UNIVERSIDADE FEDERAL DE PELOTAS
Faculdade de Odontologia
Programa de Pós-Graduação em Odontologia

Tese

Indicadores de qualidade de vida relacionada a saúde bucal (QVRSB) e sua relação com fatores clínicos e funcionais em usuários de overdentures mandibulares reabilitados com o sistema Facility-Equator

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Pelotas, 2019

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Tese apresentada ao Programa de Pós-Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal de Pelotas, como requisito parcial à obtenção do título de Doutor em Odontologia, área de concentração Prótese Dentária.

Orientadora: Profª. Drª. Fernanda Faot

Pelotas, 2019

Universidade Federal de Pelotas / Sistema de Bibliotecas
Catalogação na Publicação

S395i Schuster, Alessandra Juliê

Indicadores de qualidade de vida relacionada a saúde bucal (qvrsb) e sua relação com fatores clínicos e funcionais em usuários de overdentures mandibulares reabilitados com o sistema facility-equator / Alessandra Juliê Schuster ; Fernanda Faot, orientadora. — Pelotas, 2019.

135 f.

Tese (Doutorado) — Programa de Pós-Graduação em Prótese Dentária, Faculdade de Odontologia, Universidade Federal de Pelotas, 2019.

1. Implantes dentários. 2. overdenture. 3. Osseointegração. 4. Prótese dentária. 5. Qualidade de vida. I. Faot, Fernanda, orient. II. Título.

Black : D52

Elaborada por Fabiano Domingues Malheiro CRB: 10/1955

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Tese aprovada, como requisito parcial, para obtenção do grau de Doutor em Odontologia, Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia de Pelotas, Universidade Federal de Pelotas.

Data da defesa: 22 de fevereiro de 2019.

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AGRADECIMENTOS

À Universidade Federal de Pelotas, por meio do seu magnífico Reitor, Prof. Dr. Pedro Rodrigues Curi Hallal, à Faculdade de Odontologia, na pessoa de sua Diretora, Profª. Drª. Adriana Etges, e ao Programa de Pós-Graduação em Odontologia/UFPel, por meio da coordenadora Profª. Drª. Tatiana Pereira Cenci.

À CAPES pela bolsa concedida durante o desenvolvimento do meu doutorado.

À minha orientadora Profª. Drª. Fernanda Faot pelo acolhimento, pela oportunidade de convívio e aprendizado diário, por dividir seu conhecimento e me fazer acreditar que com o esforço de nosso trabalho, podemos ir sempre mais longe. Além disso, por ser um exemplo e inspiração de professora, pesquisadora, clínica e de pessoa. Foi uma honra ser sua orientada. Obrigada pela amizade e confiança que depositou em mim.

À Profª. Drª. Luciana de Rezende Pinto pela atenção que dispensou ao meu trabalho e pelas contribuições.

Ao Prof. Dr. Otacílio Luis Chagas Júnior, por toda a disponibilidade, dedicação e parceria na execução desta tese.

Às amigas Drª. Raissa Micaella Marcello-Machado e Drª. Amália Machado Bielemann que com muita dedicação auxiliaram na execução de grande parte desta tese, e me proporcionaram a experiência da recompensa que é trabalhar em equipe. Muito obrigado pela amizade, convívio e incentivo.

Aos meus pais pelo exemplo de caráter, pelo apoio incondicional, amor, paciência e zelo durante toda a minha vida. Ao meu pai, José Lauri Schuster, que fez o possível e impossível pela minha educação e felicidade quando em vida. À minha mãe, Rosângela Klein Schuster por sempre acreditar nos meus sonhos.

Aos meus irmãos Bruno Schuster e Gustavo Schuster, pelo afeto e por me encorajarem em todos os momentos. O apoio de vocês foi fundamental nesta etapa da minha vida.

A todos os meus familiares por serem meus maiores incentivadores, e por estarem sempre comigo.

Ao Gerson, meu companheiro, obrigada por sua amizade, paciência,

cumplicidade, colaboração e esforço para não me deixar desanimar nos momentos difíceis ao longo desta trajetória. Obrigada pelo apoio e por sempre estar presente.

Aos colegas de pós-graduação e IC'S que fizeram e/ou fazem parte do especial #teamfaot, Anna Paula da Rosa Possebon, Ana Paula Martins, Diego Abreu Pastorino e Samille Biasi, obrigada pela amizade e companheirismo.

Ao amigo Dr. David Debruyne pela disponibilidade de sempre realizar revisões, contribuições e discussões enriquecedoras para a finalização desta tese.

Às amigas que o curso de odontologia me trouxe de presente, Aline de Lima Harter e Anna Brasil, que de diversas maneiras me incentivaram e me ajudaram a seguir em frente.

À Deus pela vida e por me guiar sempre pelos melhores caminhos

A todos que acreditaram e contribuíram direta ou indiretamente para a realização deste trabalho, muito obrigada!

“A menos que modifiquemos a nossa maneira de pensar,
não seremos capazes de resolver os problemas causados pela forma
como nos acostumamos a ver o mundo”.
(Albert Einstein)

Notas Preliminares

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Resumo

SCHUSTER, Alessandra Juliê. **Indicadores de qualidade de vida relacionada a saúde bucal (QVRSB) e sua relação com fatores clínicos e funcionais em usuários de overdentures mandibulares reabilitados com o sistema Facility-Equator.** 2019. 135f. Tese (Doutorado em Odontologia) – Programa de Pós-Graduação em Odontologia. Universidade Federal de Pelotas, Pelotas, 2019.

A avaliação da qualidade de vida relacionada a saúde bucal (QVRSB) é um importante desfecho centrado no paciente que pode ser utilizado como indicador de sucesso do tratamento com overdentures mandibulares implanto-retidas (OM). No entanto, estudos pareados e randomizados que investiguem a relação entre a QVRSB e melhorias funcionais advindas de diferentes interevenções em pacientes desdentados totais com atrofia óssea mandibular e que passam pela reabilitação com OM ainda são escassos. Assim, o objetivo desta tese foi investigar a influência da reabilitação com OM na QVRSB. Bem como verificar as possíveis influências das variáveis independentes: idade, tempo de edentulismo dos pacientes, diferentes tipos de carregamento oclusal (carregamento convencional – CC e imediato - CI); e intercorrências protéticas resultantes da reabilitação com OM retidas por 2 implantes de diâmetro reduzido (IDR) não esplintados na QVRSB. Para isto, foram delineados quatro estudos:

i) Estudo clínico prospectivo de curta duração que avaliou o impacto do tratamento com OM retidas por 2 IDR na QVRSB através de três questionários (OHIP-EDENT, DIDL e GOHAI) em 25 pacientes antes e após 3 meses do carregamento oclusal das próteses;
ii) Estudo clínico pareado prospectivo longitudinal com 12 meses de acompanhamento que investigou a influência da idade (divisão em dois grupos: ≤65 e >65 anos) e do tempo de edentulismo (divisão em dois grupos <25 anos e ≥25 anos) de 33 pacientes na função mastigatória (FM) e na QVRSB em indivíduos edêntulos, antes e durante o primeiro ano de reabilitação com OM. A FM foi avaliada através dos testes de performance mastigatória (PM) e limiar de deglutição (LD) antes e após 1, 3, 6 e 12 meses do carregamento das OM. A QVRSB foi avaliada através dos questionários OHIP-EDENT e GOHAI, antes e após 3, 6 e 12 meses.
iii) Ensaio clínico randomizado de acordo com o carregamento oclusal, CI (10 pacientes) ou CC (10 pacientes), com 1 ano de acompanhamento em que se investigou a influência do tipo de carregamento oclusal em IDR como retentores de OM através do comportamento clínico, biológico, funcional, e percepção subjetiva do paciente, além da observação da incidência das intercorrências protéticas de cada grupo. As variáveis de desfechos foram: saúde peri-implantar (índice de placa visível – IPV, cálculo - C, grau de inflamação - GI, índice de profundidade de sondagem – IPS e índice de sangramento gengival – ISG), estabilidade primária e secundária dos implantes (ISQ), sobrevivência, sucesso, perda óssea marginal (POM), remodelação óssea (RO), concentração de citocinas IL-1β e TNF-α presentes no fluído crevicular periimplantar, avaliação da

FM através do teste de PM e da QVRSB pelo questionário OHIP-EDENT e descrição de complicações/manutenções durante o tratamento;

iv) Estudo clinico longitudinal que avaliou o desempenho do componente protético Equator como retentor de OM em 24 pacientes através da perspectiva protética em 2 anos de carregamento das próteses; e investigou se os eventos de manutenções e complicações protéticas afetariam a QVRSB. A QVRSB foi acessada através dos questionários OHIP-EDENT e GOHAI.

Os resultados do estudo I mostraram que a QVRSB de usuários de próteses totais convencionais (PT) foi significativamente melhorada já após 3 meses de tratamento com OM, especialmente em relação aos domínios dos questionários que englobam aspectos funcionais e relacionados à dor com o uso das próteses. No estudo clínico II observamos que a idade e o tempo de edentulismo não influenciaram a FM de pacientes usuários de OM após 1 ano da instalação das próteses. No entanto, a OM melhorou significativamente a FM de todos os pacientes, sendo esta melhora mais evidente em pacientes mais jovens (≤65 anos) e com menor tempo de edentulismo mandibular (<25 anos). Já a QVRSB foi influenciada pela idade e tempo de edentulismo em somente enquanto os pacientes eram usuários de PT, sendo que o tratamento com OM eliminou essas diferenças. De acordo com os resultados do artigo III, foi evidenciado que o CI promoveu melhor adaptação dos tecidos periimplantes ao redor dos componentes protéticos em decorrência da observação de menor profundidade de sondagem e menor número de intercorrências protéticas. Diferença significativa entre CC e CI foi observada para o desfecho IPS aos 12 meses, e para a concentração de TNF-α e IL-1β em 6 meses de cicatrização. Ainda, a melhoria na FM e na QVRSB foi observada independentemente do tipo de carregamento utilizado. Os resultados do artigo IV revelaram que complicações relacionadas à manutenção protética, como fratura da prótese, soltura do componente Equador, necessidade de reembasamento de prótese e confecção de nova overdenture, afetaram a QVRSB dos usuários de OM, principalmente nos domínios dor física e desconforto, com maior significância no primeiro ano de uso das OM. Além disso, todos os domínios dos questionários GOHAI e OHIP-EDENT apresentaram diferença significativa entre as avaliações iniciais e após 1 e 2 anos do carregamento das próteses, exceto para o domínio de incapacidade social e desconforto psicológico do OHIP-EDENT após 1 ano. Através dos resultados dos 4 estudos, pode-se concluir que a QVRSB é significativamente melhorada já em 3 meses após a instalação de OM retidas por 2 IDR em uma população com baixa disponibilidade óssea na região anterior da mandíbula, sendo independentemente da idade, tempo de edentulismo dos pacientes e do tipo de carregamento oclusal utilizado. No entanto, os eventos de complicações protéticas advindas deste tratamento podem ainda continuar interferindo na QVRSB de usuários de OM até 2 anos após o carregamento das próteses.

Palavras-chave: Implantes dentários; osseointegração; overdenture; qualidade de vida; prótese dentária.

Abstract

SCHUSTER, Alessandra Juliê. **Oral Health-Related Quality of Life (OHRQoL) indicators and their relation with clinical and functional factors in mandibular overdenture wearers rehabilitated with the Facility-Equator system.** 2019. 135f. Thesis (PhD in Dentistry). Graduate Program in Dentistry. Federal University of Pelotas, Pelotas, 2019.

The assessment of Oral health-related quality of life (OHRQoL) is an important patient-centered outcome to measure and predict the treatment with implant-retained mandibular overdentures (MO). However, the OHRQoL aspects of fully edentulous patients with mandibular bone atrophy rehabilitated with MO are still not well understood, as there are currently no paired or randomized clinical trials available. Thus, the objective of this thesis was to investigate the influence of MO rehabilitation in the patients OHRQoL. As well as verifying the possible influences of the independent variables: age, time since edentulism, different types of occlusal loading (conventional loading - CL and immediate - IML); and prosthetic intercurrences resulting from rehabilitation with MO retained by 2 narrow diameter implants (NDI) in the OHRQoL. or this, four studies were planned:

i) A prospective short-term clinical study that evaluated the impact of treatment with MO retained by 2 NDI on OHRQoL using three questionnaires (OHIP-EDENT, DIDL, and GOHAI) completed by 25 fully edentulous patients before and after 3 months of MO loading;

ii) A 1-year prospective paired longitudinal clinical study that investigated the influence of age (≤ 65 and > 65 years) and time since edentulism (< 25 years and ≥ 25 years) of 33 patients on masticatory function (MF) and OHRQoL in edentulous individuals, before and during the first year of MO usage. The MF was evaluated through the masticatory performance (MP) and swallowing threshold (ST) tests before and after 1, 3, 6, and 12 months of MO loading. The OHRQoL was evaluated through the OHIP-EDENT and GOHAI questionnaires, before and after 3, 6, and 12 months.

iii) A 1-year randomized clinical trial that randomized the occlusal load protocol of IML (10 patients) or CL (10 patients) and investigated the influence of the occlusal loading type on NDI as MO retainers through clinical, biological, functional, and OHRQoL, along with the incidence of the prosthetic intercurrences in each group. The outcomes were: peri-implant health indices (plaque index - PI, calculus presence - CP, gingival index - GI, probing depth - PD and bleeding on probing - BOP), primary and secondary stability of implants (ISQ), survival and success rates, marginal bone loss (MBL), marginal bone change (MBC), concentration of IL-1β and TNF-α cytokines in the peri-implant crevicular fluid, MF was evaluated using the MP test and OHRQoL was analyzed via the OHIP-EDENT questionnaire and via description of intercurrences during treatment.

iv) A 2-year longitudinal clinical study that evaluated the performance of the

Equator abutment as MO retainer in 24 patients from the prosthetic perspective during 2 years of prosthesis loading and investigated whether maintenance events and prosthetic complications can affect OHRQoL. OHRQoL was assessed through the OHIP-EDENT and GOHAI questionnaires.

The results of study I showed that the OHRQoL of conventional denture (CD) wearers was significantly improved after 3 months of treatment with MO, especially in the domains of questionnaires that include functional and pain-related aspects. The second clinical study showed that the age and time since edentulism did not influence the MF of MO wearers after 1 year. However, MO significantly improved the MF of all patients, and this improvement was more evident in younger patients (≤ 65 years) with a shorter time of mandibular edentulism (< 25 years). The OHRQoL was influenced only by age and time since edentulism in CD wearers, and treatment with MO eliminated these differences. The randomized clinical trial (study III) showed that IML generates a better adaptation of the peri-implant tissues around the prosthetic components, as indicated by a lower probing depth and fewer prosthetic intercurrences. Significant differences in TNF-α and IL-1β levels between the CL and IML groups at 6 months of healing likely relate different time under function in both protocols. The improvement in MF and OHRQoL was observed regardless of the type of occlusal loading used. However, the IML group perceived OHRQoL improvements faster, yet this group needed more time to attain comparable MF improvements. The results of the fourth study show that certain complications and prosthetic maintenance events, such as fracturing of the prosthesis, Equator dislodgment, prosthesis rebase, and confection of new overdentures, affect patients' OHRQoL. The physical pain and discomfort domains were most affected and the effects were largest during the first year of MO usage. In addition, all domains of the GOHAI and OHIP-EDENT questionnaires showed a significant improvement when comparing the baseline and the final evaluations after 1 and 2 years of MO loading, except for the social disability and psychological disability domains of OHIP-EDENT after 1 year. In conclusion, the four studies demonstrate that OHRQoL is significantly improved as early as 3 months after treatment with MO retained by 2 NDI. Considerable improvement can thus be achieved even in a population with low bone availability in the anterior region of the mandible, independent of patient's age, time since edentulism, and occlusal loading protocol. However, prosthetic complications and maintenance events can affect the patients' OHRQoL up to 2 years after loading.

Keywords: Dental implants; osseointegration; overdenture; quality of life; dental prosthesis.

SUMÁRIO

1 Introdução

A expectativa de vida da população mundial aumentou significativamente desde 2000 e passou de 64 para 71 anos, conforme a Organização Mundial da Saúde (OMS). (WORLD HEALTH ORGANIZATION, 2016). Em 2015, o número de pessoas com 60 anos ou mais atingiu 901 milhões (WORLD HEALTH ORGANIZATION, 2016). Nesse mesmo parecer emitido pela OMS, projeta-se um aumento de 56% na população - cerca de 1,4 bilhão de pessoas - para 2030, das quais 650 milhões terão acima de 70 anos (WORLD HEALTH ORGANIZATION, 2016). No Brasil, a expectativa de vida é de 76,25 anos e a estimativa do Instituto Brasileiro de Geografia e Estatistica é que até o ano de 2060 a população com mais de 60 anos irá dobrar de tamanho e atingirá 32% do total de brasileiros, sendo que um quarto da população terá mais de 65 anos (IBGE, 2018). Neste sentido, o envelhecimento populacional está entre as transformações globais mais importantes e se tornou um dos maiores desafios da saúde pública, pois, pelas modificações observadas na pirâmide populacional, doenças próprias do envelhecimento ganham maior expressão no conjunto da sociedade contemporânea, como por exemplo o edentulismo (LIMA-COSTA, VERAS 2003; TYROVOLAS et al., 2016).

O edentulismo é caracterizado pela perda de todos os dentes permanentes, sendo o resultado terminal de um processo multifatorial que têm como principais causas a cárie, doença periodontal e traumatismos (FELTON, 2009). Através dos dados do SB Brasil 2010, último levantamento epidemiológico em saúde bucal com abrangência nacional, foi observado que para a população idosa (entre 65 e 74 anos) 63,1% faziam uso de prótese total, sendo que a proporção de indivíduos que usava prótese inferior era de 46,1% (BRASIL, 2012). Assim, por muito tempo as próteses totais convencionais (PT) foram a primeira opção terapêutica para reabilitar pacientes desdentados totais (CARLSSON; OMAR, 2010; PREOTEASA et al., 2015). No entanto, as PT muitas vezes apresentam insuficiente retenção e estabilidade e esta condição pode resultar em ineficiência na função mastigatória (FM), baixa força de mordida, desconforto durante a função e insatisfação com o tratamento (HUUMONEN

et al., 2012; MARCELLO-MACHADO et al., 2017b; PEYRON et al., 2017; VAN KAMPEN et al., 2002).

Assim, o edentulismo leva a uma série de consequências deletérias para a saúde bucal e geral dos indivíduos, sendo que a resposta mais marcante após a perda de todos os dentes são as alterações que ocorrem nos tecidos duros e moles da cavidade bucal (EMAMI et al., 2013; FELTON, 2009). A reabsorção óssea do rebordo residual (RRR) é um processo contínuo que ocorre após a perda dentária, e leva a uma redução significativa do volume ósseo alveolar e da área de suporte basal da prótese (ATWOOD, 1971; TALLGREN, 1972). A evolução desse quadro pode influenciar negativamente na futura reabilitação do paciente desdentado total pois observa-se, em muitos casos, a atrofia dos maxilares (MARCELLO-MACHADO et al., 2017a; TALLGREN, 1972). Dessa forma, as inserções musculares tornam-se superficialisadas, o rebordo torna-se fino ou plano, o nervo alveolar torna-se superficial devido a reabsorção da parede superior do forame mentoniano, causando sensação dolorosa durante a utilização da PT (CARLSSON, 1998; EMAMI et al., 2008; XIE; WOLF; AINAMO, 1997). Assim, a atrofia óssea, principalmente do osso mandibular gera uma pobre retenção e estabilidade das PT, o que acarreta em prejuízos na FM e no quadro nutricional de pacientes mais idosos (BANERJEE et al., 2018; GONÇALVES et al., 2014; KOSHINO et al., 2008; SCHIMMEL et al., 2015). Em vista disso, por não afetar somente a saúde bucal, mas também a saúde geral, o edentulismo tem impacto negativo no convívio social, nas atividades do dia a dia, na autoestima e no estado psicológico dos indivíduos, sendo assim considerado uma condição que gera baixa qualidade de vida relacionada à saúde bucal (QVRSB) (LOCKER; CLARKE; PAYNE, 2000; MARCELLO-MACHADO et al., 2018c; MEHTA, 2015).

Instrumentos de avaliação da qualidade de vida relacionada à saúde bucal – QVRSB medem a extensão com que transtornos orais afetam o funcionamento e bem-estar psicossocial dos indivíduos, para isto, várias metodologias de verificação da QVRSB foram desenvolvidas, sendo validadas e amplamente utilizadas na literatura (LOCKER; CLARKE; PAYNE, 2000). Dentre os instrumentos mais empregados em estudos com amostras de pacientes idosos, destacam-se o GOHAI (Geriatric Oral Health Assessment Index) (ATCHISON; DOLAN, 1990), o DIDL (Dental Impacts on Daily Living) (LEAO; SHEIHAM, 1995), o OHIP (The Oral Health Impact Profile) (SLADE; SPENCER, 1994) e as suas versões abreviadas – o OHIP-14 (SLADE, 1997)

e OHIP-EDENT (ALLEN; LOCKER, 2002), sendo este último específico para pacientes desdentados. Os questionários são aplicados por um avaliador e respondidos pelo paciente, e indicam através de escores o grau do impacto da saúde bucal em sua qualidade de vida, contemplando aspectos físicos, sociais e psicológicos. A avaliação da QVRSB nos últimos anos se tornou um importante fator na análise do resultado de diversas terapias orais, sendo um dos elementos mais relevantes para a avaliação do sucesso do tratamento com overdentures mandibulares implanto-retidas (OM) (ABU HANTASH et al., 2011; EMAMI et al., 2015; ENKLING et al., 2017; FERNANDEZ-ESTEVAN et al., 2015; MARCELLO-MACHADO et al., 2018c; KUOPPALA , RITVA NÄPÄNKANGAS, 2013).

Pois, em vista do prognóstico desfavorável das PT mandibulares e de sua ineficiência em reestabeler as funções orais, desde a elaboração do Consenso McGill (2002) e posteriormente com o Consenso de York (2009), a instalação de dois implantes na região anterior da mandíbula para reter próteses do tipo overdentures mandibulares se tornou o padrão mínimo de cuidado recomendado para a reabilitação de indivíduos desdentados totais (FEINE et al., 2002; THOMASON et al., 2009). A eficácia a longo prazo, a previsibilidade de indicadores clínicos e a satisfação do paciente com este tipo de reabilitação oral foram estabelecidas com sucesso por muitos estudos, uma vez que as OM proporcionam aumento da retenção e estabilidade da prótese, melhora da função mastigatória, aumento da força de mordida e melhora da QVRSB (BAKKE; HOLM; GOTFREDSEN, 2002; BILHAN et al., 2012; FONTIJN-TEKAMP et al., 2000; MARCELLO-MACHADO et al., 2018b, 2018c).

No entanto, os pacientes com indicação a receber este tratamento muitas vezes apresentam um longo tempo de edentulismo, o que frequentemente está ligado a um cenário clínico de severa RRR (MARCELLO-MACHADO et al., 2018a, 2017b). Assim, a atrofia do rebordo residual resulta em uma crista óssea com pouca espessura na região cervical vestíbulo-lingual, o que impede ou dificulta a instalação de implantes de diâmetro convencional (Ø>3.5mm), pois, exige-se ao menos 5,5mm de espessura óssea em leito ósseo para a instalação de implantes (ELSYAD; HAMMOUDA, 2017; KLEIN; SCHIEGNITZ; AL-NAWAS, 2014). Desse modo, a principal dificuldade associada ao tratamento com implantes osseointegraveis em uma população idosa com alto tempo de edentulismo são as características morfológicas do rebordo alveolar decorrentes da atrofia óssea mandibular (MARCELLO-MACHADO et al., 2018a; PREOTEASA et al., 2015). Nestes casos, a instalação de implantes com mais

de 3mm de diâmetro requer procedimentos cirúrgicos de aumento ósseo do rebordo alveolar através de enxertos ósseos, no entanto, esses procedimentos aumentam o risco de complicações pós-operatórias, o tempo de tratamento e apresentam alta morbidade, ainda mais considerando-se uma população idosa (ELSYAD; HAMMOUDA, 2017; KUOPPALA et al., 2013). Como alternativa para a reabilitação de mandíbulas atróficas, implantes de diâmetro reduzido (IDR), com diâmetro menor que 3mm, podem ser utilizados na reabilitação com OM, pois descartam a necessidade de procedimentos de enxertos ósseos, permitindo a realização de cirurgias menos invasivas (EL-SHEIKH; SHIHABUDDIN; GHORABA, 2012). E ainda, estudos recentes mostram que estes implantes apresentam uma alta previsibilidade de tratamento, inclusive quando comparados a implantes de diâmetro convencional na reabilitação com OM (MARCELLO-MACHADO et al., 2018a; SOHRABI et al., 2012; TEMIZEL et al., 2017).

Desse modo, pelas possibilidades terapêuticas implicadas ao tratamento com OM, como o diâmetro dos implantes, número de implantes que podem ser instalados na mandíbula para reter as próteses, tipos de pilares protéticos dos diferentes sistemas de retenção e diferentes protocolos de carregamento oclusal, muitos estudos exploram a relação entre a transição na reabilitação de PT para OM em pacientes desdentados totais (EL-SHEIKH; SHIHABUDDIN; GHORABA, 2012; SOHRABI et al., 2012; TRAKAS et al., 2006; ZYGOGIANNIS et al., 2016). Quanto a desfechos de percepção subjetiva ao tratamento com OM implanto-retidas por IDR, a maioria dos trabalhos se concentram no uso do questionário OHIP-EDENT, sendo escassos estudos com delineamento prospectivo e o uso do questionário DIDL e GOHAI, e ainda, a maioria dos desfechos se baseiam em somente um questionário de avaliação da QVRSB (ALFADDA; ATTARD; DAVID, 2009; AWAD et al., 2003; FILLION et al., 2013; HEYDECKE et al., 2003; PACKER et al., 2009), sendo poucos os estudos com mais de um instrumento de avaliação em sua metodologia (MARCELLO-MACHADO, 2018c). Além disso, ainda não há um consenso na literatura em relação as mudanças que as OM proporcionam na FM e QVRSB em função da idade dos pacientes e do tempo de edentulismo mandibular (ENKLING et al., 2017).

Como a reabilitação com IDR possibilita a utilização de ambos tipos de carregamento oclusal, carregamento convencional (CC) e imediato (CI), o tipo de carregamento a ser adotado na reabilitação com OM é um importante fator que deve ser avaliado no planejamento do tratamento (BIDRA; ALMAS, 2013). Apesar da

adoção do CC ser consagrado na literatura, a inconveniência de um longo período de cicatrização, têm embasado a adoção do CI em OM retidas por 2 implantes, por ter se mostrado uma opção de tratamento clinicamente viável e bem-sucedida (BRÅNEMARK et al., 1969; OMURA et al., 2016; STRICKER et al., 2004). Entretanto, ainda é contraditório os benefícios da adoção de cada tipo de carregamento frente ao comportamento clínico e biológico dos implantes. Além disso, não se sabe como o CI se comportaria em uma população com pouca disponibilidade óssea e longo tempo de edentulismo, sendo indefinido até o momento o impacto deste protocolo de carregamento na função mastigatória, na percepção subjetiva do paciente com o tratamento e a relação que o carregamento dos implantes pode ter sobre a incidência de intercorrências protéticas em uma amostra de pacientes com estas características específicas.

Estudos mostram que de acordo com o sistema de conector utilizado, as manutenções e complicações protéticas observadas no tratamento com OM podem variar (CRISTACHE et al., 2014; GOTFREDSEN; HOLM, 2000; VAN KAMPEN et al., 2003), porém o nível de satisfação e qualidade de vida dos pacientes, bem como as taxas de sobrevivência dos implantes, não são afetadas pelo tipo de pilar selecionado (GOTFREDSEN; HOLM, 2000; KLEIS et al., 2010; MACENTEE; WALTON; GLICK, 2005; NAERT et al., 2004; STOUMPIS; KOHAL, 2011). São vários os tipos de sistemas de conectores que estão disponíveis no mercado e que têm sido utilizados para promover a retenção e estabilização do implante à OM. O sistema Facility é um novo sistema de IDR disponível para ser usado como retentor de OM. Este sistema de implantes de conexão morse e com angulação de 5 graus é baseado na retenção por fricção (Facility dental implant) e engloba um sistema de encaixe do tipo botão, que não usa parafuso (Equator abutment). Assim, pelas manutenções protéticas envolvidas no tratamento com OM terem impacto significativo nos custos clínicos e laboratoriais deste tratamento, a informação antecipada sobre a necessidade de manutenções é fundamental para o sucesso do tratamento e para evitar eventos e situações inesperadas entre cirurgião dentista e paciente (ALFADDA; ATTARD, 2017; ASSAF et al., 2017). Neste sentido, pelo sistema Facility e o Equator abutment serem relativamente novos no mercado, pouco se sabe sobre o seu comportamento a longo prazo, principalmente em relação as possíveis intercorrências protéticas bem como se estas intercorrências podem influenciar a QVRSB.

Diante do exposto, se faz necessário o estudo da relação entre a QVRSB e a reabilitação protética de pacientes desdentados totais que apresentam um quadro de atrofia óssea mandibular e que passam pela transição do uso de PT para OM. Bem como verificar as possíveis influências das variáveis independentes: idade, tempo de edentulismo dos pacientes, diferentes tipos de carregamento oclusal (carregamento convencional – CC e imediato - CI); e intercorrências protéticas resultantes da reabilitação com OM retidas por 2 implantes de diâmetro reduzido (IDR) não esplintados na QVRSB.

Desta forma, os objetivos do presente estudo são:

1. Através de um estudo clínico prospectivo, avaliar o impacto do tratamento com OM retida por 2 IDR na QVRSB usando três questionários (OHIP-EDENT, DIDL e GOHAI) e quantificar a melhoria relativa de cada domínio através do cálculo do tamanho do efeito, permitindo assim a identificação de qual domínio (físico, social ou psicológico) pode alcançar a maior melhora percebido pelo paciente na resposta ao tratamento.
2. Investigar a influência da idade e do tempo de edentulismo na FM e na QVRSB em indivíduos edêntulos, antes e durante o primeiro ano de reabilitação com OM por meio de um estudo clínico prospectivo.
3. Apresentar um ensaio clínico randomizado com 1 ano de acompanhamento com a finalidade de investigar a influência do tipo de carregamento oclusal, imediato e convencional, recebido por IDR como retentores de OM através do comportamento clínico, biológico, funcional, e percepção subjetiva do paciente, além da observação da incidência das intercorrências protéticas de cada grupo.
4. Avaliar o desempenho do componente protético Equator como retentor de OM através da perspectiva protética em 2 anos de carregamento das próteses e investigar se os eventos de manutenções e complicações protéticas podem afetar a QVRSB.

2 Capítulo 1

Short-term quality of life change perceived by patients after transition to mandibular overdentures [§]

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Declaration of Interest: The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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[§] Artigo Original publicado no periódico Brazilian Oral Research: *Braz Oral Res. 2017:27;31:e5*. doi: 10.1590/1807-3107BOR-2017.vol31.0005, sendo aqui apresentado com estrutura conforme normas do referido periódico.

Abstract

The aim of this longitudinal observational study was to evaluate the oral health-related quality of life (OHRQoL) following patient rehabilitation with implant-retained mandibular overdentures (IMO) and to identify the contribution of the different domains to OHRQoL. The Oral Health Impact Profile (OHIP-EDENT), Dental Impact on Daily Living (DIDL), and Geriatric Oral Health Assessment Index (GOHAI) questionnaires were completed twice by 25 patients: after 3 months of rehabilitation with complete dentures (CD) and after 3 months of IMO loading using stud abutments. The evaluation after IMO rehabilitation showed significant improvement in three DIDL domains: appearance ($p = 0.011$), eating and chewing ($p = 0.003$), and general performance ($p = 0.003$). The GOHAI results showed significant differences in two domains: psychosocial ($p = 0.005$) and pain and discomfort ($p = 0.0004$). The OHIP-EDENT outcomes showed significant improvements in five domains: functional limitation ($p = 0.0001$), physical pain ($p = 0.0002$), physical disability ($p = 0.0010$), and psychological disability and handicap ($p = 0.032$). The largest observed effect sizes were close to one standard deviation and were observed in the eating and chewing domain (0.93) of the DIDL; the pain and discomfort domain (0.83) of the GOHAI, and the functional limitation (0.89), physical pain (1.02), physical disability (0.84) domains of the OHIP-EDENT. The percentage of satisfied patients increased in all domains. Self-reported OHRQoL of CD wearers was significantly improved after 3 months of treatment with IMO, especially concerning the functional and pain-related aspects.

Keywords: Oral Health; Quality of Life; Denture, Overlay; Surveys and Questionnaires; Dental Implants.

Introduction

Edentulism is one of the most common conditions among oral health disorders and affects 2.3% of the world population, which represents 158 million people worldwide.[1,2] According to current estimates, edentulism will continue to be one of the most common diseases in the elderly.[3] Felton[4] stated that the necessity of complete denture (CD) therapy will probably not disappear over the next 4 to 5 decades. However, a substantial portion of CD wearers is not satisfied with rehabilitation.[5]

Alveolar ridge reabsorption occurs after dental extraction and modifies the oral cavity tissues due to alteration of stimuli in the jaw bone, thereby reducing the area supporting the prosthesis, which is much more severe in the mandible.[6] This important consequence of edentulism is inevitable and progressive, and results in insufficient retention and stability of CD.[5]

Other problems associated with tooth loss and alveolar ridge reduction include a painful sensation in response to occlusal loads, food intolerance and mucosal reactivity, nutritional changes resulting from eating difficulties, speech difficulties, abnormal facial appearance, social relationship impacts, and even emotional problems.[7,8] Studies report that the absence of mandibular denture retention and stability is the main reason for denture dissatisfaction and it has a direct impact on oral health-related quality of life (OHRQoL).[5,9] Aesthetics and functional aspects of conventional dentures also affect social behavior and self-confidence.[10]

Locker et al. (2000) defined OHRQoL as “the extent to which oral disorders affect the functioning and psychosocial well-being.[11] Currently, OHRQoL is considered an essential factor for assessment of the treatment success of implant-retained mandibular overdentures (IMO).[12,13,14] However, patients with long-term edentulism have thin alveolar ridges, which hinders installation of conventional diameter implants.[15] Therefore, narrow diameter dental implants (NDIs) are an effective alternative to rehabilitate edentulous mandibles with moderate to severe atrophy.[15] NDI installation is a simple surgical technique and does not require bone grafting, so this minimally invasive procedure is associated with low morbidity and high survival rates.[16,17,18] Longitudinal studies with follow-up periods of 6 years reported satisfactory NDI survival rates for mandibular overdentures, ranging from 94% to 98%.[18]

Since 1990, several measurement instruments for OHRQoL assessment have emerged, were validated, and are now widely used. Some of the most widely used tools specifically designed for edentulous patients are the GOHAI (Geriatric Oral

Health Assessment Index),[19] the DIDL (Dental Impact on Daily Living),[20] the OHIP (The Oral Health Impact Profile),[21] and abbreviated versions (the OHIP-14[22] and OHIP-EDENT[23]). These questionnaires are answered by the patient and indicate the impact of oral health on quality of life through scores of physical, social, and psychological aspects.

So far, a number of studies have examined the subjective perception of denture wearers who were converted to IMO.[9,24,25,26,27] However, the majority of these studies solely focused on the OHIP-EDENT questionnaire and the results were based on assessment of only one OHRQoL questionnaire.

The aim of the present study was to expand these previous works by evaluating the impact of IMO treatment with two implants on OHRQoL using three questionnaires (OHIP-EDENT, DIDL, and GOHAI), and by quantifying the relative improvement of each functional domain through effect size (ES) calculations. The latter allows the identification of which domain (physical, social, or psychological) achieved the highest improvement in response to treatment, as perceived by the patient.

Methods

Experimental design

In this longitudinal observational study, OHRQoL assessment was conducted before and after intervention. All procedures involving human participants were performed in accordance with the ethical standards of the institutional and national research committees, and the 1964 Helsinki declaration, as revised in 2008. The findings of this study were reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines. The study protocol was approved by the local Research Ethics Committee (approval no. 69/2013) and included conventional dentures wearers receiving treatment at the Complete Denture Clinic of the School of Dentistry, Universidade Federal de Pelotas (Pelotas, RS, Brazil) from February 2013 to April 2014. Patients in good general health and wearing new conventional CD for at least 3 months, but experienced difficulties adapting to mandibular CD, were invited to participate in this study. Of 48 patients who were examined, 15 did not fulfill the inclusion criteria and eight refused to participate. Written informed consent was obtained from all patients who fulfilled the inclusion criteria wherein each agreed to the terms of the research. Before the surgical procedure, all

patients completed the OHIP-EDENT, DIDL, and GOHAI questionnaires for the first time.

All surgeries were performed by a single experienced surgeon. Two NDIs (Facility; 2.9 × 10 mm) were installed in the mandible (interforaminal region). Once the abutments were installed and healed, the lower CD was realigned. After 3 months of osseointegration, Equator-type prosthetic components were installed prior to loading the IMO. Three months after installation of the IMO, the OHRQoL-related questionnaires were completed a second time.

The sample size calculation was based on two previous studies[25,28] using the following parameters: lower limit of the expected difference between means, standard deviation (SD) of the difference between means, a beta error of 10%, and a one-tailed alpha error of 5%. The minimal significant difference and SD for sample size estimation were calculated based on a final global score of the OHIP-EDENT questionnaire. The obtained CD and IMO values were 40.4 ± 11.6 and 54.5 ± 3.9, respectively. The sample size was increased by 20% to compensate for potential patient loss and treatment refusal. These calculations indicated that at least 16 participants were needed for this longitudinal study.

OHIP-EDENT questionnaire

Participants answered a questionnaire related to the use of CD and IMO that included questions pertaining to physical, functional, social, and psychological consequences. In its original format, each question had three possible answers: “never,” “sometimes,” or “almost always.” Questions 1–20 were reproduced from OHIP-EDENT questionnaire.[23,28]

DIDL questionnaire

The second questionnaire completed by the patients was the DIDL, which is used to assess the patient perception of oral health and the effects of the medical condition of the mouth and teeth. It is also used to determine the impact of oral intervention on quality of daily life for each domain and classifies patient satisfaction according to a scale.[13] The DIDL questionnaire consists of 36 questions grouped into five domains: oral comfort, appearance, pain, general performance, and eating and chewing capacity. Questions have three possible answers: “agree,” “neutral,” or “disagree,” graded as 1, 0, or -1, respectively.[29] The final scores for each domain

represent the average score of the questions related to each domain and are classified as dissatisfied (< 0), relatively satisfied (0–0.69), or satisfied (0.7–1.0).[20]

Auto perception of oral health (GOHAI) questionnaire

The GOHAI was used to assess the self-reported OHRQoL of the geriatric sample population.[19] This index consists of 12 multiple choice questions about dental problems that are evaluated in three dimensions: physical (alimentation, speech, and swallowing), psychosocial (care of oral health, dissatisfaction with appearance, oral health self-conscience, and avoidance of social contacts because of dental problems), and pain or discomfort, also considering the use of pain-relieving drugs. There are three possible answers for each question in the GOHAI: “always/often,” “sometimes/rarely,” and “never,” which are scored as 1, 2, and 3, respectively. The total score for each individual varied from 12 to 36, with a higher score representing better self-perceived oral health.

Statistical analysis

Data were initially subjected to descriptive analysis and testing of normality. Non-parametric tests were used for analysis of data that was not normally distributed. In order to evaluate the impact of IMO on OHRQoL, the Wilcoxon's matched-pairs signed-rank test was employed, which tests the equality of matched pairs of observations. The level of significance was set at 5%. In addition, the ES was calculated as the difference in the mean difference between the OHRQoL score before and after the IMO procedure, normalized over the initial SD. The ES was reported in addition to *p*-values, since the latter gives no direct information about the size of the effects. For this reason, reporting of both ES and *p*-values was considered essential.[30] In general, an ES of 0.2 is considered small, 0.5 is moderate, > 0.8 is large.[31] Stata 13.0 software was employed for all analyses (StataCorp LP, College Station, TX, USA).

Results

The total sample included 25 patients, 16 of whom were female (64.0%), with a mean age of 65.32 years and an average mandibular edentulism duration of 22.7 years. Tables 1, 2, and 3 present the mean, SD, median, and range values for each specific domain before and after IMO, in addition to the ES. Table 1 displays the results from the DIDL questionnaire. There was a significant difference before and after

treatment in three domains: appearance (CD = 0.6 ± 0.62, IMO = 0.96 ± 0.2; p = 0.011), chewing ability (CD = 0.12 ± 0.80, IMO = 0.87 ± 0.42; p = 0.003), and general performance (CD = 0.66 ± 0.44, IMO = 0.90 ± 0.24; p = 0.003). The scores for the pain (p = 0.44) and oral comfort (p = 0.15) domains were not significantly different before and after the IMO procedure. A large ES (0.93) was observed only in the eating and chewing domain. The sample distribution of the domains of the DIDL questionnaire and the associated satisfaction rates are displayed in Figure 1. The percentage of totally satisfied patients increased in all domains, while the percentage of totally unsatisfied patients decreased.

The analytical results of the GOHAI questionnaire are shown in Table 2. There were significant differences in the scores of two domains: psychosocial (CD = 11.92 ± 1.41, IMO = 12.92 ± 0.49; p = 0.005) and pain and discomfort (CD = 13.0 ± 7.35, IMO = 6.96 ± 0.45; p = 0.0004). The scores of the pain and discomfort domain were associated with a large ES (0.83).

Table 3 shows the results of OHIP-EDENT questionnaire. There were significant difference in the scores of functional limitation (CD = 3.28 ± 1.98, IMO = 1.52 ± 1.55; p = 0.0001), pain (CD = 5.12 ± 3.48; IMO = 1.56 ± 2.85; p = 0.0002), physical inability (CD = 1.8 ± 1.6, IMO = 0.48 ± 1.04; p = 0.0010), psychological inability (CD = 0.68 ± 0.80, IMO = 0.24 ± 0.60; p = 0.017), and difficulty (CD = 0.56 ± 0.87, IMO = 0.2 ± 0.64; p = 0.032). Furthermore, there was a significant difference between the baseline and final global scores of this questionnaire (p = 0.001). No differences were noted in the psychological discomfort and social inability domains (p > 0.05). The ES results indicate large differences in the following domains: functional limitation (0.89), physical pain (1.02), physical inability (0.84), and global score (0.97).

Discussion

Locker et al.[11] defined OHRQoL measurement instruments as those that assess the proportion of oral diseases and disorders, which in turn affect the function and assessment of psychosocial well-being. The differences between the questionnaires designed for this purpose relate to the number of questions, the question content, the answer format, the grouping of topics in different domains, and the number of domains.[32] Most studies that investigate the subjective perception of edentulous patients before and after IMO rehabilitation evaluate OHRQoL based on one questionnaire (*e.g.*, DIDL, GOHAI, or OHIP-EDENT). Consequently, the limitations and

differences in sensitivity across various domains of each questionnaire with respect to the others remain unknown. Furthermore, it is unclear which domains have the largest impact on OHRQoL after IMO treatment. Thus, the present study compared the results from three questionnaires (DIDL, GOHAI, and OHIP-EDENT) to assess the impact of IMO treatment on OHRQoL of denture wearers before IMO and after 3 months of adaptation and rehabilitation. The results showed that the self-reported OHRQoL effectively increased after rehabilitation and treatment with IMO. There were significant differences in several domains of the three questionnaires before and after IMO installation. Along with the major change in OHRQoL perception, the largest clinical effect perceived by patients occurred in areas related to the functional benefits established by IMO. The DIDL questionnaire indicated a significant improvement in the chewing and eating domain. The GOHAI questionnaire indicated a significant shift in the pain and discomfort domain, which included questions related to general mouth comfort along with pain and discomfort while chewing. The OHIP-EDENT results indicated significant improvements in the functional limitation, physical pain, and physical disability domains, which contain questions regarding comfort, ability, and retention of the prosthesis during chewing, as well as general pain and discomfort.

In a study of rehabilitated edentulous patients with total or partial dentures, Al-Omiri et al.[13] noted an increase in overall DIDL satisfaction and contentment with appearance, pain, oral comfort, general performance, and chewing after treatment. However, Hantash et al.[33] found that more than 50% of patients with conventional CD was not completely satisfied with the prosthesis. In this study, elderly patients were more satisfied with appearance and less satisfied with oral comfort and general performance. Hantash et al.[33] also observed a significant increase in mean DIDL scores for appearance, chewing, and general performance after IMO installation. This is entirely consistent with the results of the present study and may be explained by the increased retention and stability provided by IMO. The latter can improve satisfaction with chewing and increase the capacity of patients to perform daily activities and social interactions.[22,34]

The ES results after IMO treatment revealed a large improvement in patient perception of eating and chewing (ES = 0.93), and a moderate improvement in appearance, oral comfort, and general performance (ES = 0.57, 0.54, and 0.56, respectively). Therefore, the DIDL scores showed that the main improvement due to IMO treatment was related to the ability to bite and chew food. Patient classification

according to the satisfaction scale of the DIDL demonstrated the efficacy of IMO to improve quality of life. Furthermore, the percentage of totally satisfied patients increased in all domains, while the percentage totally unsatisfied patients decreased. In agreement with these findings, Packer et al.[24] used a modified version of the DIDL questionnaire for a sample of patients with Parkinson's disease and observed a significant improvement in OHRQoL after rehabilitation with overdentures and fixed prostheses, with improved satisfaction, nutrition, and oral health.

Edentulous patients wearing CD with a low GOHAI index prior to IMO treatment and fixed prostheses, recorded significant increases in mean scores that reflect improvement in OHRQoL in all three areas of the GOHAI (functional, psychosocial, pain and discomfort), while there was no difference between subjects that received fixed prostheses or overdentures.[25] The results of the present study showed that after IMO treatment, patients reported significant improvements ($p < 0.05$) in the psychosocial and pain and discomfort domains. The increase in the psychosocial domain highlights the fact that the OHRQoL of patients improved after IMO treatment, as demonstrated in previous studies.[25] Although the global score increased after IMO installation, there was no significant difference between the initial and final scores.

According to Locker et al.[35], the GOHAI questionnaire gives greater emphasis to functional limitations, as demonstrated by the physical and pain and discomfort domains. This is in accordance with the present results, where the pain and discomfort domain exhibited the largest ES. This demonstrates that the main clinical improvement in OHRQoL observed via the GOHAI resulted from an increase in oral comfort during meals, less analgesic use, and less sensitive gums. In addition, the results of the present study showed a moderate ES in the psychosocial domain after IMO treatment. The latter reflects a moderate improvement in maintaining social relationships, satisfaction with smile appearance, and decreased concern about the conditions of the gums and prostheses.

The OHIP-EDENT is one of the most widely used OHRQoL assessment tools in the literature for analysis of the perception of CD and IMO treatment.[9,16,26,27,28] This questionnaire focuses on the “social impact” of oral disorders, such as dysfunction, discomfort, and disability.[36] Higher OHIP-EDENT scores in each domain indicate poor quality of life. Souza et al.[37] used the OHIP-Edent questionnaire to compare IMO for mini-implants and IMO for conventional diameter implants, and found that the first treatment resulted in slightly better OHRQoL. An experimental study that used

evaluation with the OHIP-EDENT 2 months after IMO installation found that all seven domains and overall scores significantly improved, in accordance with previous results.[9,27] Awad et al.[26] showed that IMO treatment can improve OHRQoL as soon as 2 months after rehabilitation. Alfadda et al.[9] demonstrated OHRQoL improvement, as indicated by the OHIP-20 after rehabilitation with IMO, which remained stable in the initial 5-year period, showing that this treatment remains satisfactory for long follow-up periods.

The results of this study indicate a significant increase in OHRQoL ($p < 0.05$) after rehabilitation with IMO in the functional limitation, physical pain, physical disability, psychological disability, handicap, and global score domains. All aforementioned domains were associated with large ES, except the psychological disability and handicap domains, indicating that the magnitude of OHRQoL increase after IMO treatment is considerable, in accordance with a previous report.[27] These results are in line with a wide range of evidence demonstrating that IMO rehabilitation was viable and satisfactory for elderly patients with edentulous mandibles. The most noticeable improvements at 3 months post treatment (ES > 0.8) were observed in functional domains: i.e., eating and chewing (DIDL); pain and discomfort (GOHAI); and functional limitation, physical pain, and physical disability (OHIP-EDENT). In addition, this study provides unique results about OHRQoL evaluation from the perspective of three different questionnaires (DIDL, GOHAI, and OHIP-EDENT).

Finally, these results demonstrate the usefulness of ES calculations for the evaluation of clinical perception of oral treatment. Further studies with longer follow-up periods are needed to elucidate the long-term effects of IMO rehabilitation. The differences between the three questionnaires indicate different sensitivities of each questionnaire for various aspects of OHRQoL and that a combined approach is beneficial for extracting the maximal amount of OHRQoL-related information.

Conclusion

The DIDL, OHIP-EDENT, and GOHAI questionnaires were used to assess changes in quality of life after rehabilitation with IMO among elderly patients with difficulty adapting to conventional dentures. Elderly conventional CD wearers reported major improvements in OHRQoL 3 months after installment of IMO, with main improvements observed in the functional aspects of the prostheses and pain perception. ES calculations show that the most important improvements occurred in

the chewing and eating domain of the DIDL questionnaire, in the pain and discomfort domain of the GOHAI questionnaire, and the physical pain domain of the OHIP-EDENT questionnaire.

Acknowledgements

The authors acknowledge financial support from the CNPq (National Council for Scientific and Technological Development; grant no. 476170/2013-3).

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Table 1. Mean and SD values of the DIDL domains pre- and post-IMO treatment evaluation, and ES analysis.

DIDL	Before IMO					After IMO					p-value*	ES Mean
	Mean	SD	Median	Range	Interquartile interval	Mean	SD	Median	Range	Interquartile interval		
Appearance	0.6	0.62	1	-1–1	0–1	0.96	0.2	1	0–1	1–1	0.011	0.57
Pain	-0.04	0.74	-0.25	-1–1	-0.5–0.5	0.24	0.93	1	-1–1	-1–1	0.44	0.38
Oral comfort	0.017	0.41	0.14	-1–0.71	-0.14–0.28	0.24	0.78	0.71	-1–1	-0.57–0.71	0.15	0.54
Eating annd Chewing	0.12	0.80	0	-1–1	-0.66–1	0.87	0.42	1	-1–1	1–1	0.003	0.93
General performance	0.66	0.44	0.86	-0.73–1	0.46–1	0.90	0.24	1	0.13–1	1–1	0.003	0.56

*p-value from Wilcoxon's matched-pairs signed-ranks test; IMO: implant-retained mandibular overdentures.

Table 2. Mean and SD values of the GOHAI domains pre- and post-IMO treatment evaluation, and ES analysis.

GOHAI	Before IMO					After IMO					p-value*	ES Mean
	Mean	SD	Median	Range	Interquartile interval	Mean	SD	Median	Range	Interquartile interval		
Physical	9.12	1.01	9	7–10	8–10	9.4	0.91	10	7–10	9–10	0.33	0.27
Psychosocial	11.92	1.41	13	9–13	11–13	12.92	0.49	13	11–13	13–13	0.005	0.71
Pain and discomfort	7.6	0.96	8	6–9	7–8	6.96	0.45	7	5–8	7–7	0.0004	0.83
Global score	28.3	2.1	29	22–31	27–30	29.3	1.42	30	24–31	29–30	0.077	0.45

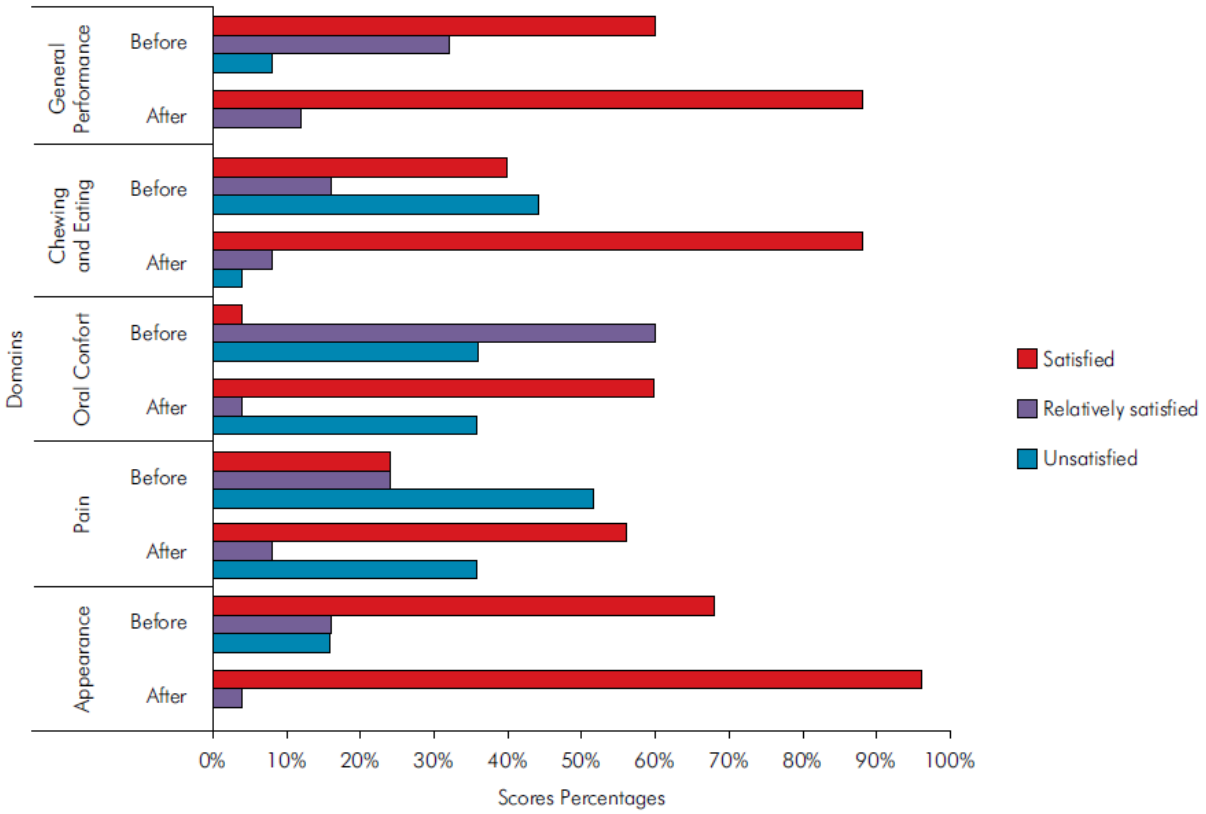
*p-value from Wilcoxon's matched-pairs signed-ranks test; IMO: implant-retained mandibular overdentures.

Table 3. Mean and SD values of the OHIP-EDENT domains pre- and post-IMO treatment evaluation, and ES analysis.

OHIP-EDENT	Before IMO					After IMO					p-value*	ES Mean
	Mean	SD	Median	Range	Interquartile interval	Mean	SD	Median	Range	Interquartile interval		
Functional limitation	3.28	1.98	3	0–6	2–5	1.52	1.55	1	0–6	0–2	0.0001	0.89
Physical pain	5.12	3.48	5	0–14	2–7	1.56	2.86	0	0–12	0–2	0.0002	1.02
Psychological discomfort	0.72	1.2	0	0–4	0–1	0.16	0.47	0	0–2	0–0	0.065	0.46
Physical disability	1.8	1.6	2	0–5	0–3	0.48	1.04	0	0–4	0–0	0.0010	0.84
Psychological disability	0.68	0.80	0	0–2	0–1	0.24	0.60	0	0–2	0–0	0.017	0.55
Social disability	0.48	0.87	0	0–3	0–1	0.12	0.33	0	0–1	0–0	0.15	0.41
Handicap	0.56	0.87	0	0–3	0–1	0.2	0.64	0	0–3	0–0	0.032	0.41
Global score	11.2	7.5	9	0–26	5–18	3.8	5.42	2	0–19	1–3	0.0001	0.97

*p-value from Wilcoxon's matched-pairs signed-ranks test; IMO: implant-retained mandibular overdentures.

Figure 1. Sample distribution in three satisfaction categories for each domain of the DIDL questionnaire.



3 Capítulo 2

Influence of age and time since edentulism on masticatory function and quality of life in implant-retained mandibular overdenture wearers: 1-year results from a paired clinical study. [§]

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[§]Artigo formatado segundo as normas do periódico The International Journal of Oral & Maxillofacial Implants

Abstract

Purpose: Investigate the influence of age and time since edentulism on masticatory function (MF) and quality of life related to oral health (OHRQoL) in totally edentulous patients while they were complete denture wereares and after implant-retained mandibular overdentures (IMO) loading.

Materials and Methods: The sample consisted of 33 patients categorized in two age groups (≤65 and > 65 years, respectively), and two time since edentulism groups (<25 and ≥25 years). The MF was evaluated through the masticatory performance (MP) and swallowing threshold (ST) tests before IMO loading, and 1, 3, 6, and 12 months after IMO loading. The OHRQoL was evaluated by applying the OHIP-EDENT and GOHAI questionnaires, before loading and after 3, 6, and 12 months. Data were subjected to the Mann-Whitney test and Wilcoxon's signed rank test for paired samples.

Results: The MP and ST were not influenced by the age nor by time since edentulism, except 6 months after IMO loading when patients with ≤65 years performed the ST test in a significantly shorter time with a reduced number of masticatory cycles ($P<0.05$). The MP and ST outcomes showed a gradual improvement up to 12 months, irrespective of the patient categorization. The GOHAI questionnaire scores showed that the OHRQoL was influenced by age in complete denture wearers with a difference between groups in the psychosocial and global domains. The time since edentulism did not affect the GOHAI scores of complete denture wearers ($P<0.05$). The OHIP-EDENT questionnaire only indicated significant differences as a function of age or time since edentulism between complete denture wearers. The age was associated with significant differences in the physical pain domain outcome, while time since edentulism did not affect only psychological discomfort, psychological inability and handicap domains.

Conclusion: age and time since edentulism did not influence MF of IMO wearing patients. However, IMO significantly improve the MF in totally edentulous patients, and this is more evident for younger patients (≤65 years) and patients with shorter time since mandibular edentulism (<25 years). The OHRQoL is only influenced by age and time since edentulism in complete dentures wearers, IMO treatment eliminates these differences.

Key-words: Totally edentulous patients, edentulism, masticatory function, quality of life, overdentures.

Introduction

The majority of the health problems faced by the growing elderly population are chronical.[1,2] One of the major problems is total edentulism, which has deleterious consequences to the oral and general health of individuals.[3] Total edentulism is the end result of a multifactorial process involving biological factors such as caries, periodontal disease, trauma, and buccal cancer and non-biological factors related to the teeth treatment, health access, patients' behavior, financial issues and treatment availability.[4] Although the prevalence of total edentulism is decreasing in high-income countries, an inverse trend is noted in low or medium- income countries, where it is closely related to caries and periodontal diseases.[5] For instance, Brazil is considered a medium-income country and 11% of its population is totally edentulous.[6]

The most important problems beside teeth loss are the alterations to the hard and soft tissues in the oral cavity.[4] Continuous and progressive residual ridge resorption (RRR) significantly reduces the alveolar bone volume and the basal support area for the prosthesis. This RRR process negatively influences the rehabilitation options when maxillary's bone atrophy is present.[7,8] Common clinical findings in these patients include superficial muscular insertions, thin or flat residual ridges, and superficialization of the alveolar nerve that results in pain during usage of the prosthesis.[9,10] Total edentulism results in loss muscle tone and mass, which probably affects the masticatory function (MF) and the nutritional choices of older patients. In addition, oral motor function decreases with age which causes a decrease in masticatory performance.[11,12] Besides oral health, total edentulism also negatively affects oral health related quality of life (OHRQoL) aspects, including social interaction, day-to-day activities, self-esteem, and the psychological health.[13] Conventional complete dentures (CCDs) are also associated with poor retention and stability, which can result in a unsatisfactory MF, low bite force, discomfort during function, and dissatisfaction with the rehabilitation.[14–17]

In 2002, the McGill Consensus defined that implant-retained overdentures (IMO) should be the minimum treatment for totally edentulous patients.[18] After IMO treatment, patients' MF, bite force and satisfaction improves while discomfort during function decreases.[19] However, mandibular bone atrophy may hinder treatment with conventional implants and the degree of bone atrophy is directly proportional to the time since edentulism.[20–22] Insufficient bone volume in patients with severe bone atrophy may necessitate reconstructive surgery or the use of narrow diameter implants. The latter have become attractive treatment option for these patients, as they

provide CCD retention and stability and involve simpler and less invasive surgical techniques. The latter enables to rehabilitate elderly patients for whom more complex and time-consuming surgical procedures are contra-indicated.[23]

Treatment with implants in elderly patients has become a routine practice and will be even more wide-spread in the near future, as IMO have a significant positive impact on the MF and OHRQoL.[22,24,25] However, there is no consensus in the current literature regarding the change in masticatory function or maximum bite force as a function of age.[26] Bilhan et al.[27] did not find a significant difference in maximum bite force in IMO-wearers above and below 65 years. Presently, it is unclear to which degree the patient's age and time since edentulism impact the MF and OHRQoL improvements that can be obtained. Thus, the aim of this study was to investigate the influence of age and time since edentulism on MF and OHRQoL in totally edentulous patients while they were CCD wereares and after IMO loading. The null hypothesis was that age and time since edentulism do not influence the MF and OHRQoL of totally edentulous individuals during transition from CCD to IMO, until one year of rehabilitation with IMO.

Material and Methods

Study design

This longitudinal clinical study was performed according to the Helnsiki Declaration, following the STROBE guidelines. The study was approved by Research Ethics Committee of the UFPel School of Dentistry (Protocol - 69/2013) and included fully edentulous patients rehabilitated at the Complete Dentures Clinic of the Dentistry School at the Federal University of Pelotas. The following inclusion criteria were applied: good systemic and oral health, CCD wearers for at least 3 months, present difficulties to adapt to their mandibular CCD, and be diagnosed with mandibular atrophy according to Kapur et al.[28] criteria.

All participants that agreed to participate in this study signed an informed consent form, and subsequently performed the masticatory performance and swallowing threshold tests. The oral health related quality of life (OHRQoL) was then measured by applying the OHIP-EDENT and GOHAI questionnaires. Immediately after these evaluations, two narrow diameter implants (2.9x10mm– Facility Neodent®) were installed between mental foramen by an experienced surgeon and healing caps were connected. After a 3 month osseointegration period, the healing caps were replaced by Equator attachments and the mandibular prosthesis was submitted to

occlusal loading. The masticatory tests were repeated after 1, 3, 6, and 12 months and questionnaires after 3, 6 and 12 months.

Patient categorization

All volunteers were categorized according to their age and time since edentulism. The participants were categorized according to the median values of the data into 2 groups: I) patients above 65 years and patients with ≤65 years, II) patients with time since edentulism of ≥25 years and ≤25 years.

Confection of the artificial food (Optocal)

Optocal artificial food is a mixture of Optosil Plus® (Bayer Dental; 58.3 wt%), conventional tooth paste (7.5 wt%), solid Vaseline (11.5 wt%), common dental plaster powder (10.2 wt%), and alginate powder (12.5 wt%). Metallic molds are used to create standardized cubes with 5.6 mm sides. All cubes were stored for 16 hours in a stove at 65 °C and subsequently disinfected in glutaraldehyde. To perform the tests, a portion of 3.7 g was weighted on an analytical balance and stored in the refrigerator.[29–31]

Masticatory Function

The masticatory function (MF) was evaluated using 2 distinct tests, the Masticatory Performance (MP) test and the Swallowing Threshold (ST) test. To perform these tests, all volunteers were instructed to chew a 3.7 g Optocal portion.[8,31] In the MP test, the patients needed chew the artificial food for 40 cycles, recorded by the evaluator. During the ST test, the volunteers were instructed to chew until they felt the desire to swallow. All the material was subsequently expelled on a paper filter. The chewed material was then washed and dried at room temperature for 7 days. After drying, the material was passed through a sieve tower with progressively decreasing mesh size. The weight retained in each sieve was then determined and inserted in Rosin-Rammler equation to calculate the X50 and B parameters. The X50 calculation determines the median particle size corresponding to the theoretical sieve aperture through which 50% of the particles weight would pass, while the B parameters describes the homogeneity of the crushed particle distribution, with lower values corresponding to more homogeneous distributions. In addition, the masticatory

efficiency was calculated as the weight percentage retained in the 5.6 mm and 2.8 sieves (ME 5.6 and ME 2.8).[8,30]

Oral Health related quality of life (OHRQoL)

I) OHIP-EDENT

This questionnaire evaluates the physical, functional, social and psychological aspects of the treatment. Each question has 3 possible answers: never, sometimes, and always, which were scored as 0, 1, and 2, respectively.[32,33] Higher OHIP-EDENT scores in each domain indicate a poor quality of life, while lower scores indicate a better health status.[32]

II) GOHAI

This questionnaire evaluates the patients' self-reported OHRQoL in 3 different domains: Physical, Psychological and Pain/discomfort. Each question has 3 possible answers: Always/ frequently; Sometimes/ rarely and Never, which were scored as 1, 2, and 3 respectively, thus, higher scores represent better self-perceived oral health.[34,35]

Statistical Analysis

The data distribution was analyzed using descriptive statistics. Non-parametric tests were used to perform the comparisons: Mann-Whitney test was used to compare the differences between the groups while Wilcoxon's signed rank test for paired samples was used to test for differences between the evaluated periods. The effect size was calculated, and the final scores were classified as: small (ES≃0.2), medium (ES≃0.5) and large (ES≃0.8).[36] All data were analyzed with the SPSS 22 software; the significance level was set at 5%.

Results

The sample population consisted of 33 patients divided into groups according to the median age and time since edentulism: i) Age ≤65 years,16 patients and >65 years, 17 patients; ii) time since edentulism <25 years, 17 patients and ≥25 years, 16 patients.

Figures 1 and 2 show the percentage improvement of MF test outcomes (MP and ST). No statistically significant differences (P>0.05) in the MP outcomes were found between the age (Figure 1) and time since edentulism (Figure 2) groups.

However, after IMO installation, a significant improvement was observed for all MP outcomes in all groups in the first month of IMO loading. Figure 1 shows that the highest percentage of improvement was observed in the ≤65 years' group, both for the MP test (MP_X50, MPB, ME 5.6, ME 2.8) and for the ST test (ST_X50, STB, ME 5.6, ME 2.8). The time and number of cycles in the ST test was only significantly different after 6 months of IMO loading, when patients above 65 years needed 35% more cycles and time. None of the applied masticatory function tests showed any statistically significant difference between the time since edentulism groups (P>0.05; Figure 2).

Figures 3 present the global OHRQoL scores of the GOHAI and OHIP-EDENT questionnaires for the groups at different time points. At the baseline, all patients were CD wearers and statistically significant differences between the groups were observed in both questionnaires. In the GOHAI questionnaire, there was a significant difference between the age groups in the psychosocial domain [≤65 years=10.81 (±1.33); >65 years=12.12 (±1.18); P=0.006] and the global score [≤65 years=25.44 (±3.39); >65 years=28.29 (±2.14); P=0.004]. The OHIP-EDENT questionnaire only showed a significant difference between the age groups for the physical pain domain at baseline [≤65 years=4.63 (±2.19); >65 years=2.94 (±2.01); P=0.049]. After the IMO installation, no significant differences were observed between the age groups, except for the pain and discomfort domain in the GOHAI questionnaire at 12 months [≤65 years=7.19 (±0.66); >65 years=6.76 (±0.42); P=0.039].

No significant differences were observed between the time since edentulism groups in the GOHAI questionnaire at the baseline. Conversely, the OHIP-EDENT questionnaire showed significant differences between the time since edentulism groups in 5 domains during the baseline evaluation: global [<25 years=14.47 (±8.47); ≥25 years=7.69 (±5.31); P=0.018], functional limitation [<25 years=3.88 (±1.73); ≥25 years=2.75 (±1.91); P=0.028], physical pain [<25 years=4.53 (±2.53); ≥25 years=2.50 (1.90); P=0.008], physical disability [<25 years=2.59 (±2.03); ≥25 years=1.38 (±1.31); P=0.034], social disability [<25 years=0.88 (±1.05); ≥25 years=0.06 (±0.25); P=0.013]. After the IMO installation, no significant difference was observed between the time since edentulism groups, except in the global GOHAI domain at 3 months post loading [<25 years=28.94 (±0.97); ≥25 years=29.63 (±1.59); P=0.014].

Tables 1 and 2 list the effect size (ES) values for the GOHAI and OHIP-EDENT questionnaire domains between all evaluation periods (0, 3, 6, and 12 months) according to age and time since edentulism, respectively. In the GOHAI questionnaire, patients with ≤65 years (Table 1) reported the highest short-term clinical effects in the

physical (ES 0-3: 1.1) and psychosocial (ES 0-3: 1.5) domains. The latter two domains maintained high ES after 1 year of treatment, (ES 0-12: 1.2 and ES 0-12: 1.5, respectively). For the >65 years age group, large short-term ES values were observed in the pain and discomfort domain (ES 0-3: 0.8) and these high ES compared to the baseline peaked at 12 months (ES 0-12: 1.1), when they were joined by high ES in the physical domain (ES 0-12: 0.9). The OHIP-EDENT questionnaire indicated large short-term clinical effects in the ≤65 years age group for the functional limitation, physical pain and physical disability domains (ES 0-3: 1.0, 1.4 and 1.3 respectively) were observed in the short period. The latter domains also showed the highest ES after 1 year of treatment (ES 0-12: 1.1, 1.8 and 1.5, respectively). In the >65 years age group, only the functional limitation (ES 0-3: 1.0) and physical pain (ES 0-3: 1.1) domains had large ES at 3 months, and these same domains remained with large ES in a long period of time (ES 0-12: 1.3 and 1.2, respectively), the long-term ES in the physical disability domain became apparent after one year (ES 0-12: 0.8).

In the GOHAI questionnaire (Table 2), the group with short time since edentulism only had large short-term ES in the psychosocial domain (ES 0-3: 0.9) and large ES persisted in this domain long-term (ES 0-12: 1.1). In the group with longer time since edentulism, the physical and psychosocial domains showed large short-term ES (ES 0-3: 0.9) and these domains maintained high ES at 12 months (ES 0-12: 0.9 and 0.8, respectively). The pain and discomfort domain also presented large long-term ES between baseline and 12 months (ES 0-12: 0.8). In the OHIP-EDENT questionnaire, the group with shorter time since edentulism showed the highest short-term clinical effects in the functional limitation, physical pain, physical incapacity and psychosocial incapacity domains (ES 0-3: 1.3, 1.3, 1.0 and 0.8, respectively). These four domains also presented higher ES after 1 year of treatment (ES 0-12: 1.6, 1.5, 1.0 and 0.8 respectively), when an improvement in the social disability domain becomes apparent (ES 0-12: 0.8). After 3 months of IMO loading, the group with long time since edentulism showed the highest ES in the functional limitation, physical pain and psychological incapacity (ES 0-3: 0.8) domains. The high ES in these three domains persisted after 1 year (ES 0-12 1.0, 1.0 and 0.9, respectively), when an improvement in the physical disability domain becomes apparent (ES 0-12: 0.9).

Discussion

The objective of this study was to verify how age and the time since edentulism functionally (MF) and subjectively (OHRQoL) affect the treatment of edentulous

patients during the first year of transition from the treatment of CCD to IMO. The MF aspect of our null hypothesis was accepted, as our results indicate that these two factors generally did not significantly influence the objectively assessed MF, when the CCD and IMO treatment results were compared over a period of 1 year. However, the subjective perception regarding CCD treatment was influenced by these two factors. Patients with shorter time since edentulism (<25 years) and ages ≤65 years reported a worse OHRQoL as CCD wearers. After IMO loading, these patients reported greater clinical effects, as they presented the highest ES values across most domains when the baseline conditions were compared to the post-loading periods.

The aging process varies widely between individuals and coincides a progressive degeneration of normal structures and a decline of the function of body peripheral tissues, including skin, mucosa, muscles, joints, glands and viscera, as sensory receptors, and the sensory motor functions of the jaws may also be affected. [37]. Thus, the physiological changes of the oral cavity during aging can modify masticatory function. This in turn has implications for the diet of elderly persons, which have a tendency to reduce food intake and an increasing preference for soft and easy to swallow foods.[38] According to Peyron et al.[39], three factors greatly impact the masticatory function of elderly persons: the number of natural antagonist teeth, the quantity and / or the quality of the saliva and the compromised motor system. Consequently, the masticatory function of totally edentulous CCD wearers is poor compared to healthy dentate individuals.[30]

In our study, we expected a compromised masticatory function of patients with advanced age and prolonged edentulism, believing that a decrease in muscle tone for older patients, leading to a decreased bite force, which could have implications for the MF tests. However, our results showed no significant differences for both MP and ST outcomes between the two age and time since edentulism groups. One exception is that the number of cycles and the time required to complete the ST test at 6 months of function was significantly influenced by the time since edentulism (+35%, P=0.017 and 0.044, respectively). Recently, Enkling et al.[26] found that patients older than 65 years rehabilitated with IMO presented lower maximum bite force. However, when the authors evaluated masticatory efficiency through the homogenization of a two-color chewing gum, no improvement was observed. The lack of improvement was attributed to the acquisition of an inefficient masticatory behavior during CCD use, which was not altered after IMO treatment. This deleterious effect is thought to be related to tactile limitations and the mobility of conventional mandibular prosthesis acquired during >10

years of CCD use.[26] Another important inference related to these types of tests is that bite force results in clinical studies with edentulous patients do not always match those results found in MF tests. In the bite force test, the patient applies their maximum bite force capacity for a given time, usually in the first molar region. By contrast, most of the MF tests (MP and ST) involve chewed artificial (Optocal) food particles, following the methodology of Fontjin-Tekamp et al.[30] In the MP and ST tests, the patient does not necessarily need to use their maximum bite force and may have different distributions of muscular forces during the execution of the masticatory cycles.[26,30] However, we highlight that ST test was more sensitive than MP in our study, since after 6 months of IMO loading, older patients needed more time and a greater number of cycles to grinding the test food (~+35%). The latter can be justified by the fact that older patients have less muscle tone and muscular endurance.[40] In spite of the compromised masticatory kinetics in patients above 65 years, these patients did not present worse food homogenization in the ST test.

A recent literature review that investigated changes in masticatory mechanisms as a function of age showed that CCD wearers present adaptations in their mastication to compensate for their deficient masticatory apparatus, even with foods that are easy to chew.[39] These authors identified that the effects of aging on mastication and swallowing of CCD wearers include an increase in the number and duration of the masticatory cycles, reduction of muscle strength, decreased tactile sensitivity and reflex responsiveness, and changes in the sequence and coordination of oropharyngeal muscle contractions. Such changes may affect dietary behavior, nutritional status, and also increase the risk of mortality.[39] In this context, our ST results show that the adaptation to the IMO can be observed after 6 months, but only in older patients and this effect disappears after one year of IMO loading as new habits are created.

Treatment with IMO significantly improved the MF and ST over time irrespective of age or time since edentulism. In particular, the masticatory behavior obtained by the patients during the ST test in our study were similar to those described by Van der Bilt et al.[41] After the installation of IMO, patients showed not only superior quality in mastication, but it is also believed that they developed of greater muscle strength.[41] In addition, Enkling et al.[26] observed that the bite force of edentulous patients rehabilitated with IMO increases by 33.23% after 3 months of loading. Consequently, an improvement in masticatory function is expected after IMO loading when compared to CCD,[26,42] consistent with the results in our study. A prospective study by Van der

Bilt et al.[43] found that the maximum bite force and masticatory performance increased significantly after IMO treatment and remained unchanged over the 10-year follow-up period. Other studies have shown that the muscle activity of the muscles involved in mastication is altered according to prosthetic rehabilitation performed in edentulous patients.[15,41] Van der Bilt et al.[41] observed that temporal muscle activity was significantly lower than masseter activity when subjects bit with CCD. Conversely, the muscular activity of the temporal and masseter did not differ when the patients are rehabilitated with IMO.[41] These authors suggest that part of the muscle activity performed during mastication in CCD rehabilitation is used to manipulate the prosthesis in order to keep it in a comfortable place, instead of focusing on grinding food.[41] The latter is consistent with Caloss et al.,[16] who stated that the instability of the prosthesis inhibits the masticatory muscles, especially during unilateral bite and mastication. The neuromuscular adaptation after treatment with IMO can be compared to electromyography results of healthy dentate individuals.[44] Studies show that the maximum bite force increases significantly after 3 months of IMO rehabilitation, which reflects in improved masticatory function when compared to CCD treatment.[15,45] Therefore, we suggest that the bite force of the individuals in our sample increased after IMO loading and equalized over time, contributing to the improved masticatory function observed in all groups after 1 year of IMO treatment.

The success of rehabilitation depends on the re-establishment of the patient's oral function, satisfaction, and OHRQoL. Assessing the impact of the IMO treatment on the OHRQoL is essential to provide a more complete view of the rehabilitation along with the objective MF tests. The positive impact of IMO on the quality of life of patients rehabilitated in our study was confirmed by both questionnaires (Figures 3 and 4) and are in agreement with the results of previous studies. [8,24,46] Our findings also showed that the perception of the clinical treatment effect was greater in the ≤65 years age group, which perceived higher ES values in most domains and it was better perceived by patients with shorter time since edentulism, as these patients perceived large ES across more domains at the end of the follow-up period.

The between groups results show that age and time since edentulism influenced the OHRQoL, as there were statistically significant differences in both GOHAI and OHIP-EDENT scores while patients were CCD wearers, and the groups with ages above 65 and longer time since edentulism (≥25 years) reported better OHRQoL. These findings may be justified because the groups of patients with age >65 years and patients with time since edentulism ≥25 years have a greater prosthetic

experience, and thus have less expectations regarding CCD rehabilitation and oral discomfort, and also are more habituated with the treatment and, consequently, report better scores in the OHRQoL. Patients with age ≤65 years and the group of patients with time since edentulism <25 may have higher expectations regarding the installation of a new CCD. The adaptation to the use of CCD is difficult in conditions with poor motoric control, greater fragility of the oral tissues, and reduced neuroplasticity, which could account for the greater frustration in this group of patients.[47] The ES of patients aged ≤65 years and time since edentulism <25 were evaluated after 12 months were higher than those of patients with age >65 years and time since edentulism ≥25 years for most domains of the questionnaires. This suggests a greater clinical effect of IMO treatment for these patients. However, between groups comparisons after IMO installation were only significantly different for the pain and discomfort domain of the GOHAI questionnaire at 12 months.

Both the OHIP-EDENT and GOHAI scores indicate that the majority of the positive impact of rehabilitation with IMO occurred at 3 months of loading, followed by additional improvements at 6 months. In addition, our ES results show that IMO treatment had the greatest clinical impact on the physical and functional domains. The studies of Schuster et al.[24] and Marcello-Machado et al.[48] also describe similar results regarding the short-term perception of positive treatment effects on the patients' quality of life. This finding may be justified due the application of the questionnaires shortly after surgery, as the positive impact of IMO on functionality and psychological comfort may be easier to perceive three months after rehabilitation compared to longer periods. After a longer time of IMO treatment, the patient's memory regarding their mastication as CCD wearers fades as they become accustomed to the IMO.

The limitations of the present study include the lack of maximum bite force and salivary flow monitoring. Especially latter is directly related to the masticatory function and the homogenization capacity of the bolus. More studies with longer follow-up times and additional mastication-related parameters are necessary to evaluate the long-term evolution of masticatory function and OHRQoL after rehabilitation with IMO.

Conclusion

Age and time since edentulism did not affect the MP outcomes of totally edentulous CCD or IMO wearers. However, after 6 months of IMO loading the more sensitive ST test showed that older patients needed ~35% more time and more cycles,

and this likely reflects a more intense IMO adaptation period in this group. In addition, IMO significantly improved MF of edentulous patients compared to CCD treatment.

The OHRQoL of CCD wearers was affected by age and time since edentulism. Younger patients with shorter time since edentulism had higher expectations with the new treatment, who have greater resilience to this treatment. The physical and functional domains exhibited the highest clinical effect after IMO treatment, and the greatest improvements were observed for younger patients and with less time since edentulism.

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Table 1. Effect size (ES) for each domain of the GOHAI and OHIP-EDENT questionnaires according to the age groups.

	ES 0 – 3		**ES 0 - 6**		**ES 0 - 12**		**ES 3 - 6**		**ES 3 – 12**		**ES 6 - 12**	
	≤65 years	>65 years	≤65 years	>65 years	≤65 years	>65 years	≤65 years	>65 years	≤65 years	>65 years	≤65 years	>65 years
GOHAI												
Physical	**1.1**	0.7	**1.3**	0.7	**1.2**	**0.9**	0.4	0.0	0.3	0.4	0.2	0.4
Psychosocial	**1.5**	0.7	**1.5**	**0.8**	**1.5**	0.6	0.0	.	0.0	.	0.0	**0.8**
Pain and Discomfort	0.3	**0.8**	0.3	0.7	0.1	**1.1**	0.0	0.2	0.5	0.7	**0.9**	0.7
OHIP-EDENT												
Functional limitation	**1.0**	**1.0**	**1.1**	**0.9**	**1.1**	**1.3**	0.1	0.1	0.1	0.5	0.0	0.5
Physical Pain	**1.4**	**1.1**	**2.0**	**1.1**	**1.8**	**1.2**	0.6	0.1	0.3	0.1	**1.4**	0.2
Psychological Discomfort	0.5	0.5	0.6	0.6	0.7	0.4	0.2	0.2	0.3	0.4	0.2	**0.8**
Physical Disability	**1.3**	0.7	**1.6**	**0.8**	**1.5**	**0.8**	0.4	0.3	0.2	0.3	0.3	0.0
Psychological Disability	**0.9**	0.6	**1.0**	0.7	**1.0**	0.6	0,2	0.3	0.2	0.0	0.0	.
Social Disability	0.6	0.2	0.7	0.4	0.6	0.2	0.4	0.4	0.2	0.0	.	.
Handicap	0.7	0.6	**1.0**	0.6	0.7	0.6	0.3	.	0.0	.	**1.0**	.

Table 2. Effect size (ES) for each domain of the GOHAI and OHIP-EDENT questionnaires according to the time since edentulism groups.

	ES 0 – 3		**ES 0 – 6**		**ES 0 - 12**		**ES 3 – 6**		**ES 3 - 12**		**ES 6 - 12**	
	<25 years	≥25 years	<25 years	≥25 years	<25 years	≥25 years	<25 years	≥25 years	<25 years	≥25 years	<25 years	≥25 years
GOHAI												
Physical	0.7	**0.9**	0.8	**0.9**	**0.8**	**0.9**	0.1	0.0	0.1	0.0	0.0	0.0
Psychosocial	**0.9**	**0.9**	**1.1**	**0.9**	**1.1**	**0.8**	0.2	0.2	0.2	0.3	0.0	0.8
Pain and Discomfort	0.3	0.7	0.4	0.6	0.3	**0.8**	0.3	0.2	0.0	0.1	0.4	0.5
OHIP-EDENT												
Functional limitation	**1.3**	**0.8**	**1.4**	**0.8**	**1.6**	**1.0**	0.1	0.0	0.2	0.3	0.2	0.4
Physical Pain	**1.3**	**0.8**	**1.6**	**1.1**	**1.5**	**1.0**	0.4	0.2	0.2	0.2	0.2	0.1
Psychological Discomfort	0.7	0.5	0.7	0.6	0.7	0.5	0.2	0.2	0.2	0.0	0.0	0.4
Physical Disability	**1.0**	0.7	**1.1**	**0.9**	**1.0**	**0.9**	0.3	0.3	0.1	0.3	0.3	0.0
Psychological Disability	**0.8**	**0.8**	**0.8**	**1.0**	**0.8**	**0.9**	0.1	0.4	0.1	0.2	0.0	.
Social Disability	0.7	0.3	**0.8**	0.3	**0.8**	0.3	0.4	0.4	0.2	0.0	.	.
Handicap	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.3	0.0	0.0	.	0.2

Figure 1. Percentage of MF improvement for (A) the MP test and (B) the ST test according to the age group, calculated as the percentage of improvement between the baseline and the mean at the evaluated time interval (1,3, 6, and 12 months; Mann-Whitney test, p <0.05).

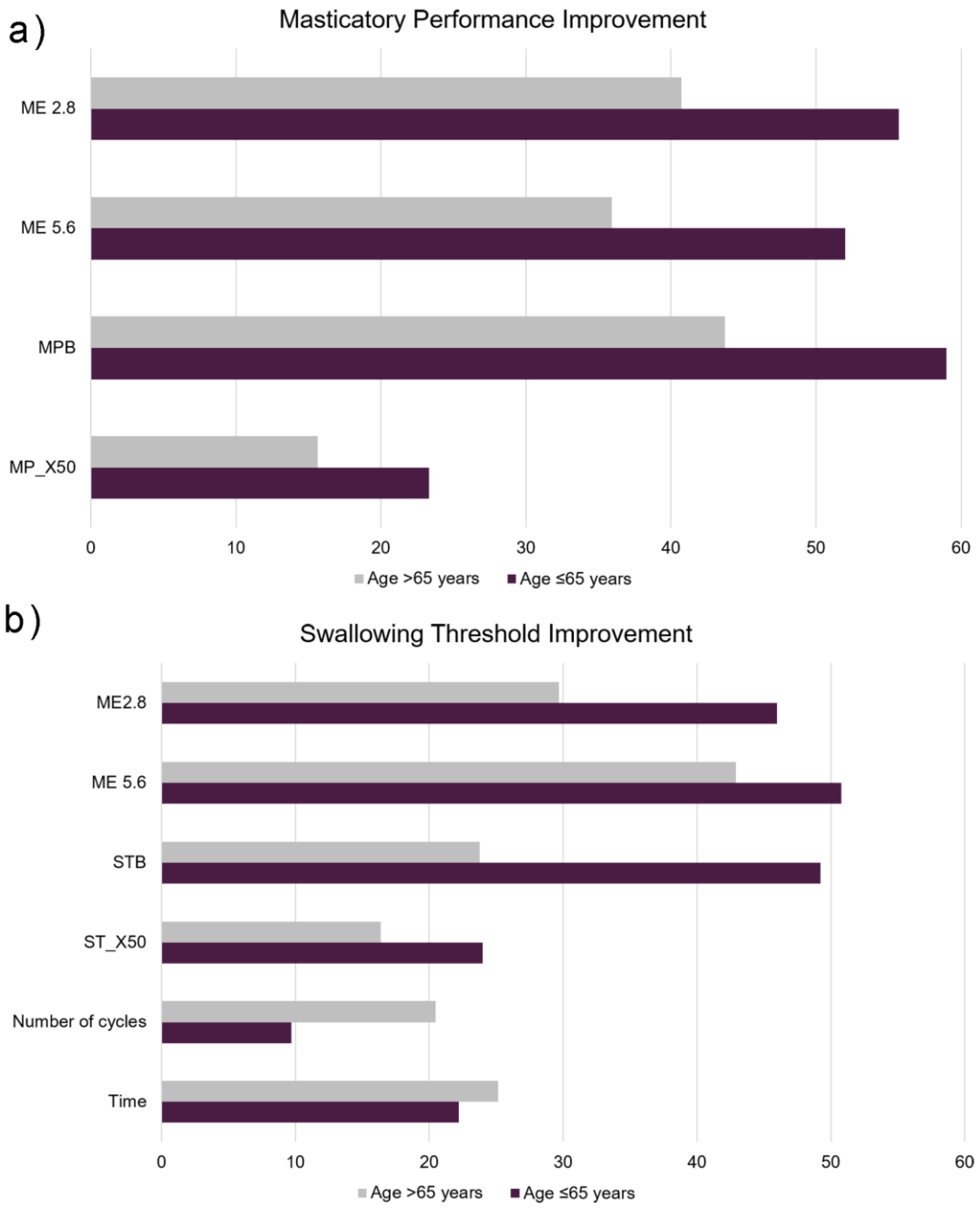


Figure 2. Percentage of MF improvement for (A) the MP test and (B) the ST test according to time since edentulism, calculated as the percentage of improvement between the baseline and the mean at the evaluated time interval (1,3, 6, and 12 months; Mann-Whitney test, p <0.05).

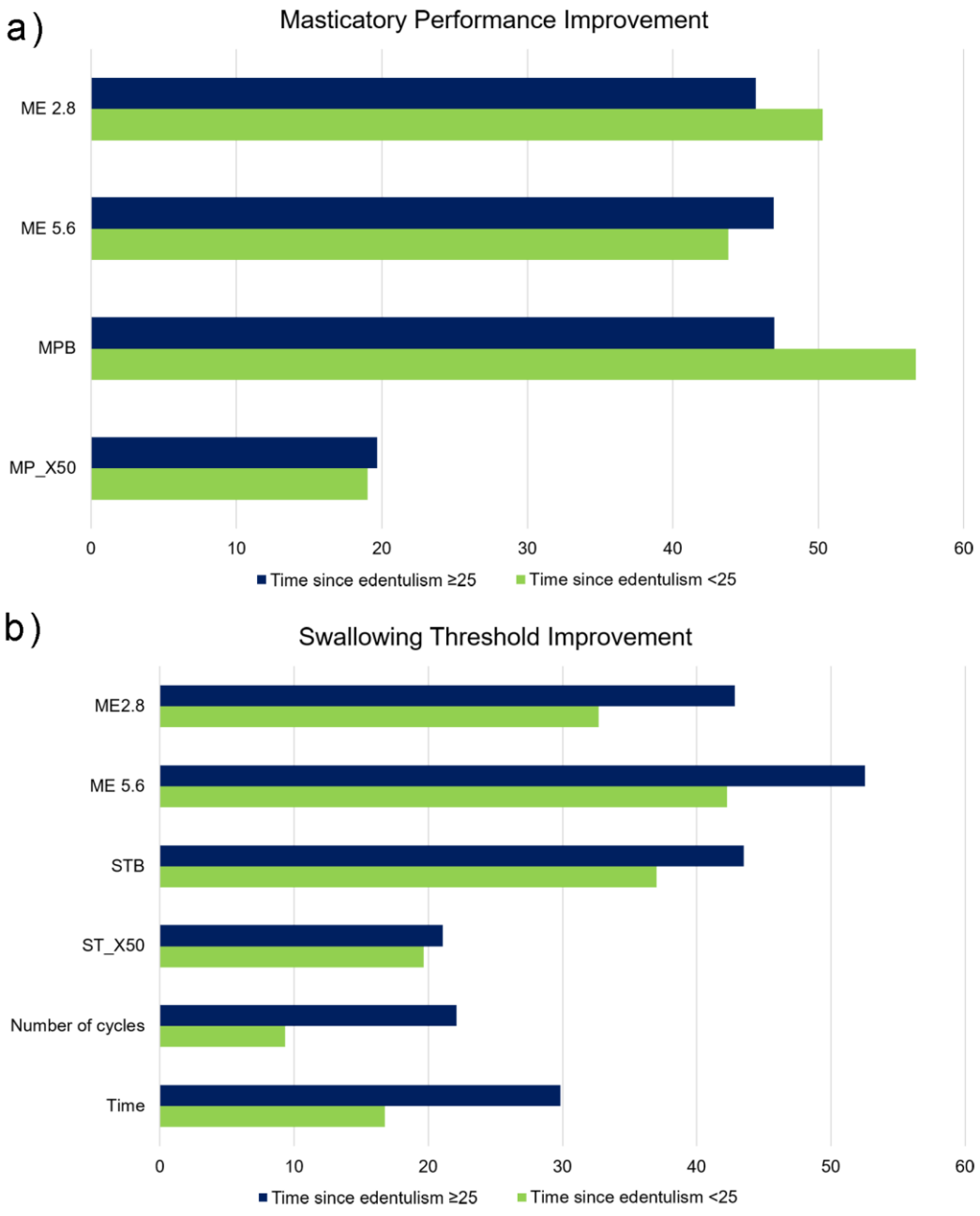
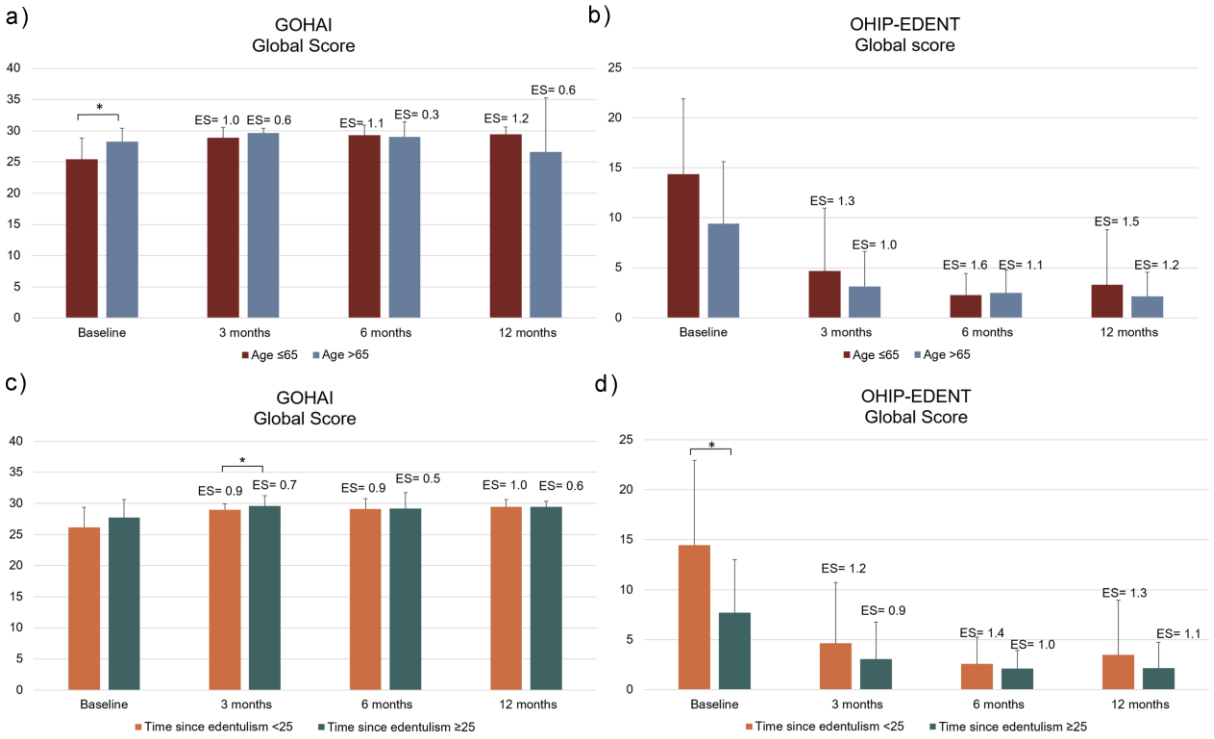


Figure 3. Mean and standard deviation of the global (A) GOHAI according to age; (B) OHIP-EDENT according to age; (C) GOHAI according to time since edentulism; (D) OHIP-EDENT according to time since edentulism, scores for each group obtained at the different evaluation times (Mann-Whitney test, p <0.05). Asterisks indicate significant differences between the groups. ES: effect size observed for the global scores at the respective evaluation times in comparison to the baseline.



4 Capítulo 3

Immediate versus conventional loading of Facility-Equator system in mandibular overdenture wearers: 1-year RCT with clinical, biological, and functional evaluation §

Running title: Immediate and conventional loading in mandibular overdenture

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Conflict of Interest Statement

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

Author Contribution Statement: AADBC, FF and OLCJ conceived the ideas; AJS, RMMM, AMB, OLCJ and FF collected the data; AJS, RMMM, AMB, OLCJ, AADBC and FF analyzed the data; and AJS, RMMM, AMB, OLCJ, AADBC and FF led the writing.

Keywords: Conventional loading, immediate loading, mandibular overdentures, narrow dental implants.

[§]Artigo formatado segundo as normas do periódico Clinical Implant Dentistry and Related Research

Abstract

Background: It is necessary to evaluate the impact of different loading protocols in elderly patients with low bone availability and long time since edentulism, the population for whom narrow diameter implants (NDI) are most frequently indicated.

Objectives: To evaluate the clinical, biological, functional, and oral health related quality of life (OHRQOL) influence of conventional (CL) and immediate (IML) loading in mandibular overdentures retained by Facility-Equator system up to one year after implant installation.

Material and Methods: Twenty edentulous patients received 2 narrow diameter implants (NDI) in the mandible; the loading type (CL or IML) was randomized. The clinical peri-implant health indices were monitored, along with prosthetic events, marginal bone loss/change, implant stability quotients (ISQ), masticatory performance (MP) outcomes (before, 1, 3, and 12 months), and IL-1β and TNF-α levels in the peri-implant crevicular fluid (3, 6, and 12 months). The OHRQoL was assessed via the OHIP-EDENT questionnaire before, 3 and 12 months after loading. Data were analyzed by the Mann-Whitney, Chi^2, Wilcoxon paired, and McNemar tests.

Results: At 3 months, the ISQ for CL group (50.6) was significantly lower than IML group (54.25; P=0.018). Probing depth at 12 months was higher in the CL group (2.19 mm) than in the IML group (1.29mm; P≤0.0001). TNF-α was 33.6% higher in the CL group at 6 months (P=0.043), while IL-1β was significantly higher in the IML group up to 6 months. Survival rate was 90% in the CL group and 85% in the IML group; 33 prosthetic events occurred in CL group and 23 in IML group.

Conclusions: Both loading protocols are viable, however, IML generates better adaptation of the peri-implant tissues around the prosthetic components, reflected in a smaller probing depth and fewer prosthetic events.

Introduction

The promising results of narrow diameter implants (NDI) as mandibular overdenture (MO) retainers led to a consensus in literature to indicate NDI for the treatment of edentulous patients with limited bone availability [1–4]. Although conventional loading (CL) has been adopted in most previous studies, the inconvenience of a long healing period led to the adoption of immediate loading (IML) in MO retained by 2 implants, as IML has been shown to be a clinically viable and successful treatment option [5–7]. However, the precise benefits associated with each type of loading are still unclear, especially for edentulous patients with advanced age. In these patients, several factors can compromise the osseointegration process, such as bone quality and microarchitecture, bone availability and degree of atrophy in the mandible, prolonged time since edentulism, and the presence of systemic or chronic diseases [8–10].

Systematic reviews still show divergent survival rates achieved by CL and IML when using implants as MO retainers [1,11–13]. The meta-analysis by Alsabeeha et al. 2010[11] suggests that IML is a predictable treatment option that presents results comparable to the CL in short-term studies. However, long-term survival rate data indicate that the CL protocol should be preferred [11]. Another meta-analysis showed that CL results in fewer implant failures during the first year of follow-up, even though IML protocol generates survival rates of 81 – 100% [12]. However, these two reviews do not differentiate the results according to the patient profile, degree of mandibular bone atrophy, retentive system, implant diameter, and number of implants installed to retain the prostheses. Furthermore, a recent systematic review with meta-analysis that evaluated randomized clinical trials that used 2 unsplinted implants as MO retainers did not find differences between CL and IML protocols in terms of implant failures or marginal bone loss around implants [13]. Until now, only one meta-analysis has evaluated the effect of CL and IML on MO retained by NDI and mini-implants, and revealed that CL is the superior protocol when mini-implants are used to retain MO. The results for NDI preliminarily prefer CL, but should be interpreted with caution, as the IML protocol was only tested in 1 study so far [1].

From a biological point of view, the benefits of each loading protocol are also still contradictory. Some studies state that CL allows lower osseocompression and tension, and that the larger space around the implant would stimulate osseointegration, considering that implant insertion with a lower load would cause less trauma to the

bone bed, resulting in a reduced release of inflammatory mediators and a less exacerbated and more balanced inflammatory wound healing reaction [14–16]. However, other studies have shown that important biomarkers are released early in the mineralization matrix when the IML protocol is used, and that these markers remain high during the osseointegration period, likely due to increased activity during bone mineralization [17–21]. Thus, it is presumed that the mechanical force exerted by the IML changes the metabolism and the action of cells involved in the osteogenesis process, in order to increase and accelerate the release of bone mediators around the implant. In addition, two studies by Guncu et al. 2008[22] and Guncu et al. 2009[23] that evaluated the bone metabolism of implants that receive IML and CL reported a different behavior in the in nitric oxide release patterns. In the IML group, a gradual decrease of the bone metabolism was observed from 6 months onwards, whereas for the CL group, the nitric oxide levels fluctuated throughout the first month, and these differences were attributed to the differences in timing of occlusal loading in each group [22,23]. Recently, Bielemann et al. 2018[10] attempted to differentiate the immunoinflammatory behavior between CL and IML during osseointegration through a randomized clinical trial with MO retained by NDI, and observed that a more exacerbated inflammatory response occurred in IML group involving 2 pro-inflammatory markers (TNF-α, and IL-1β) and 1 anti-inflammatory marker (IL-10) [10]. These results may indicate that IML is associated with a continuous, accentuated process of bone remodeling due to the mechanical stress generated around the implants, at least in the initial period until 12 weeks after implant installation [10].

In addition to the differences related to bone bed responses, the choice of occlusal loading type is also directly related to the patients' subjective perception after loading the implant-retained MO [7,24,25]. Oral health-related quality of life (OHRQoL) has been shown to improve faster when a IML protocol is adopted, and the increase in the satisfaction, stability, and retention of the prosthesis is perceived immediately after conversion of a complete denture (CD) to a MO [7,24]. The OHRQoL is best used in conjunction with objective tests, such as the masticatory function test, are equally important to a more complete prognosis of oral rehabilitation. However, there are currently few studies that compared the masticatory function achieved with the CL and IML protocol through objective tests during rehabilitation with MO retained by 2 implants. One prospective study by Giannakopoulos et al. 2017[26] investigated the evolution of masticatory performance after the IML of MO with splinted and unsplinted

systems (Locator x Bar Dolder) and showed that after 3 months of function, the masticatory capacity of the MO wearers improved, with an increase of around 13% for masticatory performance (MP) X50 and 27% for MP X10, regardless of the retention system used [26]. Another randomized clinical study with a follow-up period of 36 months compared the masticatory performance between IML and CL groups using color-changeable chewing gum and gummy jelly. They found only one difference between CL and IML in gummy jelly test after 6 months of MO installation and loading, when the MP of the IML group was 21% higher [27].

The current literature thus highlights that both IML and CL may be used in conjunction with NDI, and that the chosen protocol may affect the prognosis of oral rehabilitation with MO. Therefore, it is necessary to evaluate the impact of different loading protocols in elderly patients with low bone availability and long time since edentulism, the population for whom NDI are most frequently indicated. At present, only 1 study evaluated the clinical behavior of the Facility-Equator implant system with different occlusal loading protocols, and only peri-implant health related outcomes and immunoinflammatory response were studied during the healing of NDI [10]. The objective of this randomized clinical trial (RCT) with 1-year follow-up l was to evaluate the influence of the occlusal loading protocols, IML and CL, when using 2 NDI as MO retainers clinically, biologically, and functionally, and through the subjective perception of the patient, and to compare the incidence of the prosthetic intercurrences in each loading protocol. The null hypothesis to be tested in this RCT is that there will be no differences between the adoption of CL and IML of NDI in MO rehabilitation for the following outcomes assessed during the first year of function: peri-implant tissue health indices, IL-1β and TNF-α cytokines concentration in the PICF, implant stability quotient, bone remodeling, masticatory function, OHRQoL, and prosthetic intercurrences.

Materials and methods

Study Design

This is a randomized, parallel, controlled clinical study with a 1-year follow-up that was performed with totally edentulous patients that were CD wearers and underwent oral rehabilitation with 2 NDI as MO retainers at the complete denture clinic in the UFPel school of dentistry between 2014–2016. The study was approved by the Ethics and Local Research Committee (Nº 69 / 2013_No 1.267.086). The study was

conducted according to the Helsinki Declaration of 2008, following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for RCTs [28]. A detailed description of this study's methodology with 3 months of follow-up can be found in Bielemann et al. 2018[10]. The study includes implant stability outcomes, peri-implant clinical health indices, cytokines in peri-implant crevicular fluid, and success/survival rates. Thus, the design of the present study and the outcomes already reported by Bielemann et al. 2018[10] will be briefly described, with a greater emphasis on the new outcomes included in the study, which are the masticatory performance test, oral health impact profile questionnaire and prosthetic intercurrences.

Inclusion criteria: totally edentulous patients wearing conventional complete dentures in both arches, clinically diagnosed with mandibular bone atrophy [29], with poor bone availability in the anterior region of the mandible, with new CD and at least 3 months of prosthesis use, that presented severely reduced stability and insufficient retention of the mandibular CD were eligible for the study. The selected patients received 2 NDI (ø=2.9 x 10mm Facility, Neodent) in the mandibular mental foramina region. The patients were randomized according to the occlusal loading protocol in a CL or IML group. During surgery, the bone type of the mandibular bone (type I or type II) was recorded by the experienced surgeon (OLCJ), the insertion torque was determined using a surgical wrench with a fixed calibration of 32 Ncm, and the primary implant stability quotient (ISQ) were recorded. Insertion torque values greater than 30 Ncm were considered adequate for immediate loading. If the primary stability required for IML was not achieved in the participants allocated to the IML group, they were moved to the CL group. Details on the randomization and surgical procedure were described by Bielemann et al. 2018[10]. The flowchart of the study is shown in Figure 1.

Outcomes

The outcome variables collected at 3, 6, and 12 months after implant installation were:

I) Peri-implant health indices: i) plaque index (PI); ii) calculus presence (CP); iii) gingival index (GI); iv) Probing depth (PD); v) bleeding on probing index (BOP);

II) Primary and secondary stability of the implant (ISQ);

III) IL-1β and TNF-α concentration in the peri-implant crevicular fluid (PICF)

Marginal bone loss (MBL) and marginal bone changes (MBC) were determined immediately after surgery and 1 year after loading of MO, respectively. The MF was evaluated through the masticatory performance test (MP) before and in the post-loading periods of the prostheses at 1, 3 and 12 months. The OHRQoL was evaluated through the OHIP-EDENT questionnaire before and in the post-loading periods of the prostheses at 3 and 12 months. During the follow-up period, the prosthetic events of prosthetic maintenance and complications were recorded.

Masticatory Performance Test

The masticatory performance test is characterized by the intermittent chewing of a test food for a given number of masticatory cycles, in this study, 40 cycles [30–32]. For the evaluation of MP, an artificial test food, the Optocal, based on condensation silicone and other materials was made [33]. A fixed portion of 3.7g, approximately 17 cubes with an edge of 0.5cm, were given to each participant and they were instructed to chew naturally the cubes for 40 masticatory cycles counted by a calibrated evaluator. After chewing, the test material was expelled on filter paper followed by rinsing with water and dried at room temperature for 7 days. The dried material passed through a sieving process, where it was agitated for 20 minutes in a set of sieves with a mesh opening decreasing from 5.6mm to 0.5mm.

The material retained in each sieve was weighed and the values added into the Rosin-Rammler equation, from which the values of the X50 were obtained, which is the theoretical sieve opening whereby 50% of the total weight of chewed material to pass and the B parameter that indicates the homogeneity of the particle size distribution [30,31]. The masticatory efficiency (ME) was obtained through the evaluation of the weight percentage of material retained in the sieves with 2.8 and 5.6 mm apertures [32].

Oral Health Impact Profile Questionnaire

The OHIP-EDENT questionnaire was developed specifically for edentulous patients to assess these patients' oral health-related quality of life in relation to prosthetic therapy [34]. This questionnaire comprises 20 questions grouped into 7 domains: functional limitation, physical pain, psychological discomfort, physical incapacity, psychological incapacity, social incapacity, and difficulty. The answers for

each question are scored as follows: 'never' (0), 'sometimes' (1) or 'almost always' (2) [34,35].

Success and survival rates

The criteria proposed by Misch et al. 2008 [36] and Papaspyridakos et al. 2012 [37] were used to evaluate implant success: no pain or tenderness during function, no implant clinical mobility, radiographic marginal bone loss <1.5 from initial surgery, and no infections, dysesthesia, or exudation. If the implants remained *in situ* but did not meet the success criteria, they were categorized into the survival group.

Statistical analysis

The data were submitted to descriptive analysis to evaluate the distribution of the data and the presence of asymmetries. The PI, CP, GI, and BOP indexes were dichotomized and the scores of 0 and 1 correspond to the absence s and scores 2 and 3 correspond to their presence. As the data presented a non-normal distribution, non-parametric tests were used. The Mann-Whitney test was used to compare the possible differences between groups for continuous variables (MBL, MBC, PD, ISQ, TNF-α, IL-1β, MP, and OHIP- EDENT scores).

The Chi-square test was used to verify the possible differences between the groups for dichotomous variables (sex, atrophy, bone type, PI, GI, CP, and BOP). The paired Wilcoxon test was used for the intragroup comparisons of the continuous variables over time, while the McNemar test was used for the dichotomous variables. The survival rate of the groups was calculated through the Kaplan-Meier survival analysis. In addition, the effect size (ES) was calculated for the OHIP-EDENT questionnaire based on the final score; and ES were classified as follows: small (0.2 ≥ ES <0.5), moderate (0.5 ≥ ES < 0.8), or large (0.8 ≥ ES) [38]. The level of significance was set at 5%. The analyses were performed using SPSS 22 software (IBM SPSS Statistics 22).

Results

The CL group consisted of 7 women and 3 men with a mean age of 67 years, mandibular time since edentulism of 22.90 years. In this group the most prevalent type of bone was type II and bone atrophy was identified in 5 patients. The IML group consisted of 5 women and 5 men with a mean age of 66.8 years and a mandibular time

since edentulism of 23.5 years. The most prevalent bone type in the IML group was bone type I, and bone atrophy was observed in 6 patients.

Table 1 presents the peri-implant health monitoring outcomes. From 3 months onwards, a significant difference between the groups was only observed for the PD outcome at 12 months ($P \leq 0.0001$), when the CL group presented a 30.8% higher PD than the IML group. The intragroup evaluation revealed a gradual and significant decrease of the PD in the CL group, stabilizing in 6 months, with an average reduction of 32% at 12 months compared to the first month. The PD in the IML group was significantly reduced at 12 months, with a mean decrease of 46% compared to the first month. The PI, CP, GI, BOP outcomes did not show significant differences between the groups between 3 and 12 months after implant installation. However, the intragroup evaluation for the CL group showed that the PI at 12 months was significantly lower than at 3 months (by 40%). The MBL and MBC were not influenced ($P > 0.05$) by the loading type, the mean MBL for the CL and IML group was 0.05 mm, while the mean MBC after 1 year was -0.05 mm for the CL group and 0.02 mm for the IML group. Significant differences in secondary stability were observed between the groups only at 3 months ($P=0.018$), when the CL group had a 6% higher ISQ. The CL intragroup analysis revealed no statistical difference between the primary ISQ and the secondary ISQ, and the mean ISQ over the 12-month follow-up period was 53.7. The mean ISQ value of the IML group increased by 10.4% between 3 and 12 months, reaching values similar to the primary ISQ at the end of the follow-up period. The mean ISQ in the IML group was 51.5.

Figure 2 shows the peri-implant inflammatory marker concentrations between 3–12 months after implant installation. TNF-α levels were 33.6% higher in the CL group at 6 months of healing ($P=0.043$; Figure 2A), and while the highest mean TNF-α concentrations were observed in the IML group at 3 and 12 months, there were no significant differences between the groups ($P> 0.05$). The IL-1β release was 15.1% higher in the IML group after 3 months (Figure 2B; $P=0.001$) and 65.2% higher after 6 months ($P=0.008$) and both groups reached similar values after 12 months.

Five out of 40 implants were lost during the 1-year follow-up period, 2 in the CL group and 3 in the IML group, resulting in a survival rate of 90% and 85%, respectively. The Kaplan-Meier survival curve is shown in Figure 3. The lost NDI were replaced by

larger diameter implants (3.5 × 9.0 mm - Titamax Cone Morse Implant - Neodent Osseointegrados, Curitiba, Brazil), which presented a 100% success rate.

Table 2 presents the results of the MP test. No significant differences were observed between the groups for any of the evaluated periods. However, a significant improvement was observed in all MP outcomes after MO installation, by around 48% for CL and by 44% for IML, with the exception of the MP X50 outcome that improved around 19% for both groups. Patients in the CL group showed a significant improvement in 3 outcomes 1 month after loading (MP X50 – P=0.047, 19%, MP B – P = 0.021, 60% and ME 2.8 - P=0.007, 42%), and in 1 outcome after 3 months (ME 2.8 – P = 0.005, 49%). At 12 months, only MP B showed no significant difference. After 1 month of loading in the IML group, only the ME 2.8 outcome improved (P=0.022, 40%), and after 12 months, only MP B showed no significant improvement.

Table 3 presents the comparison between the groups for the OHIP-EDENT questionnaire. Differences between the groups were only observed while the patients were CD wearers in the physical pain, physical disability, handicap, and global score domains. After MO loading these differences disappeared. In the CL group, functional limitation (P=0.023) and global score (P=0.07) were significantly improved from the baseline at 3 months. After 12 months, the functional limitation (P=0.011), physical pain (P=0.043), physical disability (P=0.039), and global score (P=0.008) were all significantly improved with respect to the baseline. In the IML group, the functional limitation (P=0.019), physical pain (P=0.011), physical disability (P=0.011), psychological disability (P=0.046), and global score (0.008) were all significantly improved compared to the baseline. These differences were maintained after 12 months: functional limitation (P=0.017), physical pain (P=0.008), physical disability P=0.019, psychological disability (P=0.046), and global score (P=0.011). The IML group presented the largest effect size in most domains, with exception of the psychological discomfort domain.

Table 4 shows the distribution of the prosthetic complications and maintenance events that occurred in the first year of MO loading and the number of patients that presented these complications in both groups. In the CL group, 49 events were recorded, 33 (67%) were related to prosthetic complications and 16 (33%) were related to prosthesis maintenance. Of the most frequent events, 22% occurred due to adjustments of the prosthesis, 16% to the Equator dislodgment, 10% were related to the nylon O-ring replacement, and 10% to tissue reopening for abutment replacement.

In the IML group, 35 events were observed, 23 (66%) were related to prosthetic complications and 12 (34%) were related to prosthesis maintenance. Of these intercurrences, 20% involved adjustment of the prosthesis, 23% were related to recapturing of the female part, and 14% to the nylon O-ring replacement.

Discussion

This 1-year randomized clinical trial with in a sample of patients with high time since edentulism time and low bone availability showed that both loading protocols (IML and CL) are a viable option for treatment with MO retained by two unsplinted implants. The reported survival rates were similar for both protocols used, with a difference of only 5% (1 implant). However, each protocol generates a particular biological behavior at the receptor bone site, as well as a different performance in terms of functional and self-reported OHRQoL parameters, both of which tend to equalize after one year of occlusal loading of the implants. Nonetheless, the null hypothesis was rejected because differences between the loading protocols could be observed in terms of the peri-implant health outcome PD after 12 months, secondary stability at 3 months, and the concentration of pro-inflammatory cytokines in the PICF up to 6 months after the implants insertion.

Clinical Findings

Among the peri-implant health indexes, only the PD presented a significant difference between groups after 12-months of follow-up. The PD was 30.8% higher in the CL group, indicating that IML provided a better conditioning to the peri-implant tissues. It is suggested that PD can be affected by the time of loading in this sample of patients, because the IML group experienced 3 months more occlusal loading than the CL group at 12 months after implant installation. However, a longer follow-up time is necessary to confirm these findings. The study by Bellia et al. 2018[39], which uses NDI as MO retainers and adopts an IML protocol, shows comparable PD results after one year of implant installation. These authors observed that 76% of the implants had a PD of 1 mm at the end of the follow-up period [39]. In our study the mean PD in the same period was 1.5 mm. The PD difference between the groups was already reported in the study by Bielemann et al. 2018[10] at 2, 4, 8, and 12 weeks after implant installation [10]. This study confirmed that this behavior is maintained for 1 year of follow-up. However, it is important to note that both loading protocols presented excellent peri-

implant soft tissue healing, since the other peri-implant health monitoring indexes decreased during the follow-up time, demonstrating excellent biological sealing around the peri-implant bone tissue [1,40,41].

In our study, the osseointegration of the implants in the IML group was affected by the occlusal load up to 3 months after implant implantation, as significantly lower secondary stability values were observed for this group during this period. The application of mechanical loading causes stress and tension on the bone, this process can produce a positive anabolic stimulus or a catabolic negative stimulus on the bone tissue [42]. Micromovements between the implant and the host tissues may also compromise osseointegration. However, if transmission of forces between the implant and adjacent tissues is satisfactory, the applied mechanical load can stimulate peri-implant bone formation and therefore osseointegration [42]. At 12 months there was no significant difference in the secondary stability of the implants between the groups. These ISQ results are similar to those of Elsyad et al. 2014[43], who observed a significant decrease in ISQ in the IML group compared to the CL group in a patient sample of MO wearers 6 months after the implant installation, whereas differences between groups were not observed at 12 months [43]. Silva et al. 2012[44] also observed that the ISQ of implants submitted to IML as MO retainers was smaller at 3 months compared to baseline, however, the mean ISQ values increased to six points above the baseline values after 15 months [44]. The IML-specific process of bone remodeling can thus delay the secondary stability of the implant, however, after mineralization, bone tends to stabilize by the formation of dense bone or, by the trabecular bone, becoming similar to CL in 12 months after implant installation [14,43–45].

Although the evaluated clinical outcomes indicated differences between CL and IML group at various stages, the final survival rate of both groups was similar, and the MBL and MBC outcomes were statistically identical in both groups. These findings are in accordance with the results described in the systematic review by Helmy et al 2018[13] that evaluated 8 randomized clinical trials and found no significant difference between IML and CL protocols in terms of implant failure and MBL [13]. In the present study, the small sample size of each group, so the difference of only 1 implant most lost in the IML group resulted in a 5% difference in survival rate of the groups. Although predictability of IML based on implant success rates is indicated by several previous studies, these studies do not take into account factors that may influence the

osseointegration process such as implant diameter and sample-related characteristics such as time since edentulism, age, systemic diseases, and bone availability [39,46,47].

Immuno-inflammatory profile

The IML protocol is known to promote an accelerated, more intense release of bone mediators around the implants already in the first days after implant installation (Güncü et al., 2008; Güncü et al., 2009), and can be maintained until 6 months after loading [17]. In the present study a more exacerbated release of TNF-α and IL-1β in the IML group was observed. This is consistent with other studies which showed an increased release of bone response mediators during the 3 months of osseointegration, and a gradual decrease after 6 and 12 months [22,23]. Because this intensified process was not observed in the CL group, these researchers suggested that IML directly impacts the bone metabolism, generating a continuous and accentuated process of bone remodeling due to the mechanical stress to which the alveolar bone is submitted [22,23]. These pro-inflammatory cytokines have been described as synergistic contributors to various events that are essential for the initiation of an inflammatory response, such as stimulating molecule adhesion and chemokine expression, stimulating the production of inflammatory mediators, and enhancing and stimulating formation and the activity of osteoclasts, which can lead to tissue destruction [48]. In the present study, TNF-α release was 15.1% higher in the CL group 6 months post-installation, and this is probably related to having the prosthesis in function 3 months less than the IML group. In this period of early functioning, bone remodeling occurs in response to the mechanical loading. Simultaneously, IL-1β release was much higher (by 65.2%) in the IML group, although we can infer that these this cytokine did not cause tissue destruction but only a remodeling around the implants, as the MBL and MBC showed no difference between the groups.

The cytokine data in conjunction with the ISQ data indicate that IML makes the osseointegration process less predictable in elderly patients with low bone availability and long time since edentulism, as the release of pro-inflammatory cytokines was higher up to 6 months and the secondary stability was significantly lower up to 3 months after implant installation. This imbalance observed in the patients who received the IML may lead to an increased risk of implant failure. This probably occurs because the bone resorption is more active than bone neoformation [14,15]. Thus, it is believed that when this profile of patients receive an IML is required a relatively longer time to

establish osseointegration, because only at 6 months was observed a stabilization of ISQ values for this group.

Functional outcomes and patient-centered outcomes

For objective functional evaluation of masticatory function, no significant differences were observed between groups (Table 2), however, IML may need a longer time to reach the same masticatory function as CL. This is evidenced by observing the intragroup results, after one month of MO loading this group presented a significant difference in relation to the baseline only in the outcome ME 2.8 (improvement of 40%), and only in 12 months the other outcomes were improved in relation to the baseline (MP X50 = 28%, ME 2.8 = 54%, ME 5.6 = 64%), with the exception of MP B. For the CL group, significant improvement was observed in 3 outcomes after 1-month (MP X50 = 19%, MP B = 60%, ME 2.8 = 42%), for ME 2.8 at 3 months (49%), and improvement for all outcomes at 12 months of loading except for MP B (MP X50 = 23%, ME 2.8 = 51%, ME 5.6 = 60%). This differentiated performance in the evolution of MF for both groups may have occurred due to the patients experiencing pain and discomfort in the first weeks after surgery and assuming an insecure behavior in the execution of the masticatory cycles [24]. The results observed in the present study are similar with the findings of Giannakopoulos et al. 2017[26], however, the authors only evaluated the evolution of MP with the Optocal test food from 15 masticatory cycles in a group of patients who underwent IML. It was observed in the study that there was a significant difference in relation to the baseline for the MP X50 outcome after three months of implant installation, with no differences in evaluation after 72 hours of prostheses occlusal loading [26]. The values of MP X50 found by the authors in 3 months of loading were 4.19, in our study in this period we obtained an average MP X50 of 4.23, however in 12 months MP X50 was 3.62, representing an improvement of 28% in relation to the baseline.

The subjective outcomes of the OHRQoL evaluation were also similar in both groups after MO loading. However, the intra-group behavior in relation to some domains of the OHIP-EDENT questionnaire is different for each loading protocol. In the IML group at 3 months, patients reported better OHRQoL in the physical pain, physical disability, and psychological disability domains in comparison to the baseline. In the CL group, the physical pain and physical disability domains were significantly improved in relation to the baseline only at 12 months. The physical pain domain

consists of questions about how the patient feels the relationship between the base of the prosthesis with the mucosa and supporting tissues, the presence of painful spots, and discomfort when eating [34]. Since CL patients use a healing abutment in the first 3 months of healing and adaptation of the mucosa is necessary during the exchange of the prosthetic abutments, it is possible that this process may have generated greater discomfort in this period. The IML group also performed better in the physical disability domain at 3 months, which is focused on questions related to masticatory capacity [34]. Although the patients perceive that these domains are improved in 3 months, the objective masticatory performance test only shows significant improvement after 12 months. Other studies also evidence the fast improvement of OHRQoL that IML provides to the patients, sometimes even within two weeks after implant installation when this outcome is accessed by the OHIP-20 questionnaire and compared to the baseline [24,25,49].

The global OHRQoL score improved at 3 months after prostheses loading for both groups, yet the mean difference with the baseline score was 12.48 points in the IML group compared to 6 points in the CL group. The study conducted by Omura et al. 2016[7] presented similar results, but the authors observed a significant difference in the global score of the CL and IML groups at 1 and 3 months [7]. The authors stated that the most probable cause for this difference is the fact that the IML group had the prosthesis attached since the implant installation, while the CL group had to wait 3 months [7]. Omura et al. 2016[7] also reported no significant difference in the global score between the periods after implants insertion and the baseline [7]. In our study, no significant difference between baseline and post-loading periods was observed in any of the groups for the psychological discomfort, social disability, and handicap domains. This likely occurred because the patients already presented satisfactory OHRQoL at baseline.

Complications and Prosthetic Maintenance

CD wearers who undergo rehabilitation with MO through the IML protocol quickly perceive the benefits of treatment by the increasing of retention, stability, and satisfaction with the prostheses [24]. However, a prospective clinical study with MO retained by two implants and a bar-type system Attard et al. 2006[50], through a prospective clinical study with MO retained by to two implants and a bar-type system, showed that when costs with both loads, CL and IML are assessed, it is observed that

the IML protocol generates more total costs and that this is due to the differences observed for the costs of prosthetic maintenance between treatments [50]. However, the authors highlight that even with the initial extra costs associated with IML, these are justified by the better patient's quality of life in relation to CL [50]. In the present study, it was observed that IML can influence the type and number of complications and maintenance events of the prosthesis, and even with the clinical inconveniences generated by the IML, such as postoperative swelling, the use of the Facility-Equator system in the IML group presented 30% less intercurrences of prosthetic complications and 25% less complications of prosthetic maintenance events. This shows that the adaptation of the peri-implant tissues around the implant and prosthetic abutment observed in this group generates a specific profile of prosthetic behavior that is different from the CL, and that the type of prosthetic intercurrences observed is dependent on occlusal loading protocol.

The most frequent prosthetic complications in the CL group are directly related to a lower adaptation of the prosthetic component with peri-implant tissue which may have caused the higher frequency of abutment dislodgement followed by the need for tissue reopening to replace the abutment. Furthermore, this can be confirmed by the observation that these were the least frequent events for IML group. These findings are in agreement with the study of Attard et al. 2010[51], that although the authors performed an early loading protocol in which the loading was done 8.06 ± 3.67 days after the implant installation, it was observed that prosthetic maintenance events were mainly related to the acrylic structure of the base of the mandibular prosthesis [51]. Then it is believed that the more conservative CL approach makes it impairs the peri-implant soft tissue remodeling, and that after the healing period of the tissues it may be necessary MO relining procedures or to change the height of the prosthetic abutment[51].

However, we observed that the intercurrences of prosthetic maintenance of the present study, such as the adjustment of the prosthesis base and the need to change the nylon O-ring, were similar in both groups. Adjustments of the prosthesis base and occlusal adjustment are common during the first year of MO loading, and are considered routine procedures in the follow-up of oral rehabilitation [52]. In addition, studies have shown that the nylon retainer used in button-type abutments, such as the one in the present study, shows a significant wear over time and chewing is the main cause of loss of rubber retention [53,54].

Possible limitations of the present study are due to the effect that randomization generates in the division of groups, because this procedure does not take into account the individual variations of patients related to OHRQoL, which was evidenced in the baseline when the groups presented significant differences as CD wearers in some domains of the OHIP-EDENT questionnaire. In addition, studies with good design, controlled and with longer follow-up times are necessary to elucidate clinical, biological and functional behavior and the subjective perception of the patient against the treatment with NDI as MO retainers.

Conclusion

The IML of two non-splinted NDI used as MO retainers was associated with a better adaptation of the peri-implant tissues around the prosthetic abutments, which reflected a lower probing depth and fewer prosthetic intercurrences when this loading was compared to the CL in the 1-year follow-up period. The TNF-α and IL-1β cytokine expression and secondary stability were also affected by the loading protocol but tended to equalize 1 year after implant installation.

The improvement in MF and OHRQoL was observed regardless of the loading protocol used. However, patients in the IML group took a longer time to achieve a masticatory performance similar to the CL group, while IML patients perceived the OHRQoL improvement more quickly. The two loading protocols for NDI are thus both viable options for oral rehabilitation with MO. They present similar survival rates, even for patients with advanced age, long time since edentulism, and low mandibular bone availability.

ACKNOWLEDGMENTS

The authors thank to Neodent's Research Support Program for supplying the dental implants and attachments used in the study. This study was conducted in a Graduate Program supported by CAPES, Brazil.

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Table 1. Comparisons of peri-implant health and bone change outcomes between groups. Asterisks (*) indicate significant differences between the groups (Mann-Whitney, p <0.05), lowercase letters indicate significant differences at evaluation times within the CL group and uppercase letters indicate differences within the IML group (Wilcoxon Paired, p < 0.05).

	Baseline		3 months		6 months		12 months	
	CL	IML	CL	IML	CL	IML	CL	IML
% Presence								
PI			60 a	30 A	40 ac	20 A	20 bc	20 A
CP			0 a	0 A	0 a	0 A	0 a	0 A
GI			10 a	0 A	0 a	0 A	0 a	0 A
BOP			10 a	0 A	0 a	5 A	0 a	0 A
Median(range)								
MBL	0(-0.61;0.78) a	0(-0.82;0.71) A					0(-1.08;1.06) a	0(-0.85;0.75) A
MBC							0(-1.08;1.06)	0(-0.85;0.75)
ISQ	55.5(44.0;62.5) a	55.0(46.5;59.75) A	57.0(43.0;62.25) *a	50.63(36.5;57.0) *A	54.25(42.0;62.0) a	50.5(45.0;58.0) A	53.88(44.0;66.75) a	56.5(48.0;60.75) A
PD			2.63(1.63;4.88) *a	1.94(1.0;3.25) *A	2.13(1.5;4.88) b	2.13(1.0;2.75) A	2.19(1.5;2.88) *b	1.38(1.0;2.13) *B

Table 2. Comparisons between masticatory performance outcomes of each group: median (minimum; maximum). Different letters indicate intragroup differences over time. Lowercase letters indicate significant differences at evaluation times within the CL group and uppercase letters indicate differences within the IML group (Wilcoxon Paired, $p < 0.05$).

	MP_X50	MPB	ME 5.6 (%)	ME 2.8 (%)
CL				
Baseline	5.49(2.86;6.30) a	4.51(1.99;49.36) a	44.57(3.45;83.3) a	9.51(0.0;25.10) a
1 month	3.65(2.11;6.35) b	2.89(1.81;8.51) b	10,92(0.0;73.79) ab	20.83(2.65;33.78) b
3 months	4.22(2.34;6.94) ab	2.91(2.54;17.35) ab	20.38(0.0;94.91) ab	24.20(1.58;36.34) b
12 months	3.70(2.47;5.83) b	3.02(1.79;9.32) ab	11.82(0.0;59.04) b	28.38(1.39;35.88) b
IML				
Baseline	5,04(3.67;5.95) A	3.42(2.23;18.04) A	37.69(5.72;78.16) A	10.73(0.0;33.21) A
1 month	4.39(3.42;6.10) AB	3.19(2.35;6.16) A	23.00(4.13;66.13) AB	21.87(3.11;30.47) BC
3 months	4.23(2.74;5.48) AB	2.98(2.42;3.81) A	24.63(0.0;53.49) AB	27.35(10.21;31.89) AC
12 months	3.31(2.47;5.21) B	2.71(2.52;3.35) A	6.83(0.0;44.97) B	29.83(15.99;36.40) BC

Table 3. Comparisons between the OHIP-EDENT questionnaire domain scores of each group: median (minimum; maximum)/Effect size. Asterisks (*) indicate significant differences between the groups (Mann-Whitney, $p < 0.05$), lowercase letters indicate significant differences at evaluation times within the CL group and uppercase letters indicate differences within the IML group. Effect Size (ES) values refer to the comparison between baseline and the periods of 3 and 12 months (Wilcoxon paired, $p < 0.05$).

	Baseline		3 months		12 months	
	CL	IML	CL	IML	CL	IML
Global	5.0(0.0;24.0) a	18.5(6.0;26.0) *A	1.0(0.0;19.0) b	1.0(0.0;18.0) B	1.0(0.0;5.0) b	1.0(0.0;22.0) B
ES:			0.7	1.7	0.9	1.8
Functional limitation	2.5(0.0;5.0) a	3.5(1.0;6.0) A	1.0(0.0;4.0) b	1.0(0.0;4.0) B	0.5(0.0;2.0) b	1.0(0.0;6.0) B
ES:			0.9	1.3	1.2	1.2
Physical pain	2.5(0.0;8.0) a	6.0(2.0;8.0) *A	0.0(0.0;7.0) ab	0.0(0.0;6.0) B	0.0(0.0;2.0) b	0.0(0.0;4.0) B
ES:			0.7	2.1	0.8	2.5
Psychological discomfort	0.0(0.0;3.0) a	0.5(0.0;4.0) A	0.0(0.0;2.0) a	0.0(0.0;2.0) A	0.0(0.0;0.0) a	0.0(0.0;1.0) A
ES:			0.2	0.7	0.4	0.7
Physical disability	1.0(0.0;3.0) a	4.0(0.0;5.0) *A	0.0(0.0;4.0) ab	0.0(0.0;3.0) B	0.0(0.0;1.0) b	0.0(0.0;5.0) B
ES			0.6	1.8	0.8	1.8
Psychological disability	0.0(0.0;2.0) a	1.0(0.0;2.0) A	0.0(0.0;1.0) a	0.0(0.0;2.0) B	0.0(0.0;1.0) a	0.0(0.0;2.0) B
ES			0.5	1.3	0.5	1.3
Social disability	0.0(0.0;3.0) a	0.0(0.0;2.0) A	0.0(0.0;1.0) a	0.0(0.0;1.0) A	0.0(0.0;0.0) a	0.0(0.0;0.0) A
ES			0.2	0.6	0.3	0.8
Handicap	0.0(0.0;1.0) a	1.5(0.0;3.0) *A	0.0(0.0;0.0) a	0.0(0.0;3.0) A	0.0(0.0;0.0) a	0.0(0.0;4.0) A
ES			0.5	1.1	0.5	1.0

Table 4. Type, number of events, and number of patients who presented the events during the first year of occlusal loading in the CL and IML groups.

Complications	CL			IML		
	N (patients)	N (events)	%	N (patients)	N (events)	%
Healing abutment dislodgement	2	2	4	0	0	0
Equator dislodgement	2	8	16	0	0	0
Matrix (Female) dislodgement	0	0	0	1	1	3
Prosthesis fracture	1	1	2	2	2	6
New overdenture	3	3	6	1	1	3
Equator change (Transmucosal larger/smaller)	1	1	2	2	3	9
Matrix (Female) recapture	3	3	6	6	8	23
Teeth fracture	1	3	6	1	1	3
Matrix (Female) change	3	3	6	2	3	9
Tissue reopening for abutment replacement	2	5	10	0	0	0
Vestibular deepening surgery	0	0	0	1	1	3
Removal of keratinized mucosa	1	1	2	1	1	3
Prosthesis rebase	2	3	6	2	2	6
Total		33			23	
Maintenance						
Prosthesis adjustment	7	11	22	4	7	20
Nylon O-ring replacement	4	5	10	5	5	14
Total		16			12	

Figure 1. CONSORT Flow Diagram.

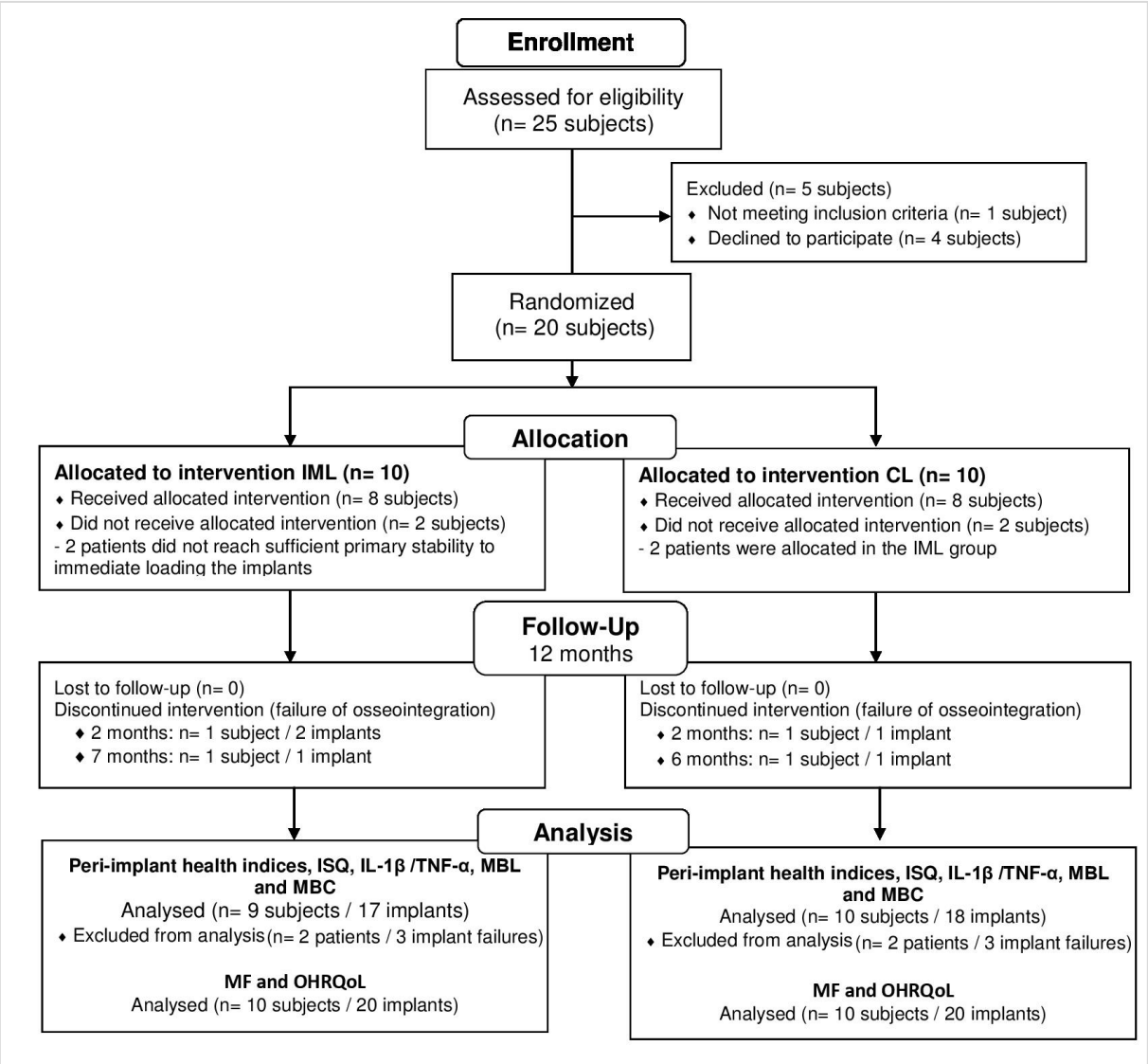


Figure 2. Box plots show and compare the cytokine release in both groups. A) TNF-α; B) IL-1β. Asterisks (*) indicate significant differences between the groups (Mann-Whitney, $p < 0.05$). Lowercase letters indicate significant differences at different evaluation times within the CL group and uppercase letters indicate this for the IML group. (Wilcoxon Paired, $p < 0.05$).

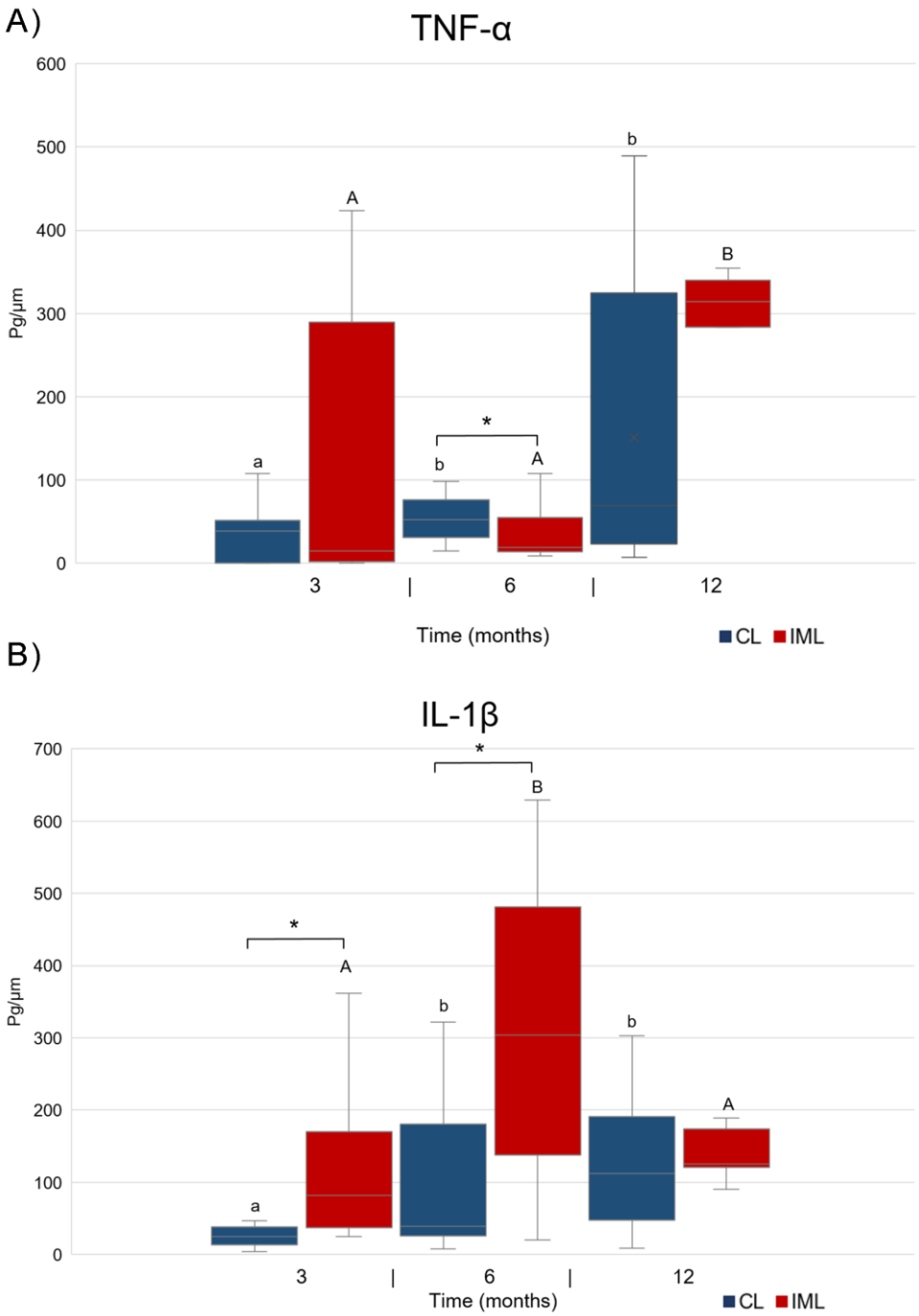
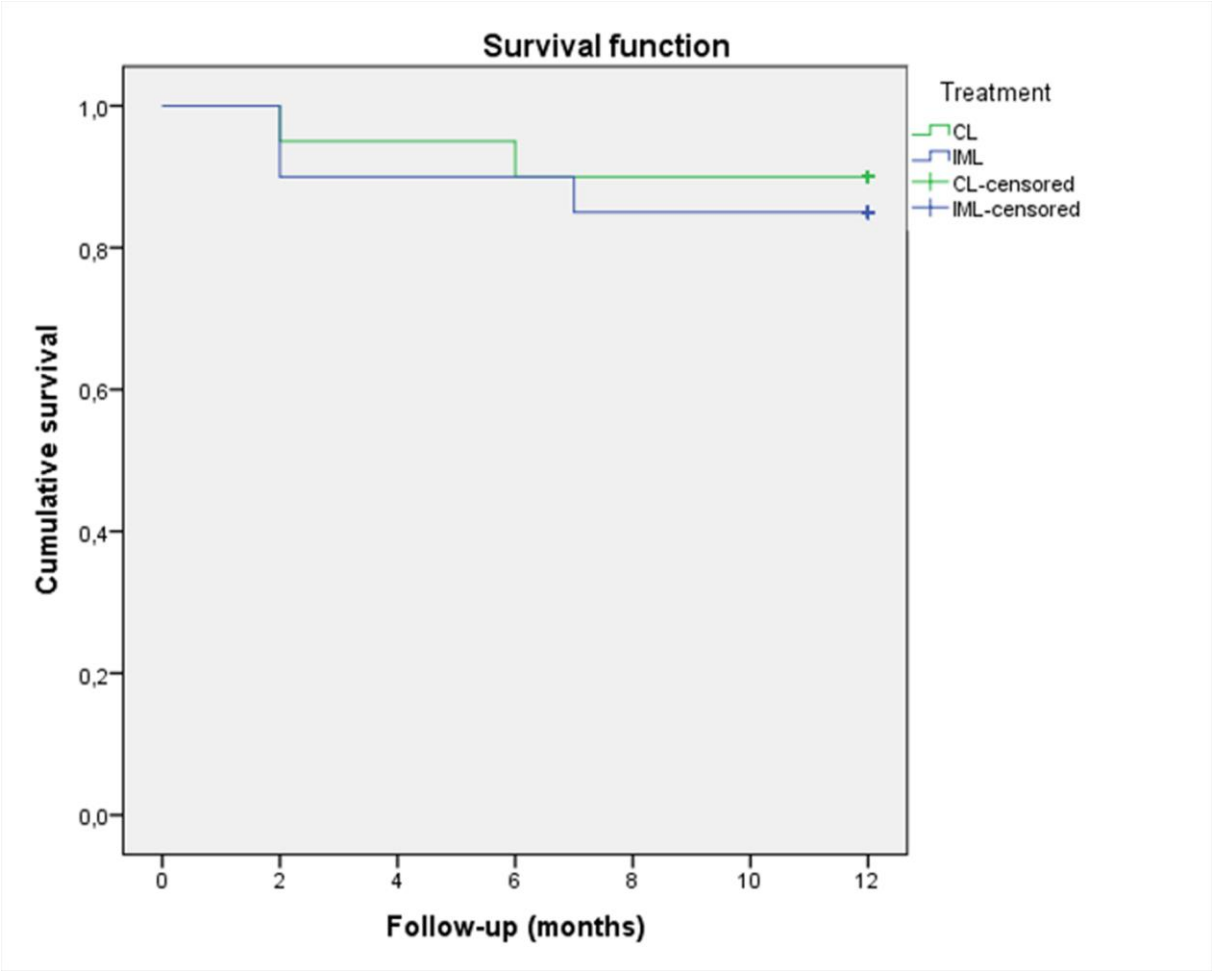


Figure 3. Kaplan-Meier survival curve for the NDI implants in the CL and IML groups during the 1-year follow-up period.



5 Capítulo 4

Facility-Equator system as a mandibular overdenture retainer: Quality of life assessment and prosthetic complications in a 2-year follow-up study[§]

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Running title: Facility-Equator system prosthetic complications

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

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

Keywords: Overdentures; Edentulous; Quality of life; Complications; Narrow implants

[§]Artigo formatado segundo as normas do periódico Journal of Oral Rehabilitation

Abstract

Background: Considering that is available a wide range of mandibular overdentures (MO) retainers' systems, it is necessary to understand how the prosthetics events can affect the oral health related quality of life (OHRQoL).

Objectives: This longitudinal study aimed i) to assess the performance of the Facility-Equator system as MO retainers from a prosthetic perspective during 2 years of loading and ii) to investigate whether prosthetic events can affect the OHRQoL.

Methods: Twenty-four patients reported their OHRQoL via the GOHAI and OHIP-EDENT questionnaires before MO loading and after 1 and 2 years of usage. Prosthetic occurrences were recorded during this period. The data were analysed with Wilcoxon test, the Mann-Whitney test and Spearman correlation.

Results: All domains of the GOHAI and OHIP-EDENT questionnaires exhibited a significant difference ($p < 0.05$) between baseline evaluations and after 1 and 2 years, except for the social inability and psychological discomfort domain of OHIP-EDENT after 1 year. Of the 127 prosthetic events in the first year, 14.17% were related to the loosening of the equator attachment, 16.5% to prosthesis adjustments, and 11.8% to O-ring replacement. In the second year, 87 prosthetic occurrences were observed, 27.6% of which were related to prosthesis adjustments, 20.7% to O-ring replacement, and 11.5% to recapturing the female matrix.

Conclusions: Complications related to prosthetic maintenance, such as fracturing of the prosthesis, loosening of the equator attachment, prosthesis relining and new overdenture, all affect the OHRQoL, primarily the physical pain and discomfort domains with greater significance in the first year of MO loading.

Introduction

Rehabilitative treatment with implant-retained mandibular overdentures (MO) is widely recognized as an effective prosthetic modality regarding biological, functional, and clinical behavior and by the positive impact on satisfaction and oral health related quality of life (OHRQoL) of edentulous patients, especially in patients with mandibular atrophy [1–3]. Since 2002, from the McGill Consensus, it is recommended that MO retained by 2 implants should be the minimum treatment in the rehabilitation of edentulous mandibles [4]. However, with the increased longevity of complete removable dental prosthesis (CRDP) wearers and the continuous resorption of the residual ridge, the main anatomical modification that restricts the MO treatment is the reduction of alveolar bone volume that is prominent in the anterior region [5]. This condition contraindicates the installation of conventional diameter implants; however, for such clinical situations, narrow diameter implants (NDI) have been used with clinical and functional success, regardless of the degree of mandibular atrophy [2,6,7]. Moreover, according to El-Sheikh et al (2012), the installation of more than 2 NDIs as MO retainers in the rehabilitation of atrophic mandibles is not necessary, since patients rehabilitated with 2 and 3 NDI at two-year follow-up had no significant differences in clinical parameters (survival rate, plaque index and calculus, gingival index, bleeding on probing, and probing depth) and radiographic parameters (marginal bone loss) [8].

Several types of attachment systems available on the market have been used to promote the retention of the MO to the implant, providing better functional stabilization. These attachments are divided into 2 major categories: splinted ones, such as the bar type, and non-splinted ones, such as the ball type, magnet and stud [9]. The Facility-Equator system (dental implant and abutment) is a new NDI system available to be used as an MO retainer with a morse connection and a five-degree angulation that is based on friction retention (Facility dental implant) and includes a screwless stud type attachment system (Equator abutment) (Figure 1). This type of abutment has a similar retention mechanism as Locator systems, but its retention to the implant is made by friction and activated using a hammer [1,2].

Studies show that according to the abutment system used, the prosthodontic maintenance and prosthodontic complications observed in MO

treatment may vary, however, the patient's satisfaction level and quality of life, as well as the survival rates of the implants, are not affected by the selected abutment [10–12]. Cakarer et al (2011) observed a lower number of prosthodontic complications and maintenance needs for the Locator system compared to the ball and bar abutment [13]. In contrast, Kleis et al (2010) observed that the Locator system shows pronounced deterioration of nylon parts, thus having a higher rate of prosthodontic maintenance compared to the ball-type abutment [14]. Several factors, including repeated insertion and removal movements of the MO, cyclic loading on the denture and the oral environment, and material-related factors, such as composition, design, dimension and retention model, can contribute to wear of the abutment system; however, the exact mechanism involved in the wear of the different attachment systems is not thoroughly understood to date [15].

The prosthodontic maintenance involved in MO treatment has a significant impact on the clinical and laboratorial costs of this treatment, and early information of the maintenance needs is essential to treatment success and to avoid unexpected events and situations between the dental surgeon and patient. [16,17]. Thus, due to the large variety of available systems, several studies present comparisons between the attachment systems, but there is limited information regarding the prosthodontic maintenance that can occur when these systems are used as MO retainers in atrophic mandibles. Moreover, because the Facility-Equator system is relatively new in the market, little is known regarding its long-term behavior, especially regarding possible prosthetic occurrences, as well as whether these occurrences may influence the OHRQoL. Thus, the objective of the present study was to evaluate the performance of the Equator abutment as an MO retainer through the prosthodontic perspective in 2 years of loading and to investigate if the prosthodontics events can affect the oral OHRQoL.

Material and Methods

This longitudinal clinical study with 2 years of follow-up was conducted in the Complete Denture Clinic at the School of Dentistry/Federal University of Pelotas (UFPel). The study design was approved by the by the Ethics Committee in Local Search for Clinical Research (UFPel, Approval number: 69/2013) and was conducted in accordance with the Helsinki Declaration, 2008. The study followed the Strengthening the Reporting of Observational Studies in

Epidemiology guidelines (STROBE). Edentulous patients rehabilitated with new CRDP in the 6 months prior to the study, who reported difficulties in oral function after the prosthetic adaptation period were invited to participate in the research and to install an MO retained by two NDI (Facility-Equator system). This implant system is composed of grade V titanium alloy (Facility NeoPoros surface - Neodent® - Curitiba, PR, Brazil) with a diameter of 2.9 mm and a length of 10 mm. The rehabilitation consisted of installing two NDI in the inter-foraminal region of the jaw, and the CRDP was transformed into an MO. Informed consent was obtained from all individual participants included in the study.

To participate in the research, the following inclusion criteria should be fulfilled by the patients: to be new CRDP wearers for at least 3 months, to have difficulty adapting to the mandibular prosthesis due to lack of retention and stability, to be patients for whom rehabilitation with conventional diameter implants is not indicated due to limitations in bone residual ridge thickness, to be available to attend at the clinic on evaluation days and to be in good general health.

After the adaptation period of the CRDP, preoperative radiological evaluations (panoramic radiographs in combination with lateral cephalograms) were performed for surgical planning. To evaluate the oral health-related quality of life (OHRQoL), each individual answered the oral health self-perceived oral health - Geriatric Oral Health Assessment Index (GOHAI) and the quality of life questionnaire - Oral Health Impact Profile Questionnaire (OHIP-EDENT) as described in the studies of Schuster et al (2017) and Marcello-Machado et al (2017) [1,18]. After the questionnaire was administered, an experienced surgeon performed the installation of two NDI and healing abutments in the inter-foraminal region of the mandible, followed by lower denture relining. The healing abutments were maintained for a period of three months when prosthetic components with a button type fitting (Equator - Neodent) were installed for the MO loading.

Annual periodic follow-ups at one and two years after MO loading were prospectively scheduled for oral cavity examination and OHRQoL evaluation. Medical histories and prosthodontic events related to prosthodontic maintenance or complications that occurred throughout this period were recorded and reviewed at the end of the study. Thus, the following data were analyzed: prosthodontic complications related to component dislodgement (loss of the

healing abutment, equator or female part - matrix), fracture of the mandibular prosthesis, confection of new overdenture, replacement of the equator abutment by the need to adjust the height of the transmucosal (major or minor), artificial tooth fracture, replacement of the female part, tissue reopening for component replacement, vestibular deepening surgery and excision of peri-implant keratinized mucosa, and need for prosthesis relining. Events related to the prosthesis prosthodontic maintenance, such as pink O-ring exchange and prosthesis adjustments, were also recorded.

Statistical analysis was performed in the SPSS 22 software (IBM SPSS Statistics 22), and significant difference was defined to be $p < 0.05$. The data were submitted to descriptive analysis to evaluate the distribution of normality and asymmetry. As the data from the OHRQoL questionnaires had a non-normal distribution, non-parametric tests were used. For comparisons over time of each domain of the OHIP-EDENT and GOHAI questionnaires, the paired Wilcoxon test was used. To evaluate the possible influences of the prosthetic events in each period (one year and two years after loading) in relation to the domains of the questionnaires, the Mann-Whitney test was used for the events that had a minimum of 4 cases in one of the evaluation periods. Spearman's correlation was used to verify a possible correlation between the events that had a minimum of 4 cases in one of the evaluation periods.

Results

The sample consisted of 24 participants with a mean age of 68.1 years; 17 women with mean mandibular and maxillary edentulism ages of 28.44 and 31.88 years, respectively; and 7 men with mean mandibular and maxillary edentulism ages of 16.14 and 27.71 years, respectively. After the first year of follow-up, 1 patient was lost, and the sample consisted of 23 participants. Table 1 shows the distribution of the prosthodontic events (complications and maintenance) observed in the first and second years of MO loading and the number of patients who had such occurrences. In the first year, 127 events were recorded, 91 (71.75%) related to prosthodontic complications and 36 (28.35%) prosthodontic maintenance. Of the most incident events, 14.17% occurred due to equatorial dislodgement, 16.54% to prosthesis adjustments and 11.81% to nylon retainer (O-rings) exchange. The least incident complications in the period were the need

for vestibular deepening surgery (0.79%), matrix (female) dislodgement (0.79%) and new overdenture confection (2.36%). In the second year, 87 events were observed, 45 (51.7%) related to prosthodontic complications and 42 (48.3%) due to prosthodontic maintenance. Of the events, 27.59% were due to the need for prosthesis adjustment, 20.69% to nylon retainer (O-rings) exchange and 11.49% to the need for female part recapture. The less frequent complications in this period were tissue reopening for abutment replacement (1.15%), removal of peri-implant keratinized mucosa (1.15%) and female part dislodgement (1.15%).

Table 2 shows the means and standard deviations of the two questionnaires' (OHIP-EDENT and GOHAI) domains before and after 1 year and after 2 years of MO loading. It was observed that most of the domains of both OHRQoL questionnaires had significant differences ($p < 0.05$) comparing the baseline and MO post-loading periods, except for the social inability and psychological discomfort domains of the OHIP-EDENT, which only showed a significant reduction after the first year. Significant differences ($p < 0.05$) were not observed between 1- and 2-year assessments for any domain of both questionnaires.

Tables 3 and 4 show the result of the Spearman correlation between the questionnaires and the prosthodontics maintenance and complications events. For the GOHAI questionnaire, a positive correlation was observed between the Equator dislodgement and the Physical ($R = 0.415$ $P = 0.044$) and Pain and discomfort ($R = 0.495$ $P = 0.014$) domains, and a positive correlation was seen between prosthesis fracture and the Psychosocial ($R = 0.424$ $P = 0.039$) domain in 1 year of MO loading (Table 2). A positive correlation between prosthesis relining and the Pain and discomfort domain ($R = 0.772$ $P < 0.001$) and Global score ($R = 0.635$ $P = 0.001$) were observed in 2 years of MO loading (Table 2). For the OHIP-EDENT questionnaire, a negative correlation was observed between the Equator dislodgement and the Physical pain domain ($R = -0.470$ $P = 0.020$), and a negative correlation was observed between prosthesis fracture and physical pain ($R = -0.583$ $P = 0.003$) and Handicap ($R = -0.466$ $P = 0.022$) domains in 1 year of loading (Table 3). In 2 years of loading, a negative correlation was observed between the confection of new overdenture and global score ($R = -0.447$ $P = 0.033$) (Table 3).

Figure 2 shows the influence of the presence or absence of events in relation to each domain of the OHIP-EDENT and GOHAI questionnaires. The fracture of the prosthesis had influence in the first year of MO loading in the psychosocial domain of the GOHAI questionnaire and in the handicap and pain and discomfort domains of the OHIP-EDENT questionnaire because a significant difference was found when patients were categorized by the presence or absence of this prosthetic complication. The Equator dislodgement also had a negative influence in the first year of MO loading on the physical domain of the GOHAI questionnaire and the physical pain domain of the OHIP-EDENT questionnaire. The prosthesis rebase requirement had a negative influence in the second year of loading in the pain and discomfort domain and in the global GOHAI questionnaire score. The confection of a new overdenture also had a negative influence on the global score of the OHIP-EDENT questionnaire in the second year of MO loading.

Discussion

The complications resulting from the treatment with dental implants can be classified into two categories: biological and technical (mechanical) complications. The latter category refers to mechanical damages that may affect the functioning of the implant and the prosthetic components that surround the implant [19]. In rehabilitation with MO, the management of prosthodontic maintenances and complications resulting from this treatment is an unavoidable reality in clinical practice [17]. For the abutment systems, it is observed that factors related to material composition, design, size and type of retention mechanism can influence the prosthetic characteristics of the different attachments systems [15]. In the present study, we verified that the prosthetic behavior of the Facility implant system and the Equator abutment retained by a friction mechanism can generate a greater number of prosthetic occurrences related to prosthodontic complications and maintenances in the first year of MO loading compared to the second year, and certain of these complications may affect patients' OHRQoL. These findings suggest that the OHRQoL is influenced by the prosthetic events that make it impossible to wear and retain the prosthesis, such as Equator's dislodgement and prosthesis fracture with consequent new overdenture confection, and by the complications that are capable of causing pain to the

support tissues, such as maladaptation of the prosthesis and the need for prosthesis relining. However, these complications are inherent to any type of non-splinted attachment system, and the Equator is a good option for treatment as an MO retainer.

Studies show that regardless of the attachment type used as a retainer, it is in the first year of MO loading that the greatest number of appointments are observed due to prosthesis adjustments and maintenance needs [16,20]. There is currently no consensus as to which prosthetic occurrences in MO treatment are considered normal prosthesis maintenance events and which are considered treatment complications, however Payne et al (2001) defined that normal maintenance would be when a maximum of two activations, repairs or replacements of the patrix or matrix occur in the first year and, at most, five occurrences and one rebase of the overdenture base in a five-year period of MO treatment [21]. However, when these events become repetitive and a burden in relation to the number of occurrences, chair or laboratory time, or when they are unexpected, they should be classified as complications [17,21].

In this sense, in our study we observed that the occurrence of events related to prosthetic needs was 31.49% higher in the first year compared to the second. This reduction in events observed in the second year occurred due to a decrease in the number of events that we considered as prosthetic complications, since we observed a 14.28% increase in the events related to the maintenance of the prosthesis in this period (O-ring change and prosthesis adjustment). During the first and second years, the most prevalent prosthetic occurrences (16.54% and 27.59%, respectively) were due to the need for adjustments in the prosthesis, including 1.6 adjustments per patient who had the event in the first year (13 patients) and 3 adjustments per patient in the second year (8 patients). We observed in our sample that the need for adjustment of the inferior prosthesis in the second year was recurrent in some individuals. Therefore, we suggested that individual characteristics, such as advanced resorption of the residual ridge from prolonged duration of edentulism and contact of the prosthesis base with flaccid tissues in the area, can lead to mucosal injury even with the use of MO, thereby necessitating frequent adjustments of the mandibular prosthesis base. Payne et al., 2001 affirms that adjustments of the prosthesis base and occlusal adjustment are common during the first year of MO treatment, and for the simplicity of its

resolution through the principles of conventional CRDP treatment, are considered routine procedures in the follow-up of oral rehabilitation [21]. MacEntte et al., 2005 also observed in a study that compared ball-clip and ball attachments that the adjustments of the prosthesis base were the most frequent occurrences observed in the first year of MO loading for both abutments [20]. Chaffe et al., 2002 observed that the mean time until the first adjustment of the prosthesis base for ball-type abutments was 89.5 days, and the mean number of adjustments per patient in their study was 1.49 in the follow-up time of 36 months [22]. We observed that the number of adjustments of the prosthesis base per patient who had this event was 2.81 at the follow-up of 2 years.

The second most prevalent event observed in the first year after MO loading (14.17%) was the abutment Equator dislodgement. This high number of occurrences (18 events) was probably due to the formation of a large amount of highly keratinized and resistant mucosa observed around the implants. After implant insertion, the soft tissues adjacent to the bone tissue undergo an adaptation process to promote the seal of the mucosa around the implant and prosthetic abutment [23]. Thus, it is suggested that this period of adaptation of the mucosa with the formation of keratinized mucosa may have influenced the recurrent loss of prosthesis retention by the Equator abutment expulsion and dislodgement in the first year of follow-up. Moreover, this attachment system is retained by a pure friction-activated mechanism (hammer), not by internal threads as seen in other systems for conventional-diameter implants, which may contribute to the recurring falls. However, in the second year, this event occurred in only 2 patients, thus showing the adaptation of the mucosa and stabilization of the abutment.

The need for replacement of the matrix nylon O-ring was the third most observed prosthetic occurrence in the first year (11.81%) and the second most observed occurrence in the second year (20.69%). Studies have shown that the nylon retainer used in button-type abutments shows significant wear over time [14]. In the *in vitro* study by Jo et al (2015), wear on the Locator's nylon rubber was significant in comparison to the O-ring retainer for the fatigue test with evident deformation in the center of the rubber, and this result was attributed to the differences in design and type of fit between the two systems [24]. In addition, the Abi Nader et al (2011) *in vitro* study observed that mastication reduced the

Locator rubber retention by 40% with only several alterations, such as a light degree of wear, on matrix internal surfaces of the ball type retainer [25]. Finally, the significant decrease in the retention values of the Locator rubber was also attributed to the insertion and removal movements of the prosthesis over time, as observed by Evtimovska et al (2009) in 20 consecutive pulls using a universal testing machine [25,26]. The randomized clinical trial performed by Kleis et al (2010) reported that the Locator system in MO and implants with conventional diameter showed a higher rate of prosthetic maintenance than ball-type abutments, and 75.5% of Locator rubber retainers lost retention after 1 year due to rubber wear, which was the primary reason for their replacement [14]. These data are different from those found in the present study, since we observed that 31.25% of the nylon rings lost their retention in the first year and 39.13% in the second year, and 10% of the change needs in the second year was for nylon rings that already had been changed in the first year. We also observed that five patients did not require any nylon ring replacement, so, 79% of patients had to perform at least 1 rubber exchange in two years of follow-up. Therefore, we can suggest that although the Locator and Equator systems are both button type attachments, the observed wear among the systems seems to be different, but comparative studies are necessary to clarify the potential of deformation when they are used.

The wear of the Equator nylon ring may also be related to the third prosthetic event with higher prevalence (11.49%) observed in the second year of MO loading, the need for recapture of the female part (matrix). As already suggested by Jo et al (2015), when button-type connectors are used, the load applied on them is relieved by the resilient nylon matrix, by the connection to the top of the abutment and by the deformation of the prosthesis base [24]. Thus, we believe that the dissipation of the load exerted on the MO during speech and masticatory movements is also capable of causing deformation of the prosthesis base and distortion of the acrylic resin adjacent to the matrix, altering the fit position of the matrix to the abutment, and thus causing the need to recapture the matrix.

Regarding OHRQoL, we observed that all domains of both questionnaires showed significant differences ($p < 0.05$) when comparing the baseline and the MO post-loading assessments of the 1-year and 2-year, except for the social incapacity domain and psychological discomfort of the OHIP-EDENT, which only

showed a difference after the first year of loading. These results agree with other studies that show that after the installation of MO, the patients satisfaction and OHRQoL increase significantly and remain increased over time regardless of the type of attachment system used [14,20,27]. In the evaluation of the influence of prosthetic events on OHRQoL, we observed that some maintenance events and prosthodontics complications can affect the patients' OHRQoL during the first and second year post-loading when the Facility-Equator system is used, since all correlations found in the Spearman correlation were confirmed by the Mann-Whitney test (Table 3, Table 4 and Figure 2)

We also observed that the occurrences that could affect the OHRQoL during the first year are related to the impossibility of the inferior prosthesis retention to the abutment due to the Equator's dislodgement and MO fracture. The Equator's fall for both the GOHAI and OHIP-EDENT questionnaire affected domains related to painful mouth sensation, inability to chew and swallow food comfortably and discomfort when the prosthesis is in function. The MO fracture resulted in patient dissatisfaction with the treatment and in social discomfort, since they felt uncomfortable being with other people as well as eating in front of others. Mundt et al (2015) observed that, in a sample of 144 overdentures installed on mini-implants (diameter 1.8 mm) and ball-type attachments over a 4-year follow-up period, the need for the prosthesis base repair due to fracture occurred in about one in five patients, and thus these authors recommend the use of metal structures as reinforcement in the prosthesis [28]. In contrast, in our study, we believe that mandibular prosthesis fracture probably occurs because of the reduced thickness of the inferior prosthesis flange provided by mandibular arch morphology and topography altered by the advanced resorption of the residual ridge, since the patients have prolonged durations of edentulism. In addition, it is highlighted that conventional CRDPs were converted into MO; thus, they had the design and biomechanics aimed at retention, stability and support of a muco-supported prosthesis, and this property, in association with the diameter of the internal connector (matrix of 4.5 mm diameter and 2 mm in height), may contribute to a greater fragility of the MO as already proposed by other authors [29].

In the second year of MO loading, the need for mandibular prosthesis rebase and the confection of a new overdenture affected the patients' OHRQoL.

The domain of the GOHAI questionnaire affected by the need for rebase was the pain and discomfort domain, which refers to the occurrence of a painful sensation during chewing and to the need for analgesics for pain relief. Attard et al (2005) reported that laboratory rebase was required every four years for MO retained by conventional diameter implants [30]. However, in our study, we observed that in two years of follow-up, 13 patients had their prosthesis rebased, of whom 4 patients had 2 events and 1 patient 3 events. This condition demonstrates that the process of bone remodeling has a large variability among edentulous individuals. Thus, implant placement may promote changes in the bone and peri-implant soft tissues that make the rebase necessary to optimize the prosthesis adjustment and refine the acrylic denture base [31].

As limitations of the present study, we can cite the absence of a control group; however, most of the attachments available in the market for rehabilitation with MO over NDI are composed of a single piece, which makes it impossible to compare the Equator system, which is composed of 2 pieces (implant and abutment). Another limitation is the use of only the pink nylon rubber. The manufacturer offers nylon rings in different colors with different degrees of retention, pink and violet; however, we only opted for the pink rubber. A larger sample size and a longer follow-up period may also provide more consistent results on the Facility-Equator system.

Conclusion

Implant mandibular overdentures retained by 2 NDI and Equator type abutments significantly improve the OHRQoL; however, the first year of treatment is characterized by a greater number of prosthetic events; therefore, more attention should be given to follow-up appointments in this period. The complications related to prosthetic complications - prosthesis fracture, component fall, prosthesis rebase and confection of new overdenture - observed for rehabilitations with Equator abutments can affect the OHRQoL, primarily in the physical and pain domains and with greater discomfort in the first year of MO loading.

ACKNOWLEDGMENTS

The authors thank to Neodent for supplying the dental implants and attachments used in the study. This study was conducted in a Graduate Program supported by CAPES, Brazil. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Table 1. Type, number of events and number of patients who had the events during the first and second years of occlusal loading.

Complications	During first year (n=24)			During second year (n=23)		
	N (patients)	N (events)	%	N (patients)	N (events)	%
Healing abutment dislodgement	4	7	5.51	-	-	-
Equator dislodgement	6	18	14.17	2	3	3.45
Matrix (Female) dislodgment	1	1	0.79	1	1	1.15
Prosthesis fracture	4	4	3.15	4	4	4.60
New overdenture	3	3	2.36	8	8	9.20
Equator change (Transmucosal bigger/smaller)	3	6	4.72	2	2	2.30
Matrix (Female) recapture	9	14	11.02	8	10	11.49
Teeth fracture	2	6	4.72	3	3	3.45
Matrix (Female) change	5	5	3.94	2	2	2.30
Tissue reopening for abutment replacement	4	10	7.87	1	1	1.15
Vestibular deepening surgery	1	1	0.79	1	1	1.15
Removal of keratinized mucosa	6	8	6.30	1	1	1.15
Prosthesis rebase	8	9	7.10	6	9	10.34
Total		91			45	
Maintenance						
Prosthesis adjustment	13	21	16.54	8	24	27.59
Nylon O-ring change	13	15	11.81	13	18	20.69
Total		36			42	

Table 2. Means and standard deviations of the two questionnaires' (OHIP-EDENT and GOHAI) domains before, after 1 year and after 2 years of MO loading. (Wilcoxon Paired Test, p <0.05).

	Baseline (n=24)	1 year (n=24)	2 years (n=23)	P-value baseline – 1year	P-value baseline – 2years	P-value 1year – 2years
OHIP-EDENT						
Global	11.13±7.43	2.42±2.67	2.04±3.13	≤0.0001	≤0.0001	0.149
Functional Limitation	3.43±1.81	0.96±0.91	0.96±1.3	≤0.0001	≤0.0001	0.745
Physical pain	3.52±2.3	0.75±1.07	0.48±1.12	≤0.0001	≤0.0001	0.228
Psychological discomfort	0.87±1.24	0.21±0.66	0.17±0.49	0.050	0.022	0.854
Physical disability	1.78±1.5	0.25±0.53	0.35±0.65	≤0.0001	0.001	0.317
Psychological disability	0.61±0.78	0.08±0.28	0.04±0.21	0.006	0.004	0.317
Social disability	0.52±0.88	0.13±0.34	0±0	0.064	0.016	0.083
Handicap	0.52±0.88	0.04±0.2	0±0	0.015	0.016	0.317
GOHAI						
Global	27.54±2.6	29.58±0.88	29.39±1.03	0.001	0.002	0.667
Physical	8.42±1.47	9.79±0.41	9.78±0.52	≤0.0001	0.001	1
Psychosocial	11.54±1.56	12.88±0.34	13.0±0.0	0.001	0.001	0.083
Pain and discomfort	7.58±0.88	6.92±0.5	6.83±0.39	0.002	0.001	0.414

Table 3. Spearman correlation between the GOHAI questionnaire domains and prosthetic events in 1 and 2 years of MO loading.

		1 Year				2 Years			
GOHAI		Physical	Psychosocial	Pain and discomfort	Global	Physical	Psychosocial	Pain and discomfort	Global
Healing abutment dislodgement	R=	0.235	-0.119	0.091	0.212	-	-	-	-
	P=	0.268	0.350	0.673	0.319	-	-	-	-
Equator dislodgement	R=	0.415	0.073	0.495	0.374	-0.141	-	-0.142	-0.220
	P=	0.044	0.736	0.014	0.072	0.521	-	0.519	0.313
Prosthesis fracture	R=	0.300	0.424	0.161	-0.166	0.131	-	-0.211	-0.061
	P=	0.155	0.039	0.451	0.590	0.551	-	0.335	0.781
New overdenture	R=	-0.217	-0.169	-0.102	-0.196	0.167	-	0.147	0.268
	P=	0.309	0.431	0.634	0.359	0.446	-	0.504	0.216
Matrix (Female) recapture	R=	0.026	0.228	0.213	0.156	-0.334	-	0.279	0.189
	P=	0.902	0.285	0.317	0.466	0.119	-	0.197	0.388
Matrix (Female) change	R=	-0.069	-0.229	0.056	-0.035	-0.141	-	0.565	0.041
	P=	0.150	0.282	0.797	0.869	0.521	-	0.221	0.852
Prosthesis rebase	R=	0.178	-0.089	0.144	0.206	-0.023	-	0.772	0.635
	P=	0.406	0.680	0.503	0.334	0.918	-	0.000	0.001
Prosthesis adjustment	R=	0.60	0.95	0.159	0123	-0.104	-	-0.094	-0.238
	P=	0.780	0.659	0.457	0.568	0.636	-	0.669	0.274
Nylon O-ring change	R=	0.060	0.348	-0.175	0.000	-0.080	-	-0.292	-0.078
	P=	0.780	0.096	0.412	1.000	0.716	-	0.177	1.000

Table 4. Spearman correlation between the OHIP-EDENT questionnaire domains and prosthetic events in 1 and 2 years of MO loading.

		1 Year								2 Years							
OHIP-EDENT		Functional Limitation	Physical pain	Psychological discomfort	Physical disability	Psychological disability	Social disability	Handicap	Global	Functional Limitation	Physical pain	Psychological discomfort	Physical disability	Psychological disability	Social disability	Handicap	Global
Healing abutment dislodgement	R=	0.247	-0.245	0.199	0.228	0.135	-0.169	-	0.033								
	P=	0.244	0.248	0.350	0.283	0.530	0.430	-	0.878								
Equator dislodgement	R=	-0.272	-0.470	-0.060	-0.206	-0.174	-0.364	0.120	-0.398	-0.103	0.181	0.119	-0.136	0.066	-	-	-0.038
	P=	0.199	0.020	0.779	0.333	0.416	0.081	0.575	0.054	0.639	0.407	0.588	0.536	0.765	-	-	0.864
Prosthesis fracture	R=	-0.282	-0.583	-0.155	-0.091	0.135	-0.169	-0.466	-0.380	-0.086	-0.202	0.177	-0.270	0.098	-	-	-0.103
	P=	0.183	0.003	0.471	0.671	0.530	0.430	0.022	0.067	0.695	0.355	0.418	0.213	0.657	-	-	0.640
New overdenture	R=	0.269	-0.147	0.169	0.193	0.114	0.143	-	0.037	-0.412	-0.367	0.024	-0.376	-0.292	-	-	-0.447
	P=	0.203	0.492	0.431	0.366	0.596	0.505	-	0.863	0.051	0.085	0.915	0.077	0.176	-	-	0.033
Equator change	R=	0.078	-0.171	0.229	0.262	0.155	-0.116	-	-0.053								
	P=	0.716	0.423	0.282	0.216	0.471	0.588	-	0.806								
Matrix (Female) recapture	R=	0.072	0.186	-0.238	0.149	-0.078	-0.228	0.234	0.006	0.252	-0.197	-0.270	0.188	0.156	-	-	0.156
	P=	0.738	0.385	0.263	0.486	0.718	0.285	0.272	0.977	0.246	0.368	0.212	0.391	0.478	-	-	0.476
Matrix (Female) change	R=	0.078	-0.171	0.229	0.262	0.155	-0.116	-	-0.053	-0.155	-0.242	-0.378	-0.227	0.066	-	-	-0.138
	P=	0.716	0.423	0.282	0.216	0.471	0.588	-	0.806	0.481	0.266	0.076	0.298	0.765	-	-	0.529
Prosthesis rebase	R=	0.142	0.126	-0.138	-0.099	-0.107	0.000	-	0.163	-0.066	-0.330	-0.370	0.087	0.127	-	-	-0.145
	P=	0.509	0.559	0.520	0.644	0.620	1.000	-	0.445	0.764	0.124	0.082	0.692	0.565	-	-	0.508
Prosthesis adjustment	R=	0.172	-0.189	-0.158	-0.273	0.025	0.158	-	0.031	0.122	0.241	0.024	0.242	0.156	-	-	0.186
	P=	0.421	0.377	0.460	0.1960	0.907	0.461	-	0.886	0.579	0.267	0.915	0.267	0.478	-	-	0.395
Nylon O-ring change	R=	-0.332	-0.150	-0.347	-0.077	0.025	-0.348	-0.192	-0.290	0.374	0.086	-0.056	0.309	-0.187	-	-	0.265
	P=	0.130	0.485	0.097	0.721	0.907	0.096	0.369	0.169	0.079	0.697	0.798	0.151	0.393	-	-	0.222

Figure 1. Facility-Equator attachment system

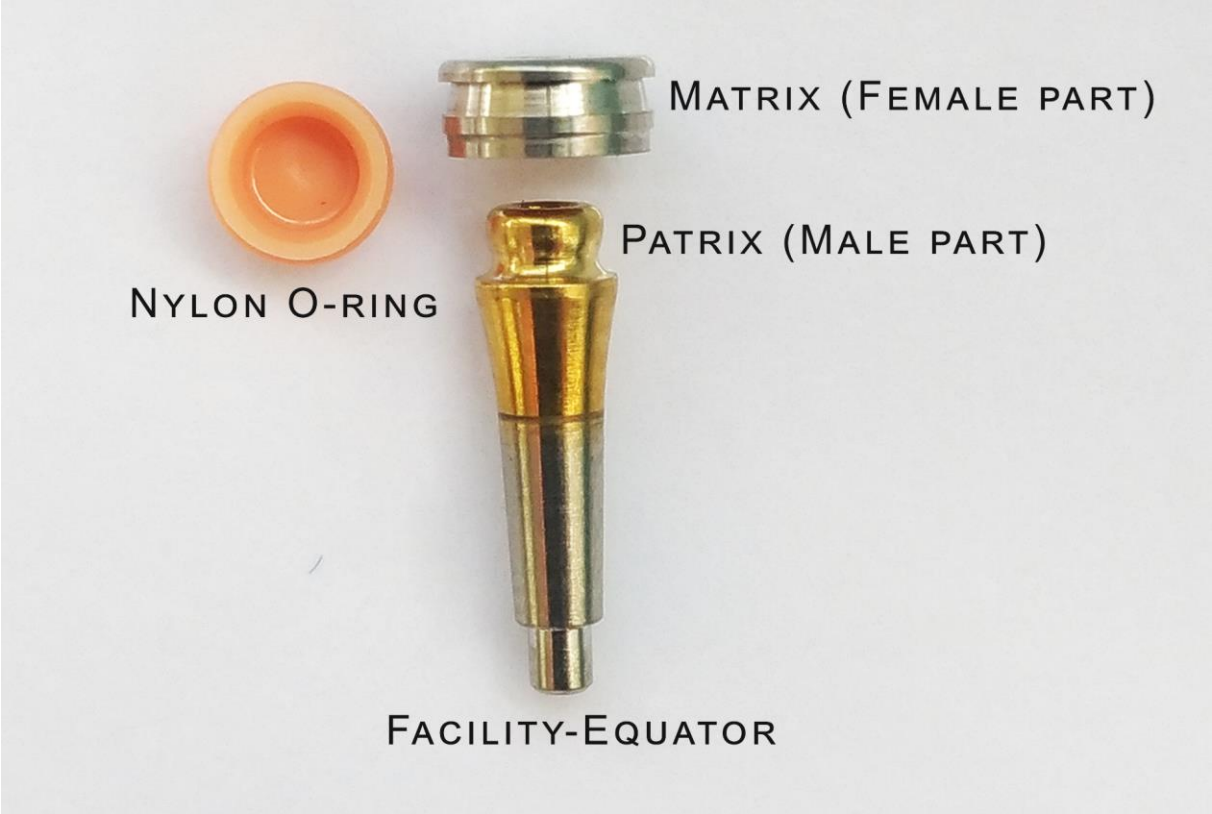

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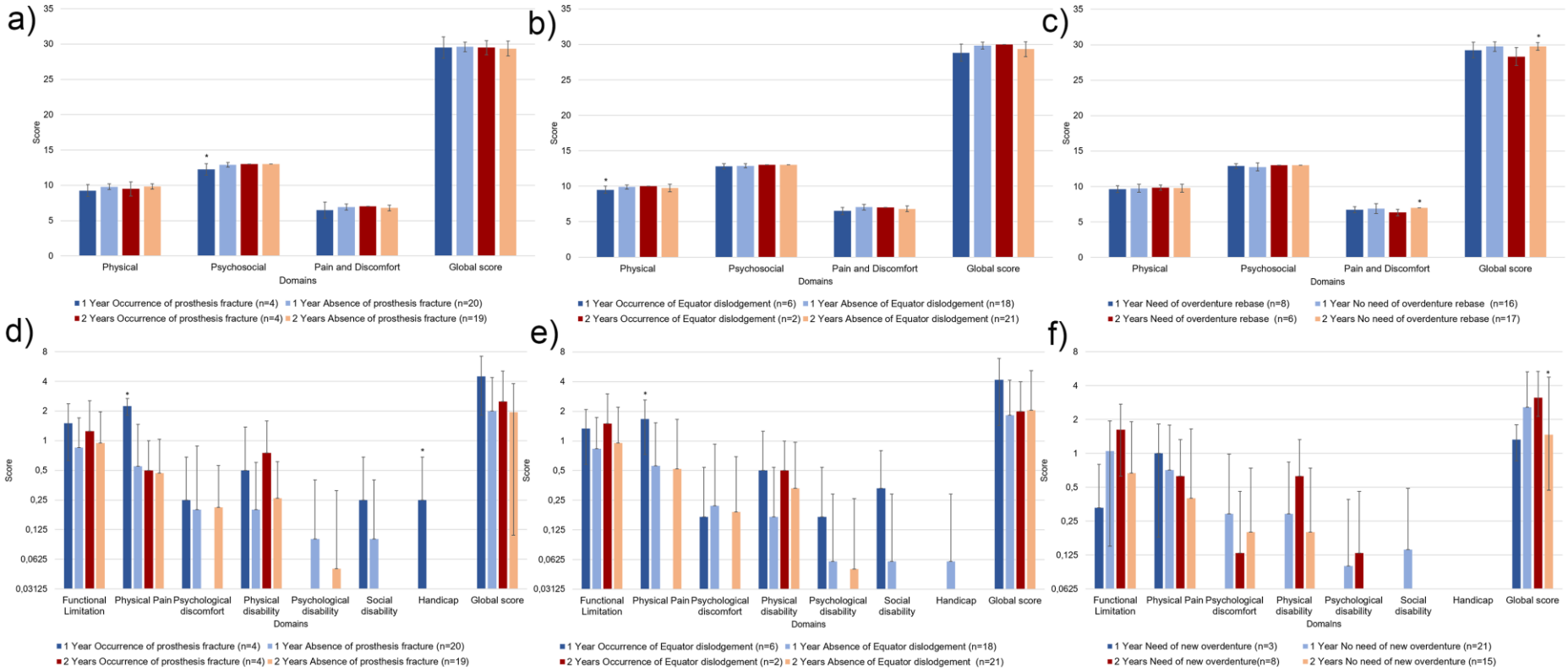
Figure 2. Influence of prosthetic events on the domains of the OHIP-EDENT and GOHAI questionnaires that had significant differences (Mann-Whitney Test. p <0.05); a) GOHAI – Prosthesis fracture; b) GOHAI – Equator dislodgement; c) GOHAI - Prosthesis rebase; d) OHIP-EDENT – Prosthesis fracture; e) OHIP-EDENT – Equator dislodgement; f) OHIP-EDENT – New overdenture



6 Conclusões Gerais

De acordo com os desfechos dos estudos desenvolvidos nesta tese torna-se evidente os inúmeros benefícios que as OM proporcionam a pacientes edêntulos que apresentam baixa disponibilidade óssea e assim, limitadas opções de tratamentos protéticos. As vantagens do uso de OM em relação à PT não se limitam a melhoria da qualidade de vida relacionada a saúde oral, mas também abrangem o reestabelecimento parcial da FM e eliminam diferenças intrínsecas dos pacientes como idade e tempo de edentulismo, caracteristicas que afetam o uso de próteses totais.

Respeitadando as limitações dos artigos elaborados, é possível observar que o estudo I concluiu que a QVRSB de usuários de PT foi significativamente melhorada já após 3 meses de tratamento com OM, especialmente em relação aos domínios dos questionários que englobam aspectos funcionais e relacionados à dor com o uso das próteses. No estudo clínico II é observado que a idade e tempo de edentulismo não influenciaram a FM de pacientes usuários de OM após 1 ano da instalação das próteses. No entanto, a OM melhorou significativamente a FM de todos os pacientes, sendo esta melhora mais evidente em pacientes mais jovens (≤65 anos) e com menor tempo de edentulismo mandibular (<25 anos). Já a QVRSB foi influenciada apenas pela idade e tempo de edentulismo em usuários de PT, sendo que o tratamento com OM eliminou essas diferenças. Os resultados do ensaio clinico randomizado do artigo III evidenciaram que o CI gera uma melhor adaptação dos tecidos periimplantes ao redor dos componentes protéticos, o que pode refletir em uma menor profundidade de sondagem e menor número de intercorrências protéticas. Diferença significativa entre CC e CI foi observada para o desfecho IPS aos 12 meses, e para a concentração de TNF-α e IL-1β em 6 meses de cicatrização. E ainda, a melhoria na FM e na QVRSB foi observada independentemente do tipo de carregamento utilizado. Por fim, os resultados do artigo IV revelam que as complicações relacionadas à manutenção protética, como fratura da prótese, soltura do componente Equator, necessidade de reembasamento de prótese e confecção de nova overdenture mandibular afetaram a

QVRSB dos pacientes, principalmente nos domínios dor física e desconforto, tendo maior significância no primeiro ano de uso das OM. Além disso, todos os domínios dos questionários GOHAI e OHIP-EDENT apresentaram diferença significativa entre as avaliações iniciais e após 1 e 2 anos do carregamento das próteses, exceto para o domínio de incapacidade social e desconforto psicológico do questionário OHIP-EDENT após 1 ano.

Dessa forma evidenciamos que a QVRSB é significativamente melhorada já em 3 meses após a instalação de OM retidas por 2 IDR em uma população com baixa disponibilidade óssea na região anterior da mandíbula, sendo independentemente da idade, tempo de edentulismo dos pacientes e do tipo de carregamento oclusal utilizado. No entanto, os eventos de complicações protéticas advindas deste tratamento podem afetar a QVRSB dos pacientes até 2 anos após o carregamento das próteses. Sugere-se ainda, que o uso do sistema Facility-Equator como pilar protético de OM implanto-suportadas por 2 implantes é uma opção previsível de tratamento para ser utilizado em pacientes que apresentam o perfil da amostra avaliada no presente estudo. Porém, atenção especial deve ser dada as consultas de acompanhamento após o carregamento das próteses, principalmento no primeiro ano. Pois, neste período ocorre a maior necessidade de monitoramento dos eventos de complicações e ajustes das próteses, bem como particularidades especificas de intercorrências protéticas de acordo com o tipo de carregamento oclusal empregado.

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Apêndices

Apêndice A – Nota da Tese

Nota da Tese

Indicadores de qualidade de vida relacionada a saúde bucal (QVRSB) e sua relação com fatores clínicos e funcionais em usuários de overdentures mandibulares reabilitados com o sistema Facility-Equator.

Oral Health related quality of life (OHRQoL) indicators and its relation with clinical and functional factors in mandibular overdentures wearears rehabilitated with the Facility-Equator system

A presente tese avaliou a influência da reabilitação oral de pacientes edêntulos com overdentures mandibulares (OM) e da qualidade de vida relacionada a saúde oral proporcionada por este tratamento em aspectos como idade, tempo de edentulismo mandibular, tipos de carregamento oclusal (convencional ou imediato), desfechos de função mastigatória e ainda, o perfil e influência das intercorrências protéticas desta abordagem terapêutica por até 2 anos de acompanhamento. A pobre disponibilidade óssea mandibular, alto tempo de edentulismo e idade avançada, muitas vezes observada em pacientes edêntulos, dificulta a realização de procedimentos cirúrgicos extensos. Sendo assim, devido aos benefícios que este tratamento proporciona, a utilização de implantes com diâmetro reduzido para reter próteses do tipo OM são a melhor opção para se evitar o sobretratamento com próteses totais. A metodologia do presente estudo se deu pela instalação de 2 implantes de diâmetro reduzido (2.9 mm) na região interformanes mentuais na mandíbula dos pacientes. O sistema Facility-Equator, considerado minimamente invasivo, foi utilizado nos 4 estudos clínicos e consiste em um implante de diâmetro reduzido com conexão morse e um componente do tipo botão. A interface protética é livre de parafuso e ativada por um mecanismo de batida com o auxílio de um martele. Os desfechos avaliados foram obtidos pelo emprego dos questionários OHIP-EDENT, DIDL e GOHAI; testes objetivos de função mastigatória; monitoramento da saúde periimplantar e osseointegração ao redor dos implantes. A análise dos dados permitiu observar que a qualidade de vida relacionada a saúde bucal é melhorada já após 3 meses da instalação das OM, sendo independentemente da idade, tempo de edentulismo dos pacientes e do tipo de carregamento oclusal utilizado. No entanto, os eventos de complicações protéticas advindas deste tratamento podem afetar a qualidade de vida relacionada a saúde oral dos pacientes até 2 anos após o carregamento das próteses.

Campo da pesquisa: Prótese Dentária

Candidato: Alessandra Juliê Schuster, Farmacêutica Generalista pela Universidade Federal de Santa Maria (2014)

Data da defesa e horário: 22/02/2019 às 9 horas

Local: Auditório do Programa de Pós-graduação em Odontologia da Universidade Federal de Pelotas. 5º andar da Faculdade de Odontologia de Pelotas. Rua Gonçalves Chaves, 457.

Membros da banca: Prof. Dra. Natália Marcumini Pola, Prof. Dra. Raissa Micaella Marcello Machado, Prof. Dra. Luciana de Rezende Pinto, Dra. Amália Machado Bielemann (Suplente), Prof. Dr. Otacílio Luis Chagas Júnior (Suplente)

Orientador: Prof. Dra. Fernanda Faot

Informação de contato: Alessandra Juliê Schuster, alejschuster@gmail.com. Rua Gonçalves Chaves, 457- Programa de Pós-Graduação em Odontologia

Apêndice B – Súmula do currículo do candidato

Alessandra Juliê Schuster, nasceu em 23 de outubro de 1991, em Santa Rosa, Rio Grande do Sul (RS). Completou o ensino fundamental e médio em Escola particular na cidade de Santa Rosa, RS. No ano de 2009, ingressou na Faculdade de Farmacologia da Universidade Federal de Santa Maria, tendo sido graduada farmacêutica generalista em 2014. Iniciou o curso de graduação em Odontologia pela Universidade Federal de Pelotas em 2014, onde atualmente realiza doutorado com orientação da Profª. Drª. Fernanda Faot. Desenvolve pesquisas relacionadas à reabilitação de pacientes edentulos que passaram pela reabilitação oral com overdentures mandibulares e estudos pré-clinicos com o uso de animais para a avaliação da osseointegração ao redor de implantes dentários. Apresenta experiência em odontologia baseada em evidência, tendo foco em estudos pré-clínicos e ensaios clínicos.

Publicações:

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Anexos

Anexo A - Parecer do Comitê de Ética

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
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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

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FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

Continuação do Parecer: 1.267.086

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
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Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

Anexo B - Questionários de avaliação da QVRSB

QUESTIONÁRIO OHIP - EDENT

- Você sentiu dificuldade para mastigar algum alimento devido a problemas com seus dentes, boca ou dentaduras?
- Você percebeu que seus dentes ou dentaduras retinham alimento?
- Você sentiu que suas dentaduras não estavam corretamente assentadas?
- Você sentiu sua boca dolorida?
- Você sentiu desconforto ao comer devido a problemas com seus dentes, boca oudentaduras?
- Você teve pontos doloridos na sua boca?
- Suas dentaduras estavam desconfortáveis?
- Você se sentiu preocupado(a) devido a problemas dentários?
- Você se sentiu constrangido por causa de seus dentes, boca ou dentaduras?
- Você teve que evitar comer alguma coisa devido a problemas com seus dentes, boca ou dentaduras?
- Você se sentiu impossibilitado de comer com suas dentaduras devido a problemas com ela?
- Você teve que interromper suas refeições devido a problemas com seus dentes, boca ou dentadura?
- Você se sentiu perturbado(a) com problemas com seus dentes, boca ou dentaduras?
- Você esteve em alguma situação embaraçosa devido a problemas com seus dentes, boca ou dentaduras?
- Você evitou sair de casa devido a problemas com seus dentes, boca ou dentaduras?
- Você foi menos tolerante com seu cônjuge ou família devido a problemas com seus dentes, boca ou dentaduras?
- Você esteve um pouco irritado(a) com outras pessoas devido a problemas com seus dente, boca ou dentaduras?
- Você foi incapaz de aproveitar totalmente a companhia de outras pessoas devido a problemas com seus dentes, boca ou dentaduras?
- Você sentiu que a vida em geral foi menos satisfatória devido a problemas com seus dentes, boca ou dentaduras?
- Você já sentiu vergonha, timidez ou incômodo em um momento de intimidade com seu cônjuge?

QUESTIONÁRIO DIDL

- Eu estou satisfeito com meus dentes em geral.
- Eu estou satisfeito com a aparência dos meus dentes.
- Eu estou satisfeito com a cor dos meus dentes.
- Eu estou satisfeito com a posição dos meus dentes.
- Eu sinto dor espontânea em meus dentes.
- Eu sinto dor de dente quando como ou bebo algo quente ou frio.
- Eu mudei minha alimentação por causa da dor.
- Eu sinto dor em minha articulação mandibular.
- Eu tenho preocupação com os dentes.
- Eu sofro com alimentos entre os dentes.
- Eu tenho halitose e mau hálito.
- Eu tenho dentes soltos.
- Eu não estou satisfeito com minhas gengivas
- Eu tenho sangramento gengival.
- Eu tenho sensibilidade com quente ou frio por causa da recessão gengival.
- Minha capacidade de trabalho é afetada pela aparência dos meus dentes.
- Minha capacidade de trabalho é afetada pela minha capacidade para comer e falar.
- Meu contato com as pessoas é afetado pela aparência de meus dentes.
- Meu contato com as pessoas é afetado pela minha capacidade para comer e falar.
- Meu contato com as pessoas é afetado pela dor de dente.
- Meu relacionamento é afetado pela dor de dente.
- Meu relacionamento é afetado pela minha habilidade para comer e falar.
- Minha autoconfiança é afetada pela aparência de meus dentes.
- Eu sinto vergonha por causa dos meus dentes.
- Meu relacionamento é afetado pela aparência de meus dentes.
- Eu tento evitar mostrar meus dentes quando sorrio.
- Eu não estou satisfeito com meu sorriso
- Minha capacidade de trabalho é afetada pela dor.
- Eu me sinto estressada por causa da dor.
- Eu durmo mal por causa da dor.
- Eu estou satisfeito com minha capacidade para mastigar.
- Eu estou satisfeito com minha mastigação em geral.
- Eu estou satisfeito com minha capacidade para morder.
- Eu estou satisfeito com minha mordida em geral.

- Eu não mudo a forma de preparar os alimentos por causa dos dentes.
- Eu não mudo o tipo de alimento por causa dos dentes.

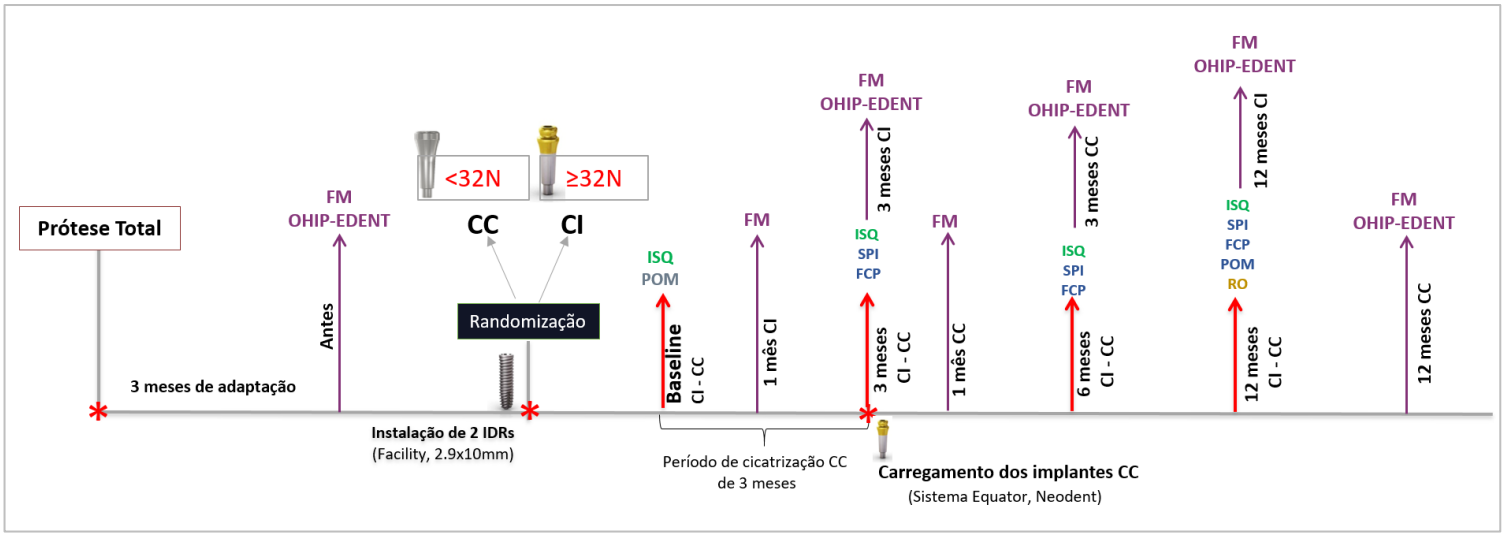
QUESTIONÁRIO GOHAI

- Limitou o tipo ou quantidade de alimentos?
- Teve problemas mordendo ou mastigando alimentos como carne sólida ou maçã?
- Foi capaz de engolir confortavelmente?
- Suas próteses (ou a falta delas) o impediram de falar da maneira como queria?
- Foi capaz de comer alimentos sem sentir desconforto?
- Limitou seus contatos com outras pessoas devido às condições de seu sorriso (dentes)?
- Sentiu-se satisfeito com o aspecto de seu sorriso?
- Usou medicamentos para aliviar dor ou desconforto relativo à boca?
- Preocupou-se com seu sorriso?
- Sentiu-se incomodado/abalado ou nervoso devido a problemas com seu sorriso?
- Sentiu desconforto ao alimentar-se em frente a outras pessoas por causa de sua boca ou dentes?
- Sentiu seus dentes ou gengivas sensíveis ao quente, ao frio ou ao doce?

ANEXO C

Linha do tempo – Estudo do Capítulo 3

Immediate versus conventional loading of Facility-Equator system in mandibular overdenture wearers: 1-year RCT with clinical, biological, and functional evaluation



Legenda: CC – carregamento convencional; CI – carregamento imediato; FM – função mastigatória; POM – perda óssea marginal; SPI – saúde periimplantar; FCP – coleta de fluíd crevicular periimplantar; RO - remodelação óssea; ISQ – estabilidade do implante; IDR – implante de diâmetro reduzido.