirmation

Print

Thank you for your submission

Submitted to	Journal of Oral Rehabilitation
Manuscript ID	JOR-17-0215
Title	Predictability of mini-implants and narrow diameter implants used to anchor mandibula overdentures: A systematic review and meta-analysis
Authors	Machado, Raissa Faot, Fernanda Schuster, Alessandra Nascimento, Gustavo Del Bel Cury, Altair
Date Submitted	14-Jun-2017

ANEXO 3 – COMPROVANTE DE SUBMISSÃO DO ARTIGO 2

Submission Confirmation

Print

Thank you for your submission

Submitted to
Clinical Implant Dentistry and Related Research

Manuscript ID
CID-17-179

Title
Narrow diameter implants connected to locking taper stud abutments as overdenture retainers: 1-year results focusing on clinical outcomes before and after occlusal loading

Authors
Marcello-Machado, Raissa
Faot, Fernanda
Schuster, Alessandra
Bielemann, Amália
Chagas Júnior, Otacílio
Cury, Altair

Date Submitted
26-Jun-2017

ANEXO 4 – COMPROVANTE DE SUBMISSÃO DO ARTIGO 3

Submission Confirmation

Print

Thank you for your revision

Submitted to
Clinical Oral Implants Research

Manuscript ID
COIR-Feb-17-OR-6104.R1

Title
How fast can treatment with overdentures improve the masticatory function and OHRQoL of atrophic edentulous patients? A 1-year longitudinal clinical study.

Authors
Marcello-Machado, Raissa
Faot, Fernanda
Schuster, Alessandra
Bielemann, Amália
Nascimento, Gustavo
Del Bel Cury, Altair

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ANEXO 5 – COMPROVANTE DE ACEITE DO ARTIGO 4

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Original Article

How does mandibular bone atrophy influence the masticatory function, OHRQoL and satisfaction in overdenture wearers? Clinical results until 1 year post-loading

Raissa Micaella Marcello-Machado, Fernanda Faot ✉, Alessandra Julie Schuster, Amália Machado Bielemann, Otacílio Luiz Chagas Júnior, Altair Antoninha Del Bel Cury

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Marcello-Machado RM and Faot F shared first authorship

ANEXO 6 – Questionários de qualidade de vida relacionado à saúde Bucal

6.1 – OHIP - EDENT

1. Você sentiu dificuldade para mastigar algum alimento devido a problemas com seus dentes, boca ou dentaduras?

□ Nunca □ Às vezes □ Quase Sempre
2. Você percebeu que seus dentes ou dentaduras retinham alimento?

□ Nunca □ Às vezes □ Quase Sempre
3. Você sentiu que suas dentaduras não estavam corretamente assentadas?

□ Nunca □ Às vezes □ Quase Sempre
4. Você sentiu sua boca dolorida?

□ Nunca □ Às vezes □ Quase Sempre
5. Você sentiu desconforto ao comer devido a problemas com seus dentes, boca ou dentaduras?

□ Nunca □ Às vezes □ Quase Sempre
6. Você teve pontos doloridos na sua boca?

□ Nunca □ Às vezes □ Quase Sempre
7. Suas dentaduras estavam desconfortáveis?

□ Nunca □ Às vezes □ Quase Sempre
8. Você se sentiu preocupado (a) devido a problemas dentários?

□ Nunca □ Às vezes □ Quase Sempre
9. Você se sentiu constrangido por causa de seus dentes, boca ou dentaduras?

□ Nunca □ Às vezes □ Quase Sempre
10. Você teve que evitar comer alguma coisa devido a problemas com seus dentes, boca ou dentaduras?

□ Nunca □ Às vezes □ Quase Sempre
11. Você se sentiu impossibilitado de comer com suas dentaduras devido a problemas com ela?

□ Nunca □ Às vezes □ Quase Sempre
12. Você teve que interromper suas refeições devido a problemas com seus dentes, boca ou dentadura?

□ Nunca □ Às vezes □ Quase Sempre

13. Você se sentiu perturbado (a) com problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre
14. Você esteve em alguma situação embaraçosa devido a problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre
15. Você evitou sair de casa devido a problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre
16. Você foi menos tolerante com seu cônjuge ou família devido a problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre
17. Você esteve um pouco irritado (a) com outras pessoas devido a problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre
18. Você foi incapaz de aproveitar totalmente a companhia de outras pessoas devido a problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre
19. Você sentiu que a vida em geral foi menos satisfatória devido a problemas com seus dentes, boca ou dentaduras?

 Nunca Às vezes Quase Sempre

6.2 – DIDL

1. Eu estou satisfeito com meus dentes em geral.

□ Concordo □ Discordo □ Neutro
2. Eu estou satisfeito com a aparência dos meus dentes.

□ Concordo □ Discordo □ Neutro
3. Eu estou satisfeito com a cor dos meus dentes.

□ Concordo □ Discordo □ Neutro

4. Eu estou satisfeito com a posição dos meus dentes.

□ Concordo □ Discordo □ Neutro
5. Eu sinto dor espontânea em meus dentes.

□ Concordo □ Discordo □ Neutro
6. Eu sinto dor de dente quando como ou bebo algo quente ou frio.

□ Concordo □ Discordo □ Neutro
7. Eu mudo minha alimentação por causa da dor.

□ Concordo □ Discordo □ Neutro
8. Eu sinto dor em minha articulação mandibular.

□ Concordo □ Discordo □ Neutro
9. Eu tenho preocupação com os dentes.

□ Concordo □ Discordo □ Neutro
10. Eu sofro com alimentos entre os dentes.

□ Concordo □ Discordo □ Neutro
11. Eu tenho halitose e mau hálito.

□ Concordo □ Discordo □ Neutro
12. Eu tenho dentes soltos.

□ Concordo □ Discordo □ Neutro
13. Eu não estou satisfeito com minhas gengivas

□ Concordo □ Discordo □ Neutro
14. Eu tenho sangramento gengival.

□ Concordo □ Discordo □ Neutro
15. Eu tenho sensibilidade com quente ou frio por causa da recessão gengival.

□ Concordo □ Discordo □ Neutro
16. Minha capacidade de trabalho é afetada pela aparência dos meus dentes.

□ Concordo □ Discordo □ Neutro
17. Minha capacidade de trabalho é afetada pela minha capacidade para comer e falar.

□ Concordo □ Discordo □ Neutro
18. Meu contato com as pessoas é afetado pela aparência de meus dentes.

□ Concordo □ Discordo □ Neutro
19. Meu contato com as pessoas é afetado pela minha capacidade para comer e falar.

□ Concordo □ Discordo □ Neutro
20. Meu contato com as pessoas é afetado pela dor de dente.

□ Concordo □ Discordo □ Neutro
21. Meu relacionamento é afetado pela dor de dente.

□ Concordo □ Discordo □ Neutro
22. Meu relacionamento é afetado pela minha habilidade para comer e falar.

□ Concordo □ Discordo □ Neutro
23. Minha autoconfiança é afetada pela aparência de meus dentes.

□ Concordo □ Discordo □ Neutro
24. Eu sinto vergonha por causa dos meus dentes.

□ Concordo □ Discordo □ Neutro
25. Meu relacionamento é afetado pela aparência de meus dentes.

□ Concordo □ Discordo □ Neutro
26. Eu tento evitar mostrar meus dentes quando sorrio.

□ Concordo □ Discordo □ Neutro
27. Eu não estou satisfeito com meu sorriso

□ Concordo □ Discordo □ Neutro
28. Minha capacidade de trabalho é afetada pela dor.

□ Concordo □ Discordo □ Neutro
29. Eu me sinto estressada por causa da dor.

□ Concordo □ Discordo □ Neutro
30. Eu durmo mal por causa da dor.

□ Concordo □ Discordo □ Neutro
31. Eu estou satisfeito com minha capacidade para mastigar.

□ Concordo □ Discordo □ Neutro

32. Eu estou satisfeito com minha mastigação em geral.

□ Concordo □ Discordo □ Neutro
33. Eu estou satisfeito com minha capacidade para morder.

□ Concordo □ Discordo □ Neutro
34. Eu estou satisfeito com minha mordida em geral.

□ Concordo □ Discordo □ Neutro
35. Eu não mudo a forma de preparar os alimentos por causa dos dentes.

□ Concordo □ Discordo □ Neutro
36. Eu não mudo o tipo de alimento por causa dos dentes.

□ Concordo □ Discordo □ Neutro

6.3 - GOHAI

1. Limitou o tipo ou quantidade de alimentos?

□ Nunca □ Às vezes □ Sempre

2. Teve problemas mordendo ou mastigando alimentos como carne sólida ou maçã?

□ Nunca □ Às vezes □ Sempre

3. Foi capaz de engolir confortavelmente?

□ Nunca □ Às vezes □ Sempre

4. Suas próteses (ou a falta delas) o impediram de falar da maneira como queria?

□ Nunca □ Às vezes □ Sempre

5. Foi capaz de comer alimentos sem sentir desconforto?

□ Nunca □ Às vezes □ Sempre

6. Limitou seus contatos com outras pessoas devido às condições de seu sorriso (dentes)?

□ Nunca □ Às vezes □ Sempre

7. Sentiu-se satisfeito com o aspecto de seu sorriso?

□ Nunca □ Às vezes □ Sempre

8. Usou medicamentos para aliviar dor ou desconforto relativo à boca?

□ Nunca □ Às vezes □ Sempre

9. Preocupou-se com seu sorriso?

□ Nunca □ Às vezes □ Sempre

10. Sentiu-se incomodado/abalado ou nervoso devido a problemas com seu sorriso?

□ Nunca □ Às vezes □ Sempre

11. Sentiu desconforto ao alimentar-se em frente a outras pessoas por causa de sua boca ou dentes?

□ Nunca □ Às vezes □ Sempre

12. Sentiu seus dentes ou gengivas sensíveis ao quente, ao frio ou ao doce?

□ Nunca □ Às vezes □ Sempre