**UNIVERSIDADE FEDERAL DE PELOTAS**

**Faculdade de Odontologia**

**Programa de Pós-Graduação em Odontologia**

Tese

# Fatores associados ao desempenho funcional e clínico de usuários de overdentures mandibulares durante 3 anos de função

**Anna Paula da Rosa Possebon**

**Pelotas, 2021**

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Orientadora: Fernanda Faot

**Pelotas, 2021**

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## Notas Preliminares

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## Resumo

POSSEBON, Anna Paula da Rosa. **Fatores associados ao desempenho funcional e clínico de usuários de overdentures mandibulares durante 3 anos de função.** Tese (Doutorado em Odontologia, Área de concentração em Prótese Dentária) - Programa de Pós Graduação em Odontologia, Universidade Federal de Pelotas, 2021.

Frente ao sucesso dos implantes osseointegráveis e concomitante a necessidade de contornar queixas do paciente, como falta de retenção e estabilidade, principalmente da prótese total convencional (PTC) mandibular, a opção por overdentures mandibulares (OM) tem sido amplamente difundida como protocolo mínimo para reabilitar indivíduos desdentados totais,devido sua excelente relaçãocusto-benefício. Em adição, com a opção de uso de implantes de diâmetro reduzido (IDR), dificuldades reabilitadoras observadas em pacientes idosos, com níveis de atrofia mandibular moderada e severa, tem sido superadastornando o tratamento com OM previsível e com altos índices de sucesso. IDR temapresentando índice de sucesso e sobrevivência em torno de 98%, e mostram- se capazes de manter a estabilidade do tecido ósseo periimplantar,o que evidencia excelente previsibilidade e sucesso ao longo dos anos. Ainda, OM implanto-retidas promovem aos indivíduos melhorias nos níveis de satisfação com o seu tratamento, qualidade de vida, além de reestabelecer a função mastigatória de forma mais eficiente em relação a PTC. Considerando todas as variáveis clínicas e funcionais relacionadas à reabilitação,que podem interferir na manutenção, longevidade e qualidade de vida, torna- se de extrema importância o acompanhamento anual de usuários de OM. Esse acompanhamento regular permite a compreensão da influência de fatores intrínsecos dos indivíduoscomo atrofia mandibular, padrão facial, classificação ântero-posterior e força de mordida,além do carregamento oclusal,na reabilitação com OM ao longo do tempo. Diante do exposto, uma coorte de pacientes desdentados totais foi avaliada anualmente ao longo de 3 anos de uso de OM, com a finalidade de investigar possíveis mudanças na função mastigatória, qualidade de vida relacionada à saúde bucal e satisfação com sua condição oral e monitorar variáveis clínicas e ósseas, que são preditivas do sucesso da reabilitação protética implantossuportada. Como resultado, esta tese apresenta através de 6 artigos um compilado de informações que determinam a previsibilidade e o impacto positivo do uso OM retidas por implantes de diâmetro reduzido na vida dos indivíduos. Após 3 anos, altas taxas de sucessoe sobrevivência e mínimas complicações biológicas e protéticasforam reportadas, independente do carregamento oclusal. Em adição, apesar do alcance do equilíbrio da força oclusal ocorrer já nosprimeiros meses de função, variações no desempenho mastigatório, qualidade de vida relacionada à saúde bucal e das variáveis clínicas e ósseas ainda são observadas durante os 3 anos de acompanhamento. Além disso, variáveis intrínsecas como morfologia facial e sexodos indivíduos seguem influenciando o comportamento clínico e funcional das OM.

**Palavras-chaves:** Overdentures mandibulares, implantes de diâmetro reduzido, função mastigatória, qualidade de vida relacionada à saúde bucal

## Abstract

POSSEBON, Anna Paula da Rosa. **Factors associated to functional and clinical performance of users of mandibular overdentures during 3 years of function**. Thesis (PhD in Dentistry, Area of concentration in Dental Prosthesis) - Postgraduate Program in Dentistry, Federal University of Pelotas, 2021.

Through the success of osseointegrated implants and concomitant to the need of circumvent patient complaints, such as lack of retention and stability, especially of the mandibular conventional complete denture (CCD), the option for mandibular overdentures (MO) has been widely disseminated as a minimum protocol to rehabilitate total edentulous individuals, due to its excellent cost-benefit ratio. In addition, with the option of using narrow diameter implants (NDI), rehabilitation difficulties observed in elderly patients, with moderate and severe levels of mandibular atrophy, has been overcome making treatment with MO predictable and with high success rates. NDI has shown a success and survival rate of around 98%, and maintaining the stability of peri implant bone tissue, showing excellent predictability and success over the years. Still, implant-retained MO promote improvements in the levels of satisfaction with their treatment, quality of life, besides restoring the masticatory function efficiently. Considering all clinical and functional variables related to rehabilitation, which can interfere in maintenance, longevity and quality of life, annual monitoring of MO users is extremely important. This regular monitoring allows the understanding of the influence of individuals' intrinsic factors such as mandibular atrophy, facial pattern, anteroposterior discrepancy and bite force, in addition to occlusal loading, in rehabilitation with MO over time. In view of the above, a cohort of total edentulous patients was assessed annually over 3 years of MO use, in order to investigate possible changes in masticatory function, oral health-related quality of life and satisfaction with their oral condition and monitor variables and bone, which are predictive of the success of implant-supported prosthetic rehabilitation. As a result, this thesis presents, through 6 articles, a compilation of information that determines the predictability and positive impact of MO use retained by narrow diameter implants in the lives of individuals. After 3 years, high success and survival rates and minimal biological and prosthetic complications have been reported, regardless of occlusal loading. In addition, despite reaching the balance of occlusal strength occurring in the first months of function, variations in chewing performance, oral health-related quality of life and clinical and bone variables are still observed during the 3-year follow-up. In addition, intrinsic variables such as facial morphology and gender of individuals continue to influence the clinical and functional behavior of OM.

**Keywords:** Mandibular overdentures, narrow diameter implants, masticatory function,oral health-related quality of life

## Sumário

# 1 INTRODUÇÃOGERAL

Durante muitos anos os serviços públicos de saúde bucal disponibilizados no Brasil eram essencialmente curativos, mutiladores, de alto custo, baixa cobertura e baixo impacto epidemiológico, resultando em extrações excessivas (PUCCA JR., 2006; VARGAS et al., 2005).Um levantamento epidemiológico, SBBRASIL, realizado em 2003, (BURDON, 2003)mostrou que na faixa etária compreendida entre os 35-44 anos, o número médio de dentes cariados, perdidos e obturados (CPOD) era de 22.5, onde 66% dos componentes eram de dentes perdidos. Dos 50-59 anos o CPOD foi ainda maior, de 27.2 e 86% dentre os componentes eram de perdidos. O último levantamento epidemiológico realizado em 2010(RONCALLI, 2011), mostrou que na faixa etária de 65-74 quase um quarto da população brasileira possui pelo menos um dos seus maxilares desdentado total e 15% dessas pessoas necessita reabilitação com próteses totais. Além disso, 30% das pessoas na faixa etária entre 30-44 anos já eram desdentadas totais e 75% dos idosos (mais de 65 anos) não possuía nenhum dente em boca (BURDON, 2003; PUCCA JR., 2006). Neste cenário, a prótese total convencional (PTC) ainda é o tratamento reabilitador mais utilizado para substituir os dentes perdidos e devolver estética e função para a grande maioria dos indivíduos, especialmente devido à limitações econômicas(CARLSSON; OMAR, 2010). Entretanto, a reabsorção do rebordo residual em pacientes desdentado totais é um processo fisiológico crônico, multifatorial e progressivo(XIE et al., 1997) e que tem como principal consequência clínica a superficialização da musculatura envolvida na mastigação resultando em uma prótese mandibular menos estável, pois a musculatura movimenta a base da prótese durante a mastigação, causando desconforto, úlcera e até mesmo hiperplasia (KOSHINO et al., 2008). Sendo assim, problemas como falta de retenção e estabilidade são as principais queixas desses indivíduos, além de uma maior dificuldade mastigatória (WITTER et al., 2013).

Alguns fatores também podem influenciar a instabilidade das PTC ea função mastigatória, como o grau de atrofia dos rebordos residuais e a força de mordida dos indivíduos. Alguns estudos apontam uma influência negativa da reabsorção óssea na função mastigatória com PTC, sugerindo que indivíduos com atrofia mandibular tem sua função mastigatória limitada(FUJIMORI et al., 2002; KOSHINO et al., 2008; MARCELLO-MACHADO et al., 2017a).Além disso, os indivíduos reabilitados com PTC possuem diminuída força de mordida, que varia em torno de 20-40% da força de mordida de um indivíduo dentado total (FONTIJN-TEKAMP et al., 2000; VAN DER BILT et al., 2010). Segundo Fontijn-Tenkamp et al. (2000), essesindivíduos necessitam de até 8x mais ciclos mastigatórios, para reduzir pela metade o tamanho das partículas mastigadas, do que àqueles com dentição completa. Dessa forma, mesmo que as PTC estejam clinicamente satisfatórias, elas diminuem a força de mordida e consequentemente influenciam no desempenho mastigatório dos indivíduos, sendo esta uma das principaisqueixasdos indivíduos portadores de PTC(VAN DER BILT, 2011).

Além disso, a função mastigatória também pode ser afetada diretamente pelo perfil facial e classificação ântero-posterior dos indivíduos desdentados totais, que podem tornar o processo reabilitadorcom PTC um desafio(OCHIAI et al., 2011). Indivíduos classe I e mesofaciais,por apresentarem crescimento horizontal e vertical equilibrados, apresentammenor dificuldades durante a reabilitação e tem sidoconsiderados os padrões para comparações. No que se refere ao perfil facial, dólicofaciais possuem uma convexidade excessiva do rosto e dificuldade respiratória e acabam empurrando a língua para melhorar a respiração, influenciando diretamente na retenção e estabilidade das próteses, enquanto braquifaciais, pela ação muscular intensa do masseter, também podem apresentar problemas na retenção e estabilidade das PTC (CHACONAS; GONIDIS, 1986). Já em relaçãoà discrepância ântero-posterior, os problemas estão relacionados a dificuldade do reestabelecimento da relação maxilo-mandibular, pois indivíduos classe III devido sua protrusão mandibular apresentam diminuída dimensão vertical, enquanto indivíduos classe II tendem a apresentar maior altura óssea do rebordo residualem ambos os arco, com efeitos diretos na obtenção de espaço interoclusal ideal (MARTINS et al., 2020). A correção dessas discrepâncias ântero-posteriores no desdentado total, realizada através da compensação dessa discrepância óssea durante a reabilitação protética, pode resultar em melhorias na função mastigatória,porém, isso nem sempre é possível com PTC(ÇIFTÇI et al., 2005; OCHIAI et al., 2011). Dessa forma, esse conjunto de características clínicas pode determinar o prognóstico do tratamento reabilitador(OCHIAI et al., 2011).

Assim, para contornar esses problemas, como falta de retenção e estabilidade,além de reduzida força de mordida e pobre desempenho mastigatório, a reabilitação mandibular com overdentures mandibulares (OM) tem sido considerada como protocolo mínimo para reabilitar indivíduos desdentados totais (THOMASON et al., 2012) por sua simplicidade ealto sucesso (BAKKE et al., 2002; FUEKI et al., 2007). Durante muitos anos, os indivíduos reabilitados com OM, ao serem tratados com implantes necessitavam aguardar o período de osseointegração(3 meses), como proposto por Brånemark et al. (1977). Segundo os autores, com as OM carregadas de forma tardia, através do carregamento convencional (CC), resultaria em melhor osseointegração, além da ausência de intercorrências e melhor sucesso e sobrevivência dos implantes (BRÅNEMARK et al., 1977). Porém, muitos desses indivíduos, durante o período de espera pela reabilitação definitiva ou pelo carregamento oclusal das suas OM, relatam esse período como traumático e desconfortável, pois as próteses totais provisórias não fornecem adequada função e estética (ESPOSITO et al., 2007). Assim, cada vez mais vem se discutindo a adoção do carregamento imediato (CI) de OM, que é uma proposta de reabilitação que visa encurtar o tempo do tratamento, aumentar o conforto e acelerar a recuperação funcional dos indivíduos (SALMAN et al., 2019), além de melhor a qualidade de vida e satisfação dos pacientes (EMAMI et al., 2016a). Esta modalidade de tratamento está amplamentediscutida na literatura atual e segundo Gallucci et al., 2009 (GALLUCCI et al., 2009) o uso da carga imediata é cientificamente e clinicamente validada(ALFADDA et al., 2009; GIANNAKOPOULOS et al., 2017; MARZOLA et al., 2007). Além disso, melhorias no desenho/macrogeometriae superfície dos implantes tem sido capazes de contribuir paraobtenção deadequada estabilidade primária do implante, contribuindo assim para a disseminação da adoção do carregamento imediato (SCHIMMEL et al., 2014).

Ainda, a literatura também mostra melhorias relacionadas aos desfechos centrados no paciente como satisfação e qualidade de vida quando utilizada próteses totaisretidas por implantes (BOVEN et al., 2015)em vários aspectos, incluindo a mastigação (NAERT et al., 2004; VAN KAMPEN et al., 2005). Sabe-se que o desempenho mastigatório é melhorado significativamente após a utilização dos implantes, assim como há uma redução do número de ciclos mastigatórios afim de reduzir pela metade o tamanho das partículas mastigadas(BAKKE et al., 2002; FONTIJN-TEKAMP et al., 2000; STELLINGSMA et al., 2005; VAN KAMPEN et al., 2004), tornando a mastigação dos alimentos mais eficiente (VAN DER BILT, 2011).Além disso, discute-se que a força de mordida é uma variável biológica capaz de influenciar a função mastigatória, e vem se tornando uma ferramenta de análise da funcionalidade do sistema mastigatório, frente à diferentes reabilitações orais, e pode explicar mais de 60% da variação do desempenho mastigatório(FONTIJN-TEKAMP et al., 2000; HATCH et al., 2001; IKEBE et al., 2007; SCHIMMEL et al., 2017). Artigos mostram que a força de mordida dos portadores de OM é 60-200% maior, em relação aos usuários de PTC (CARLSSON, 1993; FONTIJN-TEKAMPL et al., 1998; POSSEBON et al., 2020), e que o uso de OM é capaz de tornar a força de mordida 2x maior (FONTIJN-TEKAMP et al., 2000), podendo ser até 123% maior após 1 ano da instalação de implantes para retenção das OM (ENKLING et al., 2017). Assim, como consequência há uma melhor fragmentação das partículas de alimento pelos dentes posteriores da prótese, trazendo aos pacientes desdentados uma atividade muscular melhorada com a estabilização da prótese inferior por dois implantes, exercendo assim maior força de mordida(BOVEN et al., 2015; POSSEBON et al., 2020).

Outro fator importante que pode influenciar o desempenho mastigatório em usuários de OM, é a área óssea do rebordo residual posterior que suporta as OM e que pode desempenhar um papel importante em relação aos benefícios que esse tipo de reabilitação pode trazer ao indivíduo. Sugere- se que a área óssea mandibular disponível deve ser avaliada rotineiramente para garantir o sucesso desse tipo de reabilitação, principalmente na região posterior de mandíbula, área onde as OM seguem sendo mucossuportadas(GUCKES et al., 1996; PAN et al., 2010). Pan et al., 2016 verificou que independentemente da altura óssea do rebordo alveolar residual mandibular, indivíduos portadores de OM, ainda assim, possuem elevada satisfação, conforto, estabilidade e melhor capacidade mastigatória que usuários de PTC, trazendo a evidência de que possíveis perdas ósseas na região posterior de mandíbula, mesmo após uso de OM, não trazem efeitos negativos na satisfação, função e capacidade de mastigar com OM.

Quando se trata de desempenho mastigatório, que é fortemente influenciado pelos fatores citados acima, sabe- se que se tratada capacidade objetiva de um indivíduo reduzir pela metade o tamanho das partículas mastigadas após um número fixo de ciclos e existem vários métodos para obtê-lo(VAN DER BILT, 2011). A maioria dos estudos utiliza o grau de quebra das partículas mastigadas peneirando-as(FONTIJN-TEKAMP et al., 2000a; VAN DER BILT et al., 2004). Pode-se utilizar para determinar o desempenho mastigatório alimentos naturais, como amendoim e cenouras ou até mesmo alimentos sintéticos. O alimento artificial é preferível devido suas propriedades físicas como tamanho, forma e tenacidade, além de serem de fácil reprodução e de não sofrerem alterações sazonais que influenciam na textura dos alimentos (VAN DER BILT; FONTIJN-TEKAMP, 2004). Esses alimentos sintéticos são amplamente utilizados em estudos clínicos.(ENGLISH et al., 2002; FONTIJN-TEKAMP et al., 2000; SLAGTER et al., 1992; STELLINGSMA et al., 2005) . Para peneirar as partículas existem dois métodos, o método da peneira única ou das múltiplas peneiras. Alguns autores utilizam a peneira única (FELDMAN et al., 1980; GARRETT et al., 1998; HATCH et al., 2001), onde o desempenho é dado pela porcentagem (%) de peso das partículas mastigadas que passam pela peneira após um número fixo de ciclos. Mas sabe-se que o método das múltiplas peneiras fornecem informações muito mais detalhadas sobre a distribuição do tamanho das partículas mastigadas(FONTIJN-TEKAMP et al., 2000; HELKIMO; CARLSSON; HELKIMO, 1978; SLAGTER et al., 1992; VAN DER BILT, 2011). Assim, um pequeno tamanho médio das partículas após serem mastigadas, por um número fixo de ciclos, indicam um bom desempenho mastigatório, e tamanhos maiores de partículas como um ruim desempenho mastigatório (VAN DER BILT, 2011). Existe também outro método para determinar o desempenho mastigatório que é a capacidade de homogeneizar/misturar os alimentos (parâmetro B). Segundo Speksnijder et al., (2009), esse teste é bastante adequado para discriminar melhor, entre aqueles com diminuído desempenho mastigatório, quem melhor faz uma adequada homogeneização os alimentos durante a mastigação(SPEKSNIJDER et al., 2009). Além desses dois métodos para avaliar desempenho mastigatório, existe o limiar de deglutição que é a distribuição do tamanho médio das partículas mastigadas, mas sem um número fixo de ciclos, ou seja, o limiar de deglutição pode ser determinado como o tamanho médio das partículas expectorados apenas antes do indivíduo sentir vontade de engolir (FONTIJN-TEKAMP et al., 2004). Baixos valores de tamanho médio das partículas indicam um bom limiar de deglutição e altos valores como ruim (VAN DER BILT, 2011). Ainda segundo esse autor é muito interessante relacionar o desempenho mastigatório com o tamanho médio real que um indivíduo está disposto a engolir, pois indivíduos que apresentam baixo desempenho mastigatório podem seguir mastigando até sentir vontade de engolir, diminuindo mais ainda o tamanho das partículas e não necessariamente engolindo partículas grandes.

A literatura científica disponível ressalta que há duas formas de verificar o desempenho mastigatório, a de forma objetiva, com alguns dos métodos existentes acima descritos, e os de forma subjetiva. Quando se trata de uma avaliação subjetiva, Van der Bilt et al., (2011) aponta que esta pode ser determinada através de questionários ou entrevistas(VAN DER BILT, 2011). Estas informações obtidas pela autopercepção do paciente em relação a sua condição oral, podem ser avaliadas através de questionários já validados, como o OHIP-Edent(SOUZA et al., 2007) (SOUZA et al., 2007) e o GOHAI (Geriatric Oral Health Assestement Index)(ATCHISON; DOLAN, 1990). A determinação do impacto na vida diária (AL-OMIRI et al., 2011) do tratamento reabilitador também pode ser utilizada como um novo e simplificado indicador de satisfação do paciente mensurado em dimensões variadas como: conforto, aparência, dor, “performance” e restrição alimentar com o instrumento DIDL. Questões relacionadas à qualidade de vida relacionada à saúde bucal (QVRSB) também são bastante questionadas em relação às reabilitações protéticas, tanto de PTC quanto de OM. Como visto, a utilização de implantes osseointegrados tem sido amplamenteutilizado para substituição dos dentes perdidos, mas pouca atenção tem sido dada em relação a percepção do paciente com os resultados do tratamento e aos impactos psicossociais do tratamento com implantes dentários. Dessa forma, conhecer e determinar o impacto do tratamento sobre a saúde bucal e a vida diária dos pacientes, bem como a avaliação do estado clínico e psicológico do indivíduo tem grande valor quando se tem a necessidade de uma reabilitação protética e de se mensurar subjetivamente as expectativas dos pacientes(AL-OMIRI et al., 2011; DE SOUZA et al., 2012).

Assim, compreender todos os fatores associados ao desempenho mastigatório a curto, médioe a longo prazo, é de suma importância para compreender a evolução do desempenho funcional das OM com o passar dos anos de função. Nos usuários de OM, também é igualmente importante compreender o comportamento clínico e biológico dos tecidos periimplantares para evitarcomplicações, além degarantir sucesso e previsibilidade desse tipo de reabilitação. Atualmente diante da evolução de biomateriais e aprimoramento de vários de sistemas de implantes e de técnicas minimamente invasivas a previsibilidade clínica do uso de OM está diretamente relacionada a fatores que estão: I) ligados ao implante, com o desenvolvimentos de diferentes superfícies que favorecem o carregamento imediato (EMAMI et al., 2016b; GLIBERT et al., 2018; STOKER; WISMEIJER, 2011) de ligas de titânio que conferem maior resistência a implantes de diâmetro reduzido (AL-NAWAS et al., 2012; MÜLLER et al., 2015; QUIRYNEN et al., 2015; REIS et al., 2019) e/ou conexões protéticas simplificadas (BIELEMANN et al., 2018; MARCELLO-MACHADO et al., 2018a, 2020), II) a não exigência de esplintagem rígida como garantia de sucesso clinico (ANAS EL-WEGOUD et al., 2018; KAPPEL et al., 2015, 2016; LEÃO et al., 2018; MATTHYS et al., 2019; NAERT I, ALSAADI G, VAN STEENBERGHE D, 2004; TURKYILMAZ et al., 2006); III) ampla utilização de sistemas do tipo botão que possuem a versatilidade de serem usados em situações de rebordos alveolares com atrofia e com espaço interoclusal reduzido (ELSYAD; DENEWAR; ELSAIH, 2018; GUÉDAT et al., 2018; MATTHYS et al., 2018, 2019; SHAH; YILMAZ; MCGLUMPHY, 2017) e IV) possibilidade de trabalho com implantes em posição não ideal com paralelismo comprometido (MANIEWICZ et al., 2020; SRINIVASAN et al., 2019, 2020), pois atualmente encontram-se disponíveis sistemas do tipo botão capazes de compensar angulações de até $60^0$ graus entre os implantes (Locator R-Tx).

Implantes de diâmetro reduzido (IDR) foram desenhados para reverter dificuldades reabilitadoras em leitos ósseos com baixa disponibilidade óssea em espessura e quando lançados no mercado ampliaram as possibilidades do tratamento com OM, tendo alcançado resultados previsíveis e altoíndicede sucesso (EL-SHEIKH; SHIHABUDDIN; GHORABA, 2012; MARCELLO-MACHADO et al., 2018c; REIS et al., 2019; ZINSLI et al., 2004). Em uma revisão sistemática (MARCELLO-MACHADO et al., 2018b), IDRs apresentam índice de sucesso sobrevivência em torno de 98%, e os resultados mostraram que o tecido ósseo periimplantar se comporta de forma positiva, evidenciando excelente previsibilidade e sucesso ao longo dos anos. Para as OM carregadas de forma convencional (MARCELLO-MACHADO et al., 2018a), os autores verificaram que o índice de profundidade de sondagem reduziu significativamente entre 8 e 12 semanas após a instalação dos implantes, garantindo bom selamento biológico dos tecidos periimplantares, além do aumento imediato no valor de ISQ (coeficiente de estabilidade), após o carregamento oclusal. Além disso, este sistema apresentou ausência de perda óssea marginal no primeiro ano de acompanhamento, comprovando sua previsibilidade e sucesso clinico em curto prazo(MARCELLO-MACHADO et al., 2018a).

Levando em considerações todos tópicos abordados e variáveis relacionadas à reabilitação com OM, é de extrema importância que além da realização da reabilitação desses indivíduos, exista um acompanhamento dos mesmos. Além disso, compreender se os fatores intrínsecos aos indivíduos, como atrofia mandibular, morfologia facial (padrão facial e classificação da discrepância ântero-posterior) e força de mordida; além do tipo de carregamento oclusal adotado, podem ter associação com o desempenho mastigatório, pois neste sentido há falta de estudos que analisem de forma detalhada a influência e possível relação entre estes fatores. Além disso, o acompanhamento em médio prazo da reabilitação com OM deve ser realizado, afim de verificar precocemente possíveis mudanças na função mastigatória, qualidade de vida relacionada à saúde bucal e satisfação dos usuários com sua condição oral. Igualmente o monitoramento de variáveis clínicas e ósseas, que sãodeterminantesdo sucessoda reabilitação protética implantossuportada deve ser realizado anualmente no curso de vida do paciente com o objetivo de prevenir a ocorrência de complicaçõesbiológicas. Dessa forma, a presente tese abordou e acompanhou todas essas variáveis ao longo de 3 anos de usuários de OMs retidas por implantes de diâmetro reduzido atravésda condução de 6 estudos clínicos. Os resultados destes acompanhamentos estão apresentados em 6 artigos que objetivaram:

Artigo 1: Avaliar como a retenção, estabilidade, atrofia, tipo de perfil facial, discrepância esquelética ântero-posterior e tipo de carregamento interferem na função mastigatória de indivíduos edêntulos durante a transição de próteses totais convencionais para overdentures mandibulares, até um ano após a transição;

Artigo 2: Avaliar diferenças da força de mordida e performance mastigatória entre usuários de prótese total convencional e overdenture mandibulares além da correlação entre essas variáveis, por meio de testes de força de mordida e parâmetros objetivos da função mastigatória.

Artigo 3: Analisar se os resultados radiográficos, funcionais e de qualidade de vida relacionada a saúde bucal são mantidos ao longo dos 3 anos de função das overdentures mandibulares, além de quantificar as relações entre força de mordida e índice de área óssea posterior com a função mastigatória e qualidade de vida relacionada a saúde bucal, no 3º ano de função.

Artigo 4: Investigar mudanças de médio prazo nos parâmetros de função mastigatória e qualidade de vida relacionada a saúde bucal de usuários overdenture mandibular levando em consideração o perfil facial, discrepância ântero-posterior e sexo no 3º ano de função.

Artigo 5: Investigar o desempenho clínico, funcional e relacionado a qualidade de vida relacionada a saúde bucal de overdentures mandibulares retidas por implantes de diâmetro reduzido (Facility-Equator System) em um grupo de indivíduos totalmente desdentados durante 3 anos de acompanhamento, após carregamento oclusal, além de monitorar o número de complicações e manutenções protéticas.

Artigo 6: Avaliar diferenças entre os tipos de carregamento oclusal, convencional e imediato, recebido por overdentures mandibulares retidas por dois implantes de diâmetro reduzido durante 3 anos de função, além da evolução de preditores clínicos, radiográficos, qualidade de vida e função mastigatória dos 2 tipos de carregamentos de implantes.

# 2ARTIGOS

## 2.1 ARTIGO 1: Masticatory function of conventional complete denture wearers changing to 2-implant retained mandibular overdentures: clinical factor influences after 1 year of function

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## ABSTRACT

**Purpose:** Evaluate how clinical factors related to conventional complete denture (CCD) wearers, can influence masticatory function (MF) of totally edentulous patients before and after one-year transitioning to implant-retained mandibular overdentures (IMO). **Methods:** Forty patients using CCD were rehabilitated with IMO and their MF was evaluated by: (i) ST_X50: theoretical aperture through which 50 % of the weight of the particles would pass; (ii) STB: distribution homogeneity of the crushed particles. The clinical parameters analyzed were: atrophy, retention, stability, facial type, anteroposterior skeletal discrepancy, and type of loading. The statistical association was tested through crude and adjusted logistic regression. **Results:** IMO promoted improvements in the MF, irrespective of the clinical parameters. CCD wearers with poor retention had 86 % less chance of achieving a good ST_X50. STB was associated with stability, facial type, and anteroposterior discrepancy. Subjects with poor mandibular CCD stability had a 76 % lower chance of achieving a good test food homogenization, whereas brachyfacial individuals were 1.3 times more likely to have a good STB. Class II patients had an 89% lower chance of having a good homogenization of the particles as CCD users and after transition to IMO. **Conclusions:** CCD users with poor retention achieved an inferior ST_X50. The STB performance can be compromised by poor stability or Class II characteristics, while brachyfacial individuals achieve better homogenezation of the food bolus. Although the transition to IMO improved the masticatory function, the anteroposterior discrepancy still maintained an association with STB, as Class II individuals still presented difficulties homogenizing food.

Keywords:

Conventional complete dentures, Implant-retained mandibular overdenture, Masticatory function, Clinical factors

## INTRODUCTION

Conventional complete dentures (CCD) are still commonly used to replace lost teeth, and to restore esthetics and function for most individuals when there are economic limitations [1]. The main problems reported by individuals rehabilitated with CCD are insufficient retention and stability, especially of the mandibular dentures [2,3]. These complaints are directly related to progressive reabsorption of the residual ridge, which results in the superficialization of the muscles involved in chewing, thus destabilizing CCD [4]. The movement of the denture base during mastication causes discomfort and trauma to the mucous tissue, ulcers, and even recurrent hyperplasia [5]. Thus, the reduced stability and retention of the dentures cause greater masticatory difficulty for these individuals [6].

Some studies [7,8] point to a negative influence of bone resorption on CCD masticatory function, suggesting that individuals with mandibular atrophy have a limited masticatory function. Atrophic individuals have a thin, flat alveolar ridge resulting in elevation of the superficial muscles and a superficialization of the mental foramen. Both factors negatively influence the prognosis of rehabilitation. Thus, individuals with mandibular atrophy complain of discomfort, lack of retention and stability, and pain from the use of CCD.

Individuals rehabilitated with CCD also have a poor masticatory function, reduced by 50–84% in relation to the masticatory function of dentate individuals [3,9]. The time since edentulism also seems to be related to a greater masticatory difficulty [8,10]. The classic study by Kapur [10] reported a correlation between masticatory function and duration of edentulism, indicating that individuals with a longer period of edentulism and a longer experience with CCD have an inferior masticatory function. This is possibly caused by changes to the support structures after teeth loss, resulting in instability mainly of the mandibular prosthesis.

The masticatory function can also be directly affected by the facial type and anteroposterior skeletal discrepancy of the individuals [11]. Totally edentulous patients classified as Class I and mesofacial have balanced horizontal and vertical growth, and present no major difficulties during rehabilitation, and are used as the standard for comparisons. In contrast, both dolichofacial and brachyfacial types can face problems with respect to retention and stability of CCD. Dolichofacial patients experience constant instability of the mandibular denture due to the excessive convexity of the face, and respiratory distress, and end up pushing the tongue outward involuntarily to improve respiration. In the brachyfacial patients, the intense muscular action of the masseter promotes a tendency to dislocate the denture [12]. Class III individuals have a reduced vertical dimension due to their mandibular protrusion, while Class II individuals may have an increased bone height of the residual ridge, which may inhibit reestablishment of the maxillo-mandibular relationship. It is suggested that the correction of these malocclusions with the compensation of bone discrepancy during prosthetic rehabilitation may result in improvements in masticatory function, but this is not always possible with CCD [11,13]. Thus, this set of clinical information can determine the prognosis of rehabilitation treatment [11].

In order to overcome these problems, implant-retained mandibular overdentures (IMO) were recommended as the minimum protocol to rehabilitate totally edentulous individuals [14]. After treatment with IMO, individuals report improvements in satisfaction levels in several aspects, including chewing, compared to individuals with CCD [14–16]. According to the study by Giannakopoulos et al. [17], immediate loading has some benefits over conventional loading, such as good implant survival rates, few prosthetic complications, and improvements in the subjective perception of the patient over short time periods. In addition, immediate loading may be a promising treatment option, especially for elderly patients with a more resorbed mandibular ridge, where identical improvements in masticatory capacity occur more quickly compared to conventional loading. However, there are no clinical studies that report positive results of immediate loading on objective masticatory parameters.

Thus, the objective of this study was to evaluate how retention, stability, atrophy, facial type, anteroposterior skeletal discrepancy, and loading type interfere with masticatory function (MF) of edentulous individuals during the transition from CCD to IMO, up to one year after transition to IMO. The null hypothesis is that these factors do not interfere in the masticatory performance of either CCD or IMO.

## MATERIALS AND METHODS

### Study design

This longitudinal clinical study was approved by the Research Ethics Committee of the UFPel School of Dentistry (Protocol – 69/2013), and developed according to the Declaration of Helsinki, 2008, following the

Guidelines for Observational Studies (STROBE). To be selected to participate in the survey, volunteers had to be totally edentulous, in need of new CCD, have sufficient bone availability in the anterior region of the mandible to allow implant installation without bone augmentation (at least a 3.5 mm diameter and 10.0 mm length) and be willing to attend university on the evaluation days. Volunteers with decompensated diabetes, hypertension, hemorrhagic disorders, severe systemic diseases, compromised immune systems, or a history of radiotherapy in the head or neck region were excluded from the sample. All selected patients who agreed to participate in the study and subsequently signed an informed consent form.

All volunteers were rehabilitated with new CCD, which were made with thermo-polymerizable acrylic resin (VIPICRIL plus – VIPI – Pirassununga, São Paulo, Brazil), artificial acrylic resin teeth assembled in bilateral occlusion. After three months of the patients' adaptation to the CCD, the MF test was performed. Subsequently, two narrow diameter implants (Facility NeoPoros: TI grade V, NeoPoros surface – Neodent – Curitiba, Paraná, Brazil) were installed in the region between mental foramina. From this landmark, the experienced surgeon adopted a standardized measure to perform the osteotomies, prepared 5 mm anterior to the mental foramina. This technique created a distance of 20–24mm between the centers of the two implants that varies according to the arch perimeter and the distance between the mental foramen. After the installation of the implants, the insertion torque was measured using a manual wrench to define the loading protocol, and healing caps or Equator-type attachments were immediately connected. Conventional or immediate loading were adopted based on the implant insertion torque reached by the two implants. After 3 months of the surgery, patients that were recommended to receive conventional loading had their healing caps replaced by attachments and the IMO were installed immediately. The CCD and IMO loading was performed by specialists in prosthodontics. The MF test was performed again 1 year after IMO loading.

**Categorization of mandibular atrophy**

The atrophy of the patients' mandibular bone was evaluated in panoramic radiographs, following the methodology reported in previous studies

[8,18]. Afterwards, the patients were categorized as atrophic or non-atrophic according to the criteria of Cawood and Howell [19]. To be allocated to the atrophic group, the patients had to present a bone height in the anterior region below 25 mm and a posterior bone height below 16 mm. The remaining patients were classified as non-atrophic.

**Retention and stability assessment**

The mandibular CCD retention and stability was evaluated according to the methodology proposed by Sato et al. [20]. The retention was analyzed by verifying the displacement of the denture after vertically pulling the central incisors and scored as follows: S1-Good: without displacement; S2-Reasonable: displacement with difficulty and S3-Poor: easy displacement. The stability was assessed by the movement induced by applying pressure on the first molars with the middle finger, and scored as follows: S1-Good: displacement of 1–2 mm within the tissue; S2- Reasonable: greater tissue displacement than normal tissue, S3- Poor: sliding. For the purposes of analysis, the scores obtained were subsequently grouped into two categories as follows: Good/ Acceptable (S1 + S2) and Poor (S3).

**Determination of facial type and anteroposterior skeletal discrepancy**

The cephalometric evaluation of the lateral cephalograms of each patient was used for this evaluation. To determine the facial type, we performed a Ricketts analysis, which classifies the facial type as dolichofacial, mesofacial or brachyfacial according to five angles [21]. For the anteroposterior skeletal discrepancy, classification was performed by analyzing the angles of SNA (maxillary position in relation to the base of the skull), SNB (mandibular position in relation to the base of the skull) and ANB (maxillo- mandibular in the anteroposterior relationship). According to the values of the angles obtained, the patients were classified as Class I, Class II, or Class III [22,23].

## Type of implant loading

The type of loading received by the implants was determined at the time of implant surgery. Patients who presented an insertion torque of 32 N in both implants received immediate loading of the IMO after the surgical procedure. Patients who presented a torque below 32 N in at least one implant had their CCD converted to IMO after the three-month period of osseointegration (conventional loading).

## Evaluation of masticatory function

The MF was evaluated through the swallowing threshold test, in which the volunteers were instructed to chew a portion of artificial food “Optocal” [24] until they felt the desire to swallow. The chewing time and the number of masticatory cycles up to this point were recorded. The material expelled on the paper filter was then washed and dried at room temperature. After drying, the material passed through a sieve stack with progressively decreasing mesh size. The weight retained in each sieve was inserted into the Rosin– Rammler equation to calculate the mean particle size (ST_X50), the theoretical aperture through which 50% of the weight of the particles would pass, and the homogeneity outcome B (STB), which describes the homogeneity of the crushed particle distribution [25,26].

## Statistical analysis

The sample population characteristics (sex, age, and time of edentulism of the maxilla and mandible) and clinical factors (atrophy, retention, stability, facial type, anteroposterior skeletal discrepancy, and implant loading) were analyzed by descriptive statistics including mean, standard deviation, and relative frequency. For statistical analysis, the methodology proposed by Witer et al. [6], was used for ST_X50 categorization, where ST_X50 values above 3.68 were considered as poor, and less than 3.68 corresponds to a good ST_X50 outcome. The median STB values were considered to categorize the homogeneity. For STB with CCD, values 3.5 were considered as good, and values > 3.5 as poor. For IMO wearers, an STB 2.84 was considered good, and an STB > 2.84 as poor. All statistical tests were performed in Stata 12.0. The paired Wilcoxon test was used for comparison of ST_X50 and STB values of the individuals as CCD wearers, and after 1 year with IMO. A logistic regression (crude and adjusted) was also performed to determine associated factors, and to control confounding variables. The forward stepwise method of variable selection was adopted, and only the variables with p 0.20 were included in the adjusted models. In the final model, variables with p 0.05 were considered statistically significant, and odds ratios (OR) with 95 % confidence intervals were included as estimates of the effect size. The statistical power was calculated using the software G*Power 3.1.9.2, based on an error probability of 0.05, the OR values found in the significant associations between ST_X50 and STB, and the exposition variables obtained in the adjusted analysis.

## RESULTS

The sample consisted of forty individuals, and the majority was female (67.5 %). The mean age was 66.2 years (SD= 6.92). The mean time since edentulism was 29.6 years for the maxilla (SD= 12.5) and 23.2 years for the mandible (SD= 13.6). Twenty-five patients were classified as atrophic (62.5 %), 33 (82.5 %) had poor retention, and 23 (57.5 %) presented poor stability. The majority of the patients was classified as mesofacial (37.5%); only 10 individuals (25.0 %) were classified Class I. Nine patients (22.5 %) presented sufficient torque in both implants (>32Nm) to allow immediate loading (Table 1).

**Table 1.** Relative frequency of the sample according to sex, age, time since edentulism and clinical factors under study

| | | *n* | Relative frequence (%) |
|---|---|---|---|
| Sex | Males | 13 | 32.5 |
| | Females | 27 | 67.5 |
| Age | ≤ 60 years | 6 | 15 |
| | ≥ 60 years | 34 | 85 |
| Time since edentulism – maxilla | ≤ 25 years | 13 | 32.5 |
| | ≥ 25 years | 27 | 67.5 |
| Time since edentulism – mandible | ≤ 25 years | 25 | 62.5 |
| | ≥ 25 years | 15 | 37.5 |
| Atrophy | Atrophic | 25 | 62.5 |
| | Non atrophic | 15 | 37.5 |
| Retention | Good retention | 7 | 17.5 |
| | Poor retention | 33 | 82.5 |
| Stability | Good stability | 17 | 42.5 |
| | Poor stability | 23 | 57.5 |
| Facial type | Mesofacial | 15 | 37.5 |
| | Brachyfacial | 12 | 30 |
| | Dolichofacial | 13 | 32.5 |
| Anteroposterior skeletal discrepancy | Class I | 10 | 25 |
| | Class II | 12 | 30 |
| | Class III | 18 | 45 |
| Loading | Immediate | 9 | 22.5 |
| | Conventional | 31 | 77.5 |

The Fig. 1 shows the clinical factors analyzed while. Table 1 lists the relative frequency of the sample according to sex, age, time since edentulism and clinical factors under study.

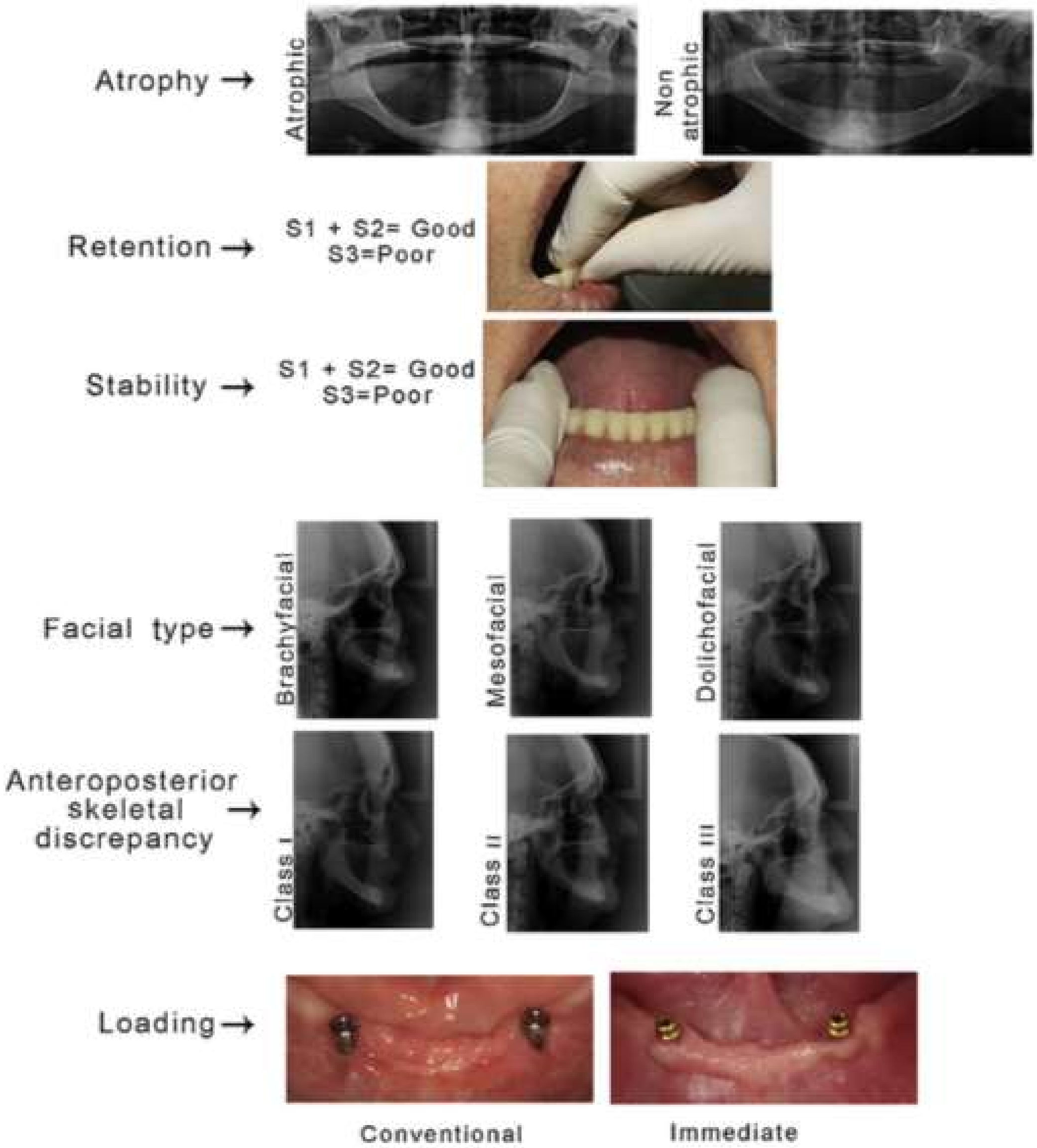


**Fig. 1.** Flowchart illustrating the clinical factors considered in the statistcal model: atrophy condition of the mandible, retention and stability of the mandibular complete denture, facial type, anteroposterior skeletal discrepancy, and loading time of the mandibular overdentures.

As for chewing in CCD users, only 8 out of 40 (20.0 %) had a good ST_X50, and 20 of the patients (50%) presented a poor homogenization. One year after transition to IMO, 22 patients had a good ST_X50, and 21 (52.5 %) had a good homogenization (STB). Table 2 lists the mean and standard deviations (SD) of the ST_X50 and STB outcomes, as well as the comparison of these means as CCD users, and one year after transition to IMO.

**Table 2.** ST_X50 and STB means of individuals as CCD wearers and post-transition to IMO (Wilcoxon-paired test)

| | | ST_X50 (SD) | | | STB (SD) | | |
|---|---|---|---|---|---|---|---|
| | | CCD | IMO | *p* value | CCD | IMO | *p* value |
| Atrophy | Atrophic | 5.03 (1.04) | 3.67 (1.30) | < 0.001 | 5.59 (5.51) | 3.23 (1.63) | 0.002 |
| | Non atrophic | 4.64 (1.46) | 3.70 (1.27) | 0.002 | 5.43 (5.59) | 3.33 (1.88) | 0.088 |
| Retention | Good retention | 4.99 (1.16) | 3.99 (1.28) | 0.010 | 5.01 (3.42) | 3.78 (1.72) | 0.063 |
| | Poor retention | 4.86 (1.24) | 3.61 (1.27) | < 0.001 | 5.64 (5.84) | 3.15 (1.72) | 0.004 |
| Stability | Good stability | 4.43 (1.30) | 3.56 (1.29) | < 0.001 | 4.10 (3.05) | 3.37 (1.74) | 0.210 |
| | Poor stability | 5.21 (1.06) | 3.76 (1.27) | < 0.001 | 6.59 (6.59) | 3.19 (1.72) | < 0.001 |
| Facial type | Mesofacial | 4.76 (1.09) | 3.40 (1.40) | < 0.001 | 4.37 (3.02) | 3.30 (1.91) | 0.069 |
| | Brachyfacial | 5.35 (1.15) | 4.24 (1.32) | 0.003 | 5.48 (2.85) | 3.63 (2.23) | 0.012 |
| | Dolichofacial | 4.59 (1.36) | 3.48 (0.95) | 0.004 | 6.91 (8.67) | 2.90 (0.59) | 0.116 |
| Anteroposterior skeletal discrepancy | Class I | 4.99 (1.07) | 3.84 (1.40) | 0.005 | 4.44 (3.36) | 3.53 (2.32) | 0.169 |
| | Class II | 4.65 (1.43) | 3.28 (0.98) | 0.005 | 7.25 (8.95) | 2.90 (0.47) | 0.071 |
| | Class III | 4.97 (1.18) | 3.85 (1.37) | < 0.001 | 4.99 (2.76) | 3.37 (1.88) | 0.007 |
| Loading | Immediate | 4.84 (1.22) | 3.18 (0.78) | 0.008 | 4.12 (5.57) | 2.71 (0.57) | 0.11 |
| | Conventional | 4.89 (1.21) | 3.82 (1.36) | < 0.001 | 5.94 (5.46) | 3.43 (1.89) | 0.003 |

Table 3 lists the logistic regression values for the factors associated with the ST_X50 and STB outcomes as CCD users. The outcome variables atrophy, retention, stability, facial type, and anteroposterior skeletal discrepancy were not statistically associated with the ST_X50 in the crude analysis. In the adjusted analysis, the retention was associated with ST_X50 (p = 0.03), indicating that patients with poor mandibular CCD retention had 86 % less chance of achieving a good particle reduction (OR: 0.14, IC: 0.01–1.15). In the crude regression, the anteroposterior skeletal discrepancy had a statistical association with STB (p=0.03), and the individuals classified as Class II had a 90% lower chance of properly homogenizing the particles during mastication (OR: 0.10, IC: 0.01–0.63). After adjusting for possible confounding factors, stability (p = 0.05) and facial type (p = 0.04) were associated with the STB test, and anteroposterior skeletal discrepancy (p=0.03) maintained its association with STB. The individuals had poor CCD stability had a 76 % lower chance of achieving a good homogenization of the particles during mastication (OR: 0.24, IC: 0.05–1.09), whereas brachyfacial individuals were 1.3 times more likely to have a good STB (OR: 1.30 CI: 0.21–7.93), and those classified as Class II had an 89 % lower chance of having a good homogenization of the particles as CCD users (OR: 0.11, IC: 0.01–1.15).

**Table 3.** Crude and adjusted regression between the exposure variables and ST_X50 and STB before transition to IMO

| | | ST_X50 | | | | | | STB | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Crude | | | Adjusted | | | Crude | | | Adjusted | | |
| | | OR | CI (95 %) | *p* value | OR | CI (95 %) | *p* value | OR | CI (95 %) | *p* value | OR | CI (95 %) | *p* value |
| Atrophy | Atrophic | 1.00 | . | 1.00 | . | . | . | 1.00 | . | 0.32 | . | . | . |
| | Non atrophic | 1.00 | 0.20–4.95 | | . | . | | 0.52 | 0.14–1.92 | | . | . | |
| Retention | Good retention | 1.00 | . | 0.12 | 1.00 | . | 0.03 | 1.00 | . | 0.67 | . | . | . |
| | Poor retention | 0.23 | 0.04–1.40 | | 0.14 | 0.01–1.15 | | 0.70 | 0.13–3.65 | | . | | |
| Stability | Good stability | 1.00 | . | 0.74 | . | . | . | 1.00 | . | 0.10 | 1.00 | . | 0.05 |
| | Poor stability | 1.29 | 0.26–6.37 | | . | . | | 0.35 | 0.09–1.28 | | 0.24 | 0.05–1.09 | |
| Facial type | Mesofacial | 1.00 | . | 0.20 | 1.00 | . | 0.08 | 1.00 | . | 0.20 | 1.00 | . | 0.04 |
| | Brachyfacial | 0.40 | 0.06–2.56 | | 0.32 | 0.04–2.44 | | 0.93 | 0.19–4.37 | | 1.30 | 0.21–7.93 | |
| | Dolichofacial | 0.16 | 0.01–1.67 | | 0.10 | 0.00–1.34 | | 0.29 | 0.06–1.41 | | 0.14 | 0.02–0.98 | |
| Anteroposterior skeletal discrepancy | Class I | 1.00 | . | 0.39 | . | . | . | 1.00 | . | 0.03 | 1.00 | . | 0.03 |
| | Class II | 0.21 | 0.01–2.46 | | . | . | | 0.10 | 0.01–0.63 | | 0.11 | 0.01–1.15 | |
| | Class III | 0.66 | 0.11–3.83 | | . | . | | 0.25 | 0.04–1.51 | | 0.25 | 0.03–1.63 | |

Table 4 lists the logistic regression results 1 year after transition to IMO. An association between the exposure variables with ST_X50 was not observed. However, the anteroposterior skeletal discrepancy of the individuals was associated with the STB test, both in the crude and in the adjusted regression. After adjustment, Class II individuals had a 89% lower chance of properly homogenizing the particles during IMO mastication (p = 0.05; OR: 0.11, IC: 0.01–1.06).

**Table 4.** Crude and adjusted regression between the exposure variables and ST_X50 and STB after transition to IMO

| | | ST_X50 | | | | | | STB | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Crude | | | Adjusted | | | Crude | | | Adjusted | | |
| | | OR | CI (95 %) | *p* value | OR | CI (95 %) | *p* value | OR | CI (95 %) | *p* value | OR | CI (95 %) | *p* value |
| Loading | Immediate | 1.00 | . | 0.41 | . | . | . | 1.00 | . | 0.83 | . | . | . |
| | Conventional | 0.53 | 0.11–2.52 | | . | . | | 0.85 | 0.19–3.79 | | . | . | |
| Atrophy | Atrophic | 1.00 | . | 0.41 | . | . | . | 1.00 | . | 0.21 | . | . | . |
| | Non atrophic | 0.58 | 0.16–2.12 | | . | . | | 0.44 | 0.12–1.64 | | . | . | |
| Facial type | Mesofacial | 1.00 | . | 0.31 | . | . | . | 1.00 | . | 0.14 | 1.00 | . | 0.12 |
| | Brachyfacial | 0.70 | 0.14–3.36 | | . | . | | 0.70 | 0.14–3.36 | | 0.99 | 0.18–5.40 | |
| | Dolichofacial | 0.31 | 0.06–1.47 | | . | . | | 0.22 | 0.04–1.09 | | 0.18 | 0.03–0.99 | |
| Anteroposterior skeletal discrepancy | Class I | 1.00 | . | 0.08 | 1.00 | . | 0.08 | 1.00 | . | 0.02 | 1.00 | . | 0.05 |
| | Class II | 0.12 | 0.01–0.88 | | 0.12 | 0.01–0.88 | | 0.10 | 0.01–0.63 | | 0.11 | 0.01–1.06 | |
| | Class III | 0.31 | 0.05–1.90 | | 0.31 | 0.05–1.90 | | 0.31 | 0.05–1.90 | | 0.31 | 0.05–1.93 | |

The statistical power analyses indicate that 40 patients were sufficient to provide high power tests in the CCD users, as shown for the significant associations between the retentionST_X50 (Power: 98%), stability STB (Power: 91%) and facial type STB (Power: 98 %). Furthermore, the associations found in the CCD and IMO users between anteroposterior skeletal discrepancy STB also had high power (CCD = Power: 99 %; IMO = Power: 99 %).

**DISCUSSION**

The benefits of IMO are already widely accepted in the specialized literature [27,28]. The use of implants as complete denture retainers eliminates problems such as lack of retention and stability, contributing to a significant improvement in masticatory function with IMO, as reported by Marcello-Machado et al. [8]. After the transition to IMO, the regression analysis showed that only the anteroposterior skeletal discrepancy interfered in the masticatory function, and only for the STB parameter. Thus, instability and facial type lost their association with the homogenization of food, thereby reducing the factors that determine the masticatory pattern of individuals with IMO. However, little is known about how anteroposterior skeletal discrepancy influences the masticatory performance during transition from CCD to IMO [11].

It is known that factors such as lack of CCD retention and stability directly interfere in the chewing quality of the patients, resulting in an impaired mastication [6]. The adjusted analysis of our data indicate that only CCD retention was significantly associated with the ST_X50, as individuals who had poor retention had an 86% lower chance of achieving a good particle breakdown. A similar result was observed by Marcello-Machado et al. [8], in their study the totally edentulous patients with poor CCD retention presented higher values of X50 in the masticatory performance test, thus showing that the lack of retention negatively affected the performance mastication of these individuals.

Stability, facial type, and anteroposterior skeletal discrepancy were associated with STB in individuals with CCD in the adjusted analysis, after elimination of possible confounding factors. Masticatory function is closely related to particle size reduction and the ability to grind food homogeneously in the oral cavity [18]. Thus, the STB variable of the swallowing threshold test is of great importance in understanding and differentiating the masticatory function of these individuals. Subjects with a chewing impairment may adapt to this limitation and swallow larger food particles, which has a negative impact on the digestive process, and may affect the function of the gastrointestinal tract [29]. Our findings indicate that the lack of CCD stability negatively affected achievement of homogeneous mastication, corroborating the results from Demers et al. [30], who noticed that individuals with poor CCD stability have difficulty breaking and homogenizing foods, especially harder food like fresh apples, carrots and celery sticks. In contrast, Marcello-Machado et al. [8] found no association between stability and masticatory function evaluated through the masticatory performance test that uses a fixed number of cycles. The elimination of confounding factors in the present multivariate study may have allowed to detect this association. Furthermore, in this study the swallowing threshold test was performed to determine the masticatory function instead of standardized tests based on fixed number of masticatory cycles. Thus, the results of this study demonstrate that the STB outcome is important to understand the masticatory function, considering that the abilities to homogenize and crush food are complementary.

Our findings also showed that brachyfacial individuals had achieved a better food homogenization. These individuals are thought to present a greater bite force due to the intense muscular action of the masseter, which probably influences the trituration of the particles during mastication with CCD [12,25]. Conversely, Ochiai et al. [11] found that these individuals experienced a greater difficulty in chewing, and that they had lower odds of good food homogenization in the swallowing threshold test. These authors also emphazised a slight trend towards poorer masticatory function for dolichocephalic subjects and attributed this to the greater range of mandibular movements that the dolichofacial individuals perform during mastication, which probably affects the bite force, and consequently the reduction of the test food particles.

In terms of the anteroposterior skeletal discrepancy, Class II patients presented greater difficulty to homogenize food. This is believed to be due to a greater difficulty adaptation to the CCD, mainly related to the compensation of the malocclusion required in those patients to allow them to establish a Class I antero-posterior relationship. The higher ridge height of these patients interferes with the maxillo-mandibular relationship during rehabilitation, limiting the positioning of the artificial teeth, and inhibiting compensation of the occlusion. Two studies evaluated masticatory performance with differing anteroposterior classifications, one in totally edentulous patients [11] and the other in a large sample of dentate patients [31]. Both showed that Class I patients present a better masticatory performance, as the particle size was reduced more easily. However, these studies presented divergent results regarding the group that obtained a worse masticatory performance. English et al. [31] found that Class III subjects presented greater difficulty in food fragmentation, and a worse masticatory performance for Class II individuals, followed Class III, and Class I subjects, as found in our study. The study of Ochiai et al. [11] did not demonstrate any significant influence of the facial forms in the masticatory performance neither for CD nor for IMO users. The only interesting finding reported for this small sample population, was that the swallowing threshold performance in Class II was significantly worse than in Class I participants.

The present study showed that 1 year after transition from CCD to IMO, the use of IMO did not significantly improve the masticatory function for Class II individuals, as they still presented difficulties in homogenizing food. The Class II individuals likely present difficulties in food homogenization because their anteroposterior discrepancy can hardly be corrected during rehabilitation. Even after installing IMO, Class II subjects were 89 % less likely to have a good homogenization of food compared to the Class I individuals. It is difficult to compensate for the Class II anteroposterior discrepancy by taking the individual to a Class I position, as is often achieved during rehabilitation of Class III individuals.

This is the first study that uses a detailed statistical analysis to study the association between masticatory function (ST_X50 and STB) and exposure variables inherent to the individual morpho- logical characteristics of each patient. The effect of anteroposterior skeletal discrepancy and facial type on masticatory function in both CCD and IMO is still scarcely discussed in the literature. Hence, in this study, patient-related and mandibular complete denture factors that could be associated with masticatory function were tested using logistic regression, eliminating possible confounding factors, and thus verifying the variables that are true predictors of masticatory function. All of these factors should be analyzed together and with caution during a rehabilitation with both CCD and IMO, to predict their possible influence on the masticatory function. Future studies that analyze the predictors of masticatory function are necessary to understand how masticatory performance can be improved in individuals wearing IMO. Studies with larger sample sizes that have differing characteristics to our sample, and which have a longer follow-up period may complement and enrich our findings. The limitations of this study include the size and homogeneity of the sample, in addition to a relatively short follow-up period. Furthermore, studies comparing of the satisfaction between CCD and IMO wearers could help to clarify the relationship between patients' perception and objective measurements of the masticatory function.

**CONCLUSION**

Poor retention and stability are the main factors that influence limited masticatory function of CCD wearers. Rehabilitation with IMO largely eliminates these two problems. However, the use of IMO for 1 year did not significantly improve the food homogenization in Class II individuals. Thus, the poor ability to break down and homogenize food presented by these patients should not be underestimated.

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## 2.2 ARTIGO 2: Evaluation of Bite Force and Masticatory Performance: Complete Denture vs Mandibular Overdenture Users

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**ABSTRACT**

This cross-sectional observational study with 24 patients evaluated differences in bite force (BF) and masticatory performance (MP) between conventional complete denture (CCD) and implant mandibular overdenture (IMO) users and the correlation between these variables. The BF test was performed bilaterally with an occlusal force device. During the MP test, patients were asked to chew Optocal particles for 40 cycles. The Shapiro Wilk test was employed to verify the normality of the data, the student t test to identify differences between groups, and Pearson's correlation to investigate interrelationships between variables. A multiple linear regression was subsequently performed via the stepwise method. P values ≤0.05 were considered statistically significant. Unlike IMO users, CCD users presented a significant difference (25.6%) in BF between the dominant and non-dominant chewing side (p=0.04). IMO users presented significantly higher BF (p=0.01) without presenting a dominant side (p=0.38), and also performed significantly better for the following MP parameters: MPX50 values decreased by 27.25% in IMO users (p=0.01), MPB decreased by 48.38% (p=0.01), and ME 5.6 decreased by 53.25% (p=0.02), while ME2.8 increased by 151.57% (p=0.01). The BF and MPX50 in the IMO

wearers group were negatively correlated (-0.57; p=0.05); this correlation coefficient was the only parameter included in the multivariate regression model. IMO users have higher BF and better masticatory performance than CCD users, especially in terms of chewed particles size reduction. MP is correlated with a higher BF in IMO users through better particle trituration.

Key Words: bite force, masticatory performance, conventional complete dentures, implant mandibular overdentures.

**INTRODUCTION**

The masticatory function of patients rehabilitated with conventional complete dentures (CCD) is impaired when compared to alternatives such as implant-retained prostheses (1,2). The McGill (3) and the York Consensus (4) recommended that implant mandibular overdentures (IMO) supported by two implants are the minimum treatment offered to edentulous patients. IMO have increased retention and stability, which translate into an improvement in masticatory performance (MP). In addition, a large part of this improvement can be attributed to the increase in bite force (BF) after rehabilitation with IMO (5,6).

The BF is a biological variable that is potentially associated with MP, and has become a widely used proxy for analyzing the masticatory functionality resulting from different oral rehabilitations (5,7-9). Some studies (10-13) reported that the BF of patients using IMO is much higher than the BF of CCD users; the BF doubles soon after implant installation (14), and can be up to 123% higher after 1 year of implant placement, reflecting improved food trituration by the posterior teeth of the prosthesis (9). Thus, edentulous patients benefit from improved muscle activity after stabilization of the lower denture by two implants (15).

In addition, the BF is also affected by aging, since aging is associated with both loss in quantity and size of the muscle fibers in the masticatory muscles. In situations with a long period of edentulism, this condition is aggravated by the decrease in muscle density, which leads to muscular atrophy (16,17). Thus, the weakening of the muscles involved in mandibular closure contributes to the decreased maximum bite force observed among CCD users (18).

The instability of the CCD is also thought to inhibit the full potential of the jaw muscles during chewing, since muscle strength increases immediately after stabilization of the implant prostheses by IMO (18). Furthermore, IMO users have thicker masseter muscles than completely edentulous CCD users (16). The beneficial impact on the neuromuscular system after transition to IMO is thought to occur within a rapid adaptation period with duration between 2 and 12 months, as additional changes are not observed after 1 year, even over long follow-up periods (13,19).

Although BF is intrinsically linked to MP, so far there are no studies that evaluated how these parameters are correlated in totally edentulous patients rehabilitated with CCD and IMO. Thus, the present study aims to evaluate differences in BF and MP between CCD and IMO users and the correlation between these variables, using BF tests and objective masticatory function parameters. The null hypothesis to be tested is that there will be no difference between the CCD and IMO groups and no correlation between BF and MP.

## MATERIAL AND METHODS

### *Study Design*

This observational study with a cross-sectional design was approved by the Research Ethics Committee of the UFPEL School of Dentistry (protocol - 2.197.630/2017), and was carried out in accordance with the Declaration of Helsinki and described following the Guidelines for reporting Observational Studies (STROBE). The following inclusion criteria were applied for the CCD group: individuals should be totally edentulous and rehabilitated with new CCD made with thermo-polymerizable acrylic resin (VIPICRIL plus - VIPI® - Pirassununga, SP, Brazil) and artificial acrylic resin teeth (Trilux - VIPI® - Pirassununga, SP, Brazil) mounted in bilaterally balanced occlusion. For inclusion in the IMO group, individuals should have mandibular overdentures retained by two reduced-diameter Facility implants (grade V Ti, NeoPoros surface - Neodent® - Curitiba, PR, Brazil) between the mental foramen, loaded with conventional loading (3 months after osseointegration). Individuals who were using their CCD or IMO for at least 3 months were invited to participate in the study. The sample size calculation was based on the MP (×50) outcome in the study by Van Kampen et al. (20), using the following mean ± standard deviation data: CCD group (4.5±0.8) and IMO group (3.6±0.6). Taking into account 80% power (α=20%), 95% CI, 10 patients in each group were required, totaling 20 patients. To take dropouts into account, this was increased by 20%. Thus, 24 individuals (12 CCD users and 12 IMO users) were invited to participate in the study, and everyone who agreed to participate signed an informed consent form. Sociodemographic sample characteristics such as gender, age, time since maxillary and mandibular edentulism, and mandibular degree of bone atrophy were all collected by the same evaluator (APP).

***Bite Force***

The bite force was analyzed using an Occlusal Force- Kratos gnatodynamometer (model IDDKv4) using three 30-second measurements on each side of the patient's arch (21). The sensor was positioned between the 2nd premolar and the 1st molar and the measurement was performed by a trained evaluator (BLP). The final reported value was calculated as the average of the 3 measurements. The sides with the highest and lowest BF values are hereafter referred to as the dominant side and non-dominant side, respectively (22).

***Masticatory Performance***

The masticatory function was assessed through the Masticatory Performance Test (MP) in which individuals chew a standardized portion (3.7g) of test food (Optocal) for 40 cycles counted and timed by a single evaluator (AMB). The masticated material was expelled in a paper filter and dried at room temperature for 7 days and subsequently processed by a stack of 9 sieves with decreasing mesh sizes ranging from 5.6 mm to 0.5 mm coupled on a shaker. The material retained in each sieve was weighed, and the MPX50 and MPB outcomes were calculated using the Rosin- Rammler formula. The MPX50 value obtained reflects the average particle size and corresponds to the theoretical sieve opening through which 50% of the crushed particles would pass. The MPB index reflects homogenization of the triturated particles, with lower MPB values corresponding to more homogeneous particle size distributions (5). The percentage of test food retention in the 5.6, 4.0, and 2.8 mm sieves is known as the masticatory efficiency (ME 5.6, ME 4.0, and ME 2.8, respectively).

***Statistical Analysis***

The data normality was tested by the Shapiro Wilk test. The Student t-test was used to check for differences between the groups, Pearson's correlation coefficient was used to test for associations between the MP with BF and sample characteristics. A subsequent multiple linear regression was performed via the stepwise method. P values ≤0.05 were considered statistically significant for all analyses.

## RESULTS

The CCD group consisted of 8 women (66.67%) and 4 men (33.33%) with an average age of 62.33 ± 7.35 years and an average time since maxillary and mandibular edentulism of 24.00 ± 15.03 and 19.65 ± 15.69 years, respectively. The IMO group consisted of 9 women (75%) and 3 men (25%) with an average age 70.16 ± 7.73 years and an average time since maxillary and mandibular edentulism of 24.89 ± 15.36 and 19.65 ± 15.68 years, respectively. The CCD group contained 7 (58.33%) clinically atrophic individuals whereas the IMO group contained 9 (75%). The majority (n=16) of the participants are retired (66.66%), 13 are married (54.16%), and 15 lost their teeth due to periodontal disease (62.5%).

Table 1 lists the intergroup BF data and shows that the average BF of IMO users was 127.52% higher than the average BF of CCD users (p=0.01). All evaluated MP parameters were significantly different between the groups, except for the percentage of material retained in the 4.0 mm sieve (ME 4.0). Compared to CCD users, IMO users had 27.25% lower MPX50 values (p=0.01), 48.38% lower B-values (p=0.01), and 53.25% lower ME 5.6 (p=0.02), while ME 2.8 was 151.67% higher (p=0.01).

Table 1. Intergroup differences: means (standard deviation; SD) (t-test;p≤0.05)

| | CCD | IMO | p value |
|---|---|---|---|
| | Mean (SD) | Mean (SD) | |
| Bite force | 3.27 (0.90) | 7.44 (5.20) | 0.01 |
| MPX50 | 5.54 (1.22) | 4.03 (1.45) | 0.01 |
| MPB | 7.42 (3.87) | 3.83 (2.65) | 0.01 |
| ME 5.6 | 55.45 (29.12) | 25.92 (30.57) | 0.02 |
| ME 4.0 | 16.42 (10.41) | 15.34 (5.67) | 0.75 |
| ME 2.8 | 8.05 (12.05) | 20.26 (11.50) | 0.01 |

CCD: conventional complete denture users; IMO: implant mandibular overdenture users.

Table 2 lists the intragroup differences in BF between the dominant and non-dominant side of the groups. CCD wearers showed significant BF differences between the sides (p=0.04) and the BF of the non-dominant side was on average 25.6% lower. IMO users exerted statistically indistinguishable BF on each side (p=0.38).

Table 2. Intragroup differences in bite force (BF) between dominant side and non-dominant side (t-test; $p \leq 0.05$)

| | BF CCD | | BF IMO | |
|---|---|---|---|---|
| Side | Mean | P value | Mean | P value |
| Dominant | 3.75 | 0.04 | 8.00 | 0.38 |
| Non-dominant | 2.79 | | 6.40 | |

No correlations were found between MP and BF, gender, age, time since maxillary and mandibular edentulism, and degree of mandibular bone atrophy. There was only a significant negative correlation between MPX50 and BF (Table 3) in the IMO group (coef=-0.57; p=0.05), indicating that lower MPX50 values, i.e., improved test food reduction capacity, are associated with higher BF values. When the MP variables were included in a multiple regression model, only the MPX50 outcome was significant in the final model (F=5.05; p≤0.01; r2:0.33;p≤0.01), proving an interrelation between test food reduction (MPX50) and BF for IMO users.

Table 3. Correlations between bite force and masticatory performance outcomes and sample characteristics (Pearson's correlation coefficients)

| Variables | CCD | | | | | | IMO | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | BF | MPX50 | MPB | ME 5.6 | ME 4.0 | ME 2.8 | BF | MPX50 | MPB | ME 5.6 | ME 4.0 | ME 2.8 |
| | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) | Coef. (pvalue) |
| Bite force | - | -0.29 (0.35) | 0.03 (0.90) | -0.26 (0.40) | -0.08 (0.78) | 0.18 (0.57) | - | -0.57 (0.05)* | -0.36 (0.24) | -0.45 (0.13) | -0.28 (0.37) | 0.38 (0.22) |
| Gender | 0.11 (0.71) | 0.05 (0.87) | 0.30 (0.33) | 0.02 (0.95) | -0.14 (0.96) | -0.21 (0.50) | 0.46 (0.12) | -0.33 (0.28) | -0.39 (0.20) | -0.39 (0.21) | -0.35 (0.25) | 0.22 (0.48) |
| Age | 0.34 (0.27) | -0.21 (0.51) | -0.23 (0.46) | -0.27 (0.38) | 0.03 (0.90) | -0.58 (0.85) | 0.23 (0.46) | -0.22 (0.49) | -0.14 (0.64) | -0.34 (0.27) | -0.46 (0.12) | 0.16 (0.60) |
| Time since maxillary edentulism | -0.18 (0.57) | -0.10 (0.74) | -0.22 (0.48) | -0.16 (0.60) | -0.40 (0.19) | -0.20 (0.51) | -0.32 (0.30) | 0.16 (0.61) | 0.14 (0.64) | 0.22 (0.47) | -0.70 (0.82) | -0.32 (0.30) |
| Time since mandibular edentulism | -0.21 (0.51) | 0.04 (0.89) | -0.73 (0.82) | -0.02 (0.94) | -0.49 (0.10) | -0.32 (0.30) | -0.17 (0.58) | 0.09 (0.77) | -0.55 (0.86) | -0.06 (0.84) | -0.11 (0.71) | -0.02 (0.94) |
| Mandibular bone atrophy | 0.02 (0.95) | -0.34 (0.27) | -0.20 (0.53) | -0.36 (0.24) | 0.16 (0.61) | 0.22 (0.47) | 0.28 (0.37) | -0.38 (0.22) | 0.05 (0.86) | 0.00 (0.99) | -0.20 (0.50) | -0.20 (0.53) |

CCD: conventional complete denture users; IMO: implant mandibular overdenture users; *Significant correlation.

**DISCUSSION**

Many studies (5,10,15,21,23) demonstrated that the masticatory performance of IMO users increases, likely because the implants improve retention and stability of the mandibular prostheses. This ensures that the masticatory muscles are used exclusively for chewing and homogenizing the particles, because they are no longer needed to maintain the prostheses in a resting position. After transition to IMO, improvements of around 20% to 47% are reported in outcomes such as MPB and in the ME5.6 sieve (23). So far, few studies assessed whether BF correlates with the masticatory performance of IMO users (8,15), and the majority analyzes only differences in the mean values of BF between CCD and IMO users (14,21,24). In the present clinical study, IMO users obtained superior BF and MP values than CCD users and the increased retention of the prostheses provided by two implants was able to equalize the difference in BF between dominant side and non-dominant side. Our robust statistical analysis indicates that BF was only correlated with masticatory performance via the MPX50 outcome of IMO users.

Our results are consistent with those from previous studies analyzing BF in IMO users, which show that these individuals can present BF up to 2 times higher (14) and after 1 year up to 123% higher (9), when compared to CCD users. The literature shows that CCD wearers use the perioral and masticatory muscles to compensate for the lack of retention and stability of their prostheses, especially the lower prosthesis, and this can result in a decreased BF, as observed in this clinical study. However, Schimmel et al. (21) found no significant differences in BF between the CCD and IMO groups, and this was attributed to the younger mean age of CCD group. It is well-known that age has a direct influence on BF, as increasing age interferes with muscular strength and masticatory muscles of older individuals tend to atrophy, especially when using CCD (8,21). Studies included in a recent review indeed revealed a correlation between age and BF, but the reported effect of age on BF was relatively small. The reported correlation coefficients indicate that age accounts for less than 10% of the BF variation (8).

The present study found no correlations between BF and the degree of mandibular bone atrophy, masticatory parameters, and sociodemographic variables, such as gender, age, maxillary and mandibular time since edentulism, except for a negative correlation with the MPX50 of IMO users showing that greater BF improves food comminution. This is consistent with previous studies (5,25) that also found a correlation between BF and particle comminution. The increased retention and stability generated by the implant-retained overdentures resulted in a greater BF in this group. The correlation with particle comminution can be attributed to this increased stability, as artificial teeth and cusps retained in stable positions are able to crush food more efficiently. Van der Bilt et al. (12) found a significant correlation between the average particle size and the BF immediately after implant installation and this correlation was retained after 10 years of function. Still, BF accounted for almost 60% of the variation in masticatory performance in this study. In contrast to the present study, previous studies (12,25) found that gender was also related to BF. The absence of a significant gender effect in our study can be attributed to the small number of male participants, in addition to the small absolute effect of gender on BF.

In addition, our results indicate a significant (25.6%) difference in BF between the dominant- and non-dominant side of CCD wearers. Even more pronounced differences were recently reported by Shala et al. (22), who found a BF in CCD users that was 80% lower in the non-dominant side. These authors attributed this difference to the individual preference for unilateral chewing, which contributes to muscle tonicity improvements and consequently results in greater BF (22). In our study, the BF of IMO users were similar on both sides, indicating that IMO use equalizes the BF on both sides. This finding agrees with the results of Melo et al. (26), but contrasts with the results of Rismanchian et al. (11), who found that the BF in the dominant side was 21.7% higher. Nonetheless, the superior retention and stability provided by IMO likely allow for a more balanced mastication in most cases.

The main limitations of this study include the lack of electromyographic data and quantification of saliva production during function, which are important masticatory variables and could contribute to the understanding of the relationship between bite force and masticatory performance. In addition, future studies are needed to analyze the relationship between these variables after a longer adaption period with both rehabilitation types, to assess whether the adaptation time can influence the results. Some studies have shown that the BF and MP of CCD users can improve gradually over time (21,27- 29). Clinical studies should also strive for equal gender distributions in the sample population and larger sample sizes to enable assessment of subtler (gender-related) effects.

In conclusion, IMO users achieve higher BF and better masticatory performance than CCD wearers, alongside a lower difference in BF between dominant and non- dominant sides. Masticatory performance in the IMO group correlates with higher BF through improved particle crushing capabilities.

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**2.3 ARTIGO 3:Do implant-retained mandibular overdentures maintain radiographic, functional, and patient-centered outcomes after 3 years of loading?**

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## ABSTRACT

**Objectives:** Analyzing whether radiographic, functional, and oral health-related quality of life (OHRQoL) outcomes are maintained over 3 years of implant-retained mandibular overdenture (IMO) function and investigating the bite force associations in the 3rd year of function.

**Material and methods:** A longitudinal clinical study in which 24 IMO users were evaluated during a 3-year follow-up period. Patients' posterior area index, masticatory function, OHRQoL and bite force were assessed. The masticatory function parameter ST_X50 reflects the opening through which 50% of the crushed particles would pass, ST_B describes the homogeneity of the bolus, and the masticatory efficiency parameters ME_5.6 and ME_2.8 represent the % of material retained in the 5.6 and 2.8 mm sieves, respectively.

**Results:** A significant increase in posterior area index ($p \leq .01$) was found in all evaluated periods. Minor deteriorations in ST_X50 ($p \leq .01$) and ME_5.6 ($p \leq .01$) between the 2nd and the 3rd year coincided with improvements in ST_B ($p \leq .01$), number of cycles ($p \leq .01$), and cycle time ($p = .02$). The global OHIP-Edent score ($p=.02$) and the scores in the functional limitation ($p = .02$), psychological discomfort ($p \leq .01$), and handicap domains ($p \leq .01$) increased significantly between the 2nd and the 3rd year. Correlations between bite force and cycle time ($p = .03$) and between posterior area index and ST_X50 ($p \leq .01$) and ME_2.8 ($p = .02$) were also found.

**Conclusion:** Changes in posterior area index, masticatory function, and OHRQoL are still ongoing during the 3rd year of IMO function. Bite force and posterior area index influence the masticatory function outcomes in the 3rd year of IMO function.


**Keywords:** functional parameters; mandibular overdentures; masticatory function; oral health-related quality of life.

## 1 INTRODUCTION

Short-term functional improvements have been observed in both chewing, bite force (BF), and oral health-related quality of life (OHRQoL) of totally edentulous implant-retained mandibular overdenture (IMO) users (Boven, Raghoebar, Vissink, & Meijer, 2015). These improvements can be verified by assessing masticatory function (MF), which can be determined in two ways: objectively by measuring the ability to masticate synthetic (Optocal) (Marcello-Machado et al., 2018) or natural food such as peanuts and carrots (Berteretche, Frot, Woda, Pereira, & Hennequin, 2015; Kimoto & Garrett, 2003), or subjectively by recording patient-centered outcomes that measure self-perceived chewing abilities via validated questionnaires such as OHIP-Edent (Schuster et al., 2017; Souza, Patrocínio, Pero, Marra, & Compagnoni, 2007; Van der Bilt, 2011). Some studies that objectively measured MF of totally edentulous patients show that IMO use contributes positively to an average reduction by 25 masticatory cycles along with a reduction in time needed to perform masticatory cycles until swallowing, alongside improvements of around 45% and 52% in masticatory efficiency, based on the fraction retained in 5.6 mm aperture sieves and the food homogenization (ST_B), respectively (Bakke, Holm, & Gotfredsen, 2002; Fontijn-Tekamp et al., 2000; Marcello-Machado et al., 2018; Stellingsma, Slagter, Stegenga, Raghoebar, & Mijer, 2005; Van Kampen, Cune, Van Der Bilt, & Bosman, 2005).

The current understanding of the treatment prognosis and the predictability of rehabilitation can be improved by analyzing the relationship between objectively determined MF, the impact of treatment on oral health, along with subjectively measured OHRQoL outcomes regarding prosthetic rehabilitation and their MF (AL- Omiri & Karasneh, 2010; De Souza et al., 2012; Marcello-Machado et al., 2018; Possebon et al., 2018). It is still unclear how these clinical and functional variables interfere in the MF of these individuals, since paired longitudinal clinical studies that follow changes in these parameters are currently scarce (Bakke et al., 2002; Cune, Burgers, Van Kampen, de Putter, & Van der Bilt, 2009; Enkling, Saftig, Worni, Mericske-Stern, & Schimmel, 2017; Van Der Bilt, Burgers, Van Kampen, & Cune, 2010).

The patients’ bite force can directly influence the masticatory function of patients and may account for more than 60% of the variation in masticatory function (Fontijn-Tekamp et al., 2000; Hatch, Shinkai, Sakai, Rugh, & Paunovich, 2001; Van der Bilt, 2011). However, few studies have analyzed the BF of IMO users, especially after 1 year of function (Bakke et al., 2002; Enkling et al., 2017; Geckili et al., 2012). It is well known that the decrease in BF may be related to the aging of individuals and the concomitant decrease in muscle tone, and to types of prosthetic rehabilitation that reduce the activity of mandibular muscles, such as complete dentures (CD) (Van der Bilt, 2011). A 5-year follow-up study of IMO users showed that the BF of these patients improved by about 67.45% after IMO loading and was maintained over 5 years of function (Bakke et al., 2002).

Mandibular overdentures that are retained by two implants are supported both by the implants and by the fibromucosa of the denture-bearing area (Assad, Abd El-Dayem, & Badawy, 2004; Doundoulakis, Eckert, Lindquist, & Jeffcoat, 2003). Some studies (Elsyad, Mohamed, & Shawky, 2017; Tymstra, Raghoebar, Vissink, & Meijer, 2011) have shown that the bone area of the posterior mandible plays an important role in the benefits that rehabilitation with IMO can bring to completely edentulous patients. In addition, the installation of at least two implants in the anterior region of the mandible decreases posterior bone resorption (Kordatzis, Wright, & Meijer, 2003; Radu, Marandici, & Hottel, 2004; Wright, Glantz, Randow, & Watson, 2002). The IMO benefits related to the ideal number of implants for better retention is still intensely debated (Kern et al., 2016; Klemetti, 2008; Passia et al., 2017; Roccuzzo, Bonino, Gaudioso, Zwahlen, & Meijer, 2012; Thomason, Kelly, Bendkowski, & Ellis, 2012) along with the optimal retention system options (Elsyad, Denewar, & Elsaih, 2018; Matthys, Vervaeke, Besseler, & De Bruyn, 2019; Matthys, Vervaeke, Jacquet, & De Bruyn, 2018; Payne et al., 2018; Shah, Yilmaz, & McGlumphy, 2017). IMO rehabilitation proposals frequently advocate reducing the number of implants to minimize the treatment cost and surgical invasiveness. Systematic reviews (Kern, Kern, Wolfart, & Heussen, 2016; Klemetti, 2008; Roccuzzo et al., 2012)and the consensus statement (Thomason et al., 2012) cite strong evidence that 2 implants are adequate number to retain IMO, mainly because four implants revealed only slightly reduced implant loss rates (Kern et al., 2016). That said, IMO retention by single implants installed in the mandibular midline is fairly common and reduces cost and treatment time (Carletti, Pinheiro, Meira, Amaral, & Rodrigues Garcia, 2019; Passia et al., 2017); however, MF improvements are not always observed (Amaral, Souza, Pinheiro, Campos, & Garcia, 2019) and a higher frequency of prosthesis maintenance is required (Passia, Wolfart, & Kern, 2019).

From a biomechanical point of view, IMO retained by 2 implants are still at a disadvantage as they permit IMO movement in the sagittal plane around the support line (Emami, de Souza, Bernier, Rompré, & Feine, 2015), which may contribute to bone loss in the posterior region of the mandible. For this reason, Misch (2007) proposed adding a third implant in the midline to promote greater retention and stability, without increasing the deformation in the mucosa while increasing costs of manufacture and IMO maintenance (Liu et al., 2013). In addition, this results in difficulties removing the IMO for hygiene, especially for the elderly and people with motoric difficulties. Thus, comparative clinical studies that demonstrate clinical superiority of IMO with 3 implants are scarce in the literature and, compared to the 2-implant option, few results are reported to support the adoption of this rehabilitation option. Regarding retentive systems, there is currently insufficient evidence to determine the effectiveness of different fixation systems regarding prosthetic success, maintenance, patient satisfaction, and costs (Payne et al., 2018).

Furthermore, regardless of the number of implants and the retentive system, studies suggest that the mandibular bone tissue should be routinely evaluated to demonstrate the success of IMO, especially in the posterior mandible, which may undergo remodeling over the years (Guckes, Scurria, & Shugars, 1996; Pan et al., 2010). Pan et al., (2010) found that individuals with IMO have high satisfaction, comfort, stability, and better chewing ability than CD users, irrespective of the mandibular residual alveolar ridge height. Thus, there is evidence that bone remodeling in the posterior region does not negatively affect the function of IMO. However, the influence of this bone remodeling process that can be measured by the posterior area index (PAI) and its relationship with the MF are still unknown. Thus, the present study aims to analyze whether radiographic, functional, and OHRQoL results are maintained over the 3 years of IMO function, and to quantify the relationships between BF and PAI with MF and OHRQoL in the 3rd year of function. The null hypothesis to be tested is that there are no statistically significant changes in the outcomes over time and that there is no correlation between BF and PAI with MF and OHRQoL.

# 2 MATERIAL AND METHODS

## 2.1 Study design

This longitudinal clinical study presents the results of a 3-year follow-up cohort of completely edentulous patients using IMO retained by two narrow diameter implants (Facility-Equator System Neodent, Brazil). This study was approved by the Research Ethics Committee of the School of Dentistry/UFPel (protocol nr. 1267086/2015), developed according to the Helsinki 2008 statement and followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (Bastuji-Garin et al., 2013). The sample size calculation was reported in our 1-year study (Marcello- Machado et al., 2018) and indicated that a minimum of 14 patients were necessary to detect differences in masticatory performance outcomes (Grover, Vaidyanathan, & Veeravalli, 2014) with 90% power, $\alpha$ = 5%, and 10% dropouts. Thus, 26 patients were invited to return for IMO evaluations in 2 and 3 years of function for re-assessment the radiographic, functional, and OHRQoL parameters; the baseline for the present study was the first year. All patients who agreed to participate signed an informed consent form. Functional outcomes (masticatory function and bite force) and patient-centered outcomes (OHIP-Edent questionnaire) were evaluated first, and a panoramic X-ray was subsequently requested to determine the bone remodeling according to the PAI. All evaluations were performed by the same trained and calibrated clinician.

## 2.2 Functional outcomes: chewing function and bite force

The MF was determined by the Swallowing Threshold (ST) test in which individuals chewed a portion (3.7 g) of a test food (Optocal) until they felt like swallowing. After chewing, the material was expelled in a paper filter and dried at room temperature for 7 days and processed by the sieve fractionation method, using a stack of sieves with meshes ranging from 5.6 to 0.5 mm mounted on a shaker. The material retained in each sieve was weighed, and the ST_X50 (median particle size) and ST_B outcomes were calculated using the Rosin–Rammler formula. The ST_X50 value corresponds to the theoretical sieve opening through which 50% of the crushed particles would pass by weight and the ST_B index describes the homogeneity of the particles (Fontijn-Tekamp et al., 2000).

To complement the masticatory analysis, masticatory efficiency (ME_5.6 and ME_2.8) reflects the percentages of material retained in sieves with apertures of 5.6 and 2.8 mm and the number of cycles and time until completion were also recorded. The bite force (BF) was measured via three 30-s measurements on each side using an Occlusal Force-Kratos equipment device (model IDDKv4) (Schimmel, Memedi, Parga, Katsoulis, & Müller, 2017). The sensor was positioned between the second premolar and the first molar. Subjects were instructed to bite the sensor as hard as possible during the measurement, even if there was minimal displacement of the upper CD. The final BF was calculated as average of the 3 measurements on each side.

### 2.3 Patient-centered outcomes: OHRQoL assessed by OHIP-Edent questionnaire

The OHIP-Edent questionnaire was answered by all participants and interpreted using a numerical scale. The answers for each question were scored as follows: never (0), sometimes (1), and almost always (2). The final sum of the answers in each domain was considered as the domain score; higher final values correspond to worse OHRQoL (Souza et al., 2007).

### 2.4 Radiographic outcomes: bone remodeling by posterior area index

The methodology proposed by Elsyad et al. (2017) was followed to determine the PAI of the residual mandibular ridge via standardized panoramic radiographs with 12.7 x 30 cm DentaScan (Durr Dental, Germany) digital phosphor plate sensors. After exposure, the data were processed in the scanner of the instrument, and the images were adjusted for brightness and contrast with the DBSWin software tools when necessary. Aspect ratios were used to minimize errors related to image magnification and distortion. The posterior mandibular areas (experimental areas) were delineated by the line joining the Gonius (G/G') to the lower edge of the mental foramen (M/M′) and the residual ridge crest (Figure 1). This area was expressed as a proportion of a reference bone area that is unrelated to the ridge crest and not subject to resorption: a posterior triangle formed by G/G′, M/M′ and a point [N/N′] corresponding to the center of the triangle G/G′–M/M′—sigmoid notch [S/S′]. The limits of the experimental areas were constructed as follows: MG and M′–G′, AP and A′–P′ (residual ridge crest to lower jaw edge), MA and M′–A′, and GP and G′–P′; GN and G′–N′ were extended to the residual ridge crest in P and P′. The experimental and reference areas on the left and right sides were plotted using Photoshop software and processed using the ImageJ software. The PAI was calculated by dividing the experimental area by the reference area on each side, and the average of the PAIs on both sides was reported as the final PAI. The bone remodeling of the region was calculated as the difference in yearly PAI ($PAI_{year3} - PAI_{year2}$). All measurements were performed by the same evaluator (APRP) in duplicate, 1 month apart. The data were analyzed with the intra- class correlation test (ICC).

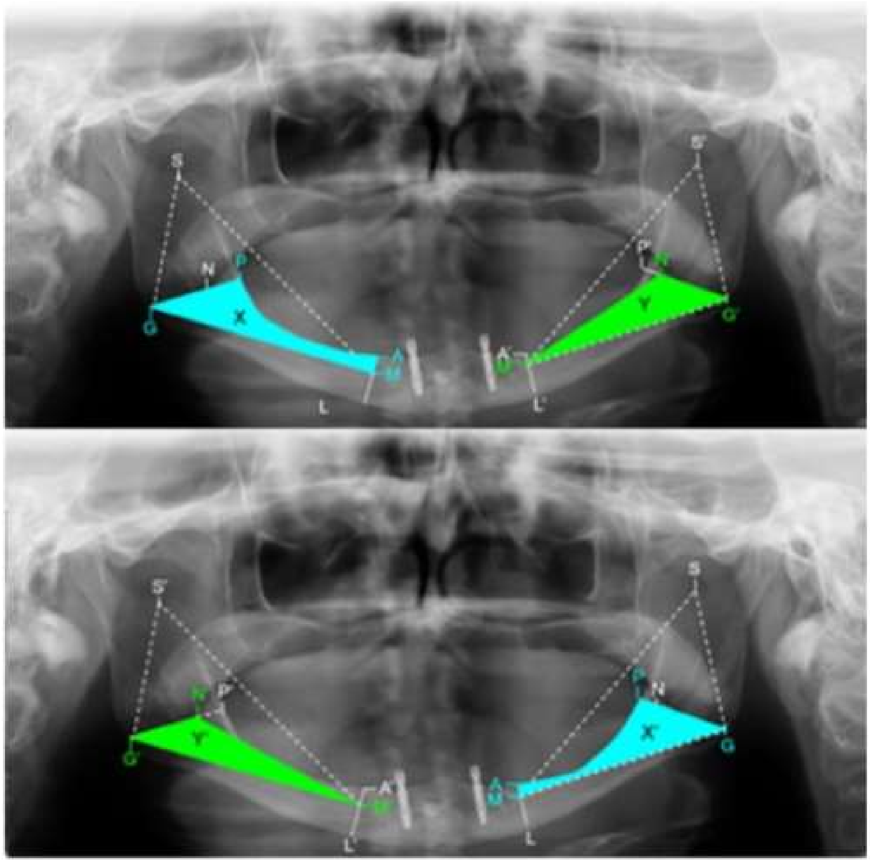


**FIGURE 1** Panoramic radiographs illustrating the procedure for calculating the PAI: X and X 'by the residual crest P–A and P′–A′ and the lines of the region A–M and A′–M′, M–G and M′–G′, and G–P and G′–P′, respectively; Y and Y′ by the triangles M–G–N and M′–G′–N′, respectively. The final PAI was calculated as (X/Y + X′/Y′)/2

## 2.5 Statistical analysis

First, the Shapiro–Wilk test was performed to verify the normality of the data. A multilevel linear mixed-effects regression was subsequently performed because our data have a hierarchical structure. This analysis was used to test the changing trends of variables over time and to fit a growth model to repeated measure data. Time points were established as a fixed effect to test linear trends and the subjects' age as a random effect. In addition, a mixed-effects multivariate regression model was performed to test the correlation between variables. These variables were included and maintained in the regression models, irrespective of their p value. The first year was used as a baseline and the second and third years were included in the statistical analysis to analyze trends in variables over time. All data were analyzed using the STATA SE 14.1 software (StataCorp; College Station, TX, USA), and significance was set at $p \leq .05$.

**3 RESULTS**

A total of 26 patients were invited to return for their IMO assessment; however, two follow-up losses occurred between the first and the second year, one due to death and the other patient moved to a different city. Thus, a total of 24 patients were assessed during the 2nd and 3rd year of their IMO function. The average age of the sample was 69.9 years, 17 individuals (70.83%) were female, and 18 individuals (75%) were classified as atrophic according the Cawood and Howell (1988). The ICC of the radiographic PAI measurements was 0.99.

Table 1 lists the results over time for masticatory function, showing significant differences for ST_X50 at all evaluated time periods. Furthermore, there was an improvement in food crushing after 2 and 3 years compared to the first year of function ($p = .02$ and $p \leq .01$, respectively) coinciding with a slight deterioration by 2.75% in particle crushing (ST_X50, $p \leq .01$) between years 2 and 3. Significant improvements in particle homogenization ((ST_B; $p \leq .01$) were observed between 1 and 2 years and between 2 and 3 years. The percentage of food retained in the 5.6 mm sieve (ME_5.6) reflected significant improvements during the 2nd ($p \leq .01$) and 3rd years ($p \leq .01$) compared to year 1. However, the amount of material retained in this sieve increased by 34.99% ($p \leq .01$) between 2 and 3 years, indicating a deterioration in the masticatory efficiency during this period. The material retained in the 2.8 mm sieve (ME_2.8) only showed a significant difference between the 1st and 3rd year, showing a minimal reduction in the retention in this sieve. The number of chewing cycles average also significantly increased from 56.37 to 59.33 between the 1st and 3rd year ($p = .04$). However, there was a small but significant reduction (1.12%) in the number of cycles between years 2 and 3 ($p \leq .01$). This was accompanied by a progressive decrease in time needed until swallowing between the 1st and 2nd year ($p \leq .01$) and between the 2nd and 3rd year ($p =$ .02).

**TABLE 1** Results of the multilevel regression of mixed effects of masticatory function (CI, Confidence Interval)

| | Masticatory function | | | |
|---|---|---|---|---|
| | 1 Year | 2 Years | 3 Years | 2–3 Years |
| | Mean/ Reference | Mean/Coefficient (p value) [95% CI] | Mean/Coefficient (p value) [95% CI] | Coefficient (p value) [95% CI] |
| ST_X50 | 4.00/1.00 | **3.63/0.30 (.02)** [0.04;0.56] | **3.73/0.66 (≤.01)** [0.40;0.92] | **0.58 (≤.01)** [0.32;0.84] |
| ST_B | 3.66/1.00 | **3.25/1.43 (≤.01)** [0.93;1.92] | 3.17/−0.00 (.91) [−0.05;0.04] | **0.09 (≤.01)** [0.08;0.10] |
| ME_5.6 | 22.99/1.00 | **13.89/0.61 (≤.01)** [0.17;1.04] | **18.75/0.63 (≤.01)** [0.27;0.99] | **0.48 (≤.01)** [0.21;0.74] |
| ME_2.8 | 23.36/1.00 | 12.68/−0.07 (.54) [−0.31;0.16] | **23.28/0.67 (≤.01)** [0.39;0.94] | 0.18 (.27) [−0.14;0.52] |
| Masticatory cycles | 56.37/1.00 | 60.00/0.26 (.20) [−0.14;0.66] | **59.33/0.37 (.04)** [0.01;0.73] | **0.43 (≤.01)** [0.12;0.73] |
| Time | 56.59/1.00 | **56.36/0.80 (≤.01)** [0.40;1.21] | 54.56/0.16 (.47) [−0.28;0.60] | **0.45 (.02)** [0.06;0.84] |

*Note:* Bold text indicates significant difference between evaluation times ($p \leq .05$)

The global OHIP-Edent score (Table 2) significantly differed between all follow-up periods: the score decreased (improved) between the 1st and the 2nd year, and subsequently increased (deteriorated) between the 2nd and the 3rd year ($p \leq .01$; $p = .02$, respectively). This evolution was reflected by concomitant decreases in the psychological discomfort ($p = .02$; $p \leq .01$ and $p \leq .01$, respectively) and psychological disability domains (all $p \leq .01$). The global scores and the scores in the psychological discomfort domain increased (worsened) after 3 years, while the score of the psychological disability domain remained constant in all periods. The functional limitation ($p \leq .01$) and physical pain ($p \leq .01$) domains improved significantly between year 1 and 2. However, the score in the functional limitation subsequently worsened between year 2 and 3 ($p = .02$). The physical disability domain showed differences between the 1st and 2nd year ($p \leq .01$) and between the 1st and 3rd year ($p = .03$). The score in the handicap domain also increased significantly between year 2 and 3 ($p \leq .01$).

**TABLE 2** Results of the multilevel regression of mixed effects of OHRQoL assessed via OHIP-Edent questionnaire (CI, Confidence Interval)

| | OHIP-Edent (OHRQoL) | | | |
|---|---|---|---|---|
| | 1 Year | 2 Years | 3 Years | 2-3 Years |
| | Mean/ Reference | Mean/Coefficient (p value) [95% CI] | Mean/ Coefficient (p value) [95% CI] | Coefficient (p value) [95% CI] |
| DOMAINS | | | | |
| Functional Limitation | 1.20/1.00 | **1.00/0.69 (≤.01)** [0.38;1.01] | 1.91/0.13 (.17) [−0.06; 0.33] | **0.24 (.02)** [0.02;0.46] |
| Physical Pain | 0.87/1.00 | **0.42/0.67 (≤.01)** [0.25;1.08] | 0.83/0.08 (.61) [−0.25;0.42] | 0.17 (.06) [−0.01;0.36] |
| Psychological Discomfort | 0.25/1.00 | **0.21/−0.33 (.02)** [−0.62;0.04] | **0.37/0.61 (≤.01)** [0.47;0.75] | **0.25 (≤.01)** [0.07;0.42] |
| Physical Disability | 0.42/1.00 | **0.33/1.24 (≤.01)** [1.01;1.46] | **0.45/0.25 (.03)** [0.01;0.49] | 0.25 (.12) [−0.06;0.57] |
| Psychological Disability | 0.16/1.00 | **0.16/0.50 (≤.01))** [0.35;0.64] | **0.16/0.50 (≤.01)** [0.37;0.62] | **0.45 (≤.01)** [0.16;0.74] |
| Social Disability | 0.12/1.00 | 0.00/1.00 (1.00) – | 0.00/1.00 (1.00) – | 1.00 (1.00) – |
| Handicap | 0.20/1.00 | **0.08/2.00 (≤.01)** [1.74;2.26] | 0.20/−0.02 (.76) [−0.21;0.15] | **0.43 (≤.01)** [0.22;0.64] |
| GLOBAL | 3.25/1.00 | **2.20/0.93 (≤.01)** [0.73;1.13] | **3.95/0.19 (≤.01)** [0.04;0.34] | **0.20 (.02)** [0.02;0.39] |

*Note:* Bold text indicates significant difference between evaluation times ($p \leq .05$)

The mean PAI values of the mandibular residual ridge (Table 3) increased significantly between years 1 and 2 ($p \leq .01$) and between years 2 and 3 ($p \leq .01$). Over the 3 years of follow-up, there was on average a small increase in the posterior bone area of the mandible (+0.02 $mm^2$), indicating an average yearly gain of 0.01 $mm^2$. Of the 24 patients included in the sample, 15

**TABLE 3** Results of the multilevel regression of mixed effects of Posterior Area Index (CI, Confidence Interval)

| Posterior Area Index | | | |
|---|---|---|---|
| 1 Year | 2 Years | 3 Years | 2-3 Years |
| Mean/Reference | Mean/Coefficient (p value) [95% CI] | Mean/Coefficient (p value) [95% CI] | Coefficient (p value) [95% CI] |
| 1.13/1.00 | **1.14/0.90 (≤.01)** [0.54;1.26] | 1.15/0.01 (.92) [−0.34;0.38] | **0.94 (≤.01)** [−0.34;0.38] |

*Note:* Bold text indicates significant differences between evaluation times ($p \leq .05$)

(62.5%) presented posterior bone gains (0.01–0.21 $mm^2$) and 9 (37.5%) presented a reduction in the posterior area (−0.02 to −0.12 $mm^2$).

The multivariate model showed a correlation between BF and time of chewing cycles (coef: 0.05; $p$ = .03). Meanwhile, the PAI was only correlated with the ST_X50 (coef: 0.06, $p \leq .01$) and the ME_2.8 (coef: 0.00, $p$ = .02) (Table 4).

**TABLE 4** Multivariate mixed-effects regression model to evaluate the correlation between bite force, posterior area index, and masticatory function parameters in the 3rd year of function (CI, Confidence Interval)

| | Bite force | | | Posterior area index | | |
|---|---|---|---|---|---|---|
| | Coefficient | p value | 95% CI | Coefficient | p value | 95% CI |
| ST_X50 | −.02 | .47 | −1.11; 0.52 | **.06** | **≤.01** | **0.02;0.11** |
| ST_B | .24 | .49 | −0.46; 0.94 | .00 | .77 | −0.03;0.05 |
| Time | **.05** | **.03** | **0.00;0.11** | .00 | .44 | −0.02;0.00 |
| Masticatory Cycles | −.51 | .06 | −0.10;0.00 | −.00 | .56 | −0.00;0.00 |
| ME_5.6 | .01 | .49 | −0.31;0.06 | .00 | .09 | −0.00;0.00 |
| ME_2.8 | .03 | .41 | −0.05;0.13 | **.00** | **.02** | **0.00;0.01** |
| Posterior area index | 2.84 | .38 | −3.51;9.20 | – | – | – |

*Note:* Bold variables indicate significant correlations between the outcomes ($p \leq .05$)

Finally, no correlation was found between BF and PAI with OHRQoL (Table 5).

TABLE 5 Mixed-effects multivariate regression model to evaluate the correlation between bite force and posterior area index with OHRQoL-related outcomes in the 3rd year of function (CI, Confidence Interval)

| | Bite force | | | Posterior area index | | |
|---|---|---|---|---|---|---|
| | Coefficient | p value | 95% CI | Coefficient | p value | 95% CI |
| Domains | | | | | | |
| Functional Limitation | 9.51 | .53 | −20.53;39.56 | −.13 | .89 | −2.14;1.86 |
| Physical Pain | 9.88 | .51 | −19.99;39.76 | −.07 | .93 | −2.07;1.91 |
| Psychological Discomfort | 10.23 | .52 | −20.89;41.35 | .17 | .86 | −1.89;2.25 |
| Physical Disability | 9.79 | .53 | −20.75;40.34 | −.00 | .99 | −2.03;2.03 |
| Psychological Disability | 16.88 | .57 | −41.94; 75.71 | −.68 | .73 | −4.58;3.22 |
| Social Disability | 1.00 | 1.00 | – | 1.00 | 1.00 | – |
| Handicap | 1.00 | 1.00 | – | 1.00 | 1.00 | – |
| Global | −9.66 | .54 | −39.82;20.48 | .09 | .92 | −1.91;2.1 |

## 4 DISCUSSION

The present study is the first that analyzed the 3-year behavior of radiographic, functional, and OHRQoL-related parameters, and the correlation between these variables for IMO users. The robust statistical analysis in the present study clearly demonstrates significant changes over time and correlation between the investigated variables, and thus, the null hypothesis was rejected. All evaluated parameters (PAI, MF and OHRQoL) changed significantly during the 3 years of evaluation. A significant increase in PAI showed that even after installation of the implants, mandibular bone remodeling continues during the 3rd year of function. Moreover, the results show that that BF and PAI still correlate with MF during the 3rd year of IMO function.

A slight deterioration of the masticatory function between the 2nd and 3rd year is indicated by a 2.75% increase of the ST_X50 parameter and a concomitant 34.99% increase in sieve 5.6 retention. However, these results were still significantly better than after the first year of IMO function. In addition, the homogenization (ST_B) of the particles continued to improve over time, and the number of chewing cycles and the time until swallowing also decreased between 2 and 3 years. Previous MF analysis has shown that this decrease in time and number of cycles can directly interfere with food trituration (ST_X50), as individuals tend to chew less and want to swallow the food earlier (Al-Magaleh, Abbas, Amer, Abdelkader, & Bahgat, 2016; Van Der Bilt et al., 2010). The systematic review by Van der Bilt. (2011) has shown that subjects with good masticatory function do not always swallow food after a smaller number of cycles, because ST is influenced both by the physiology of the individual (e.g., masticatory muscles) and by the social context. Thus, because the patients are well adapted to their IMO, their masticatory muscles work exclusively to crush and homogenize foods, as they are no longer necessary to keep the prosthesis in a resting position. However, social expectations can also drive individuals to chew faster at the expense of their masticatory performance. Our results can at least in part be attributed to these factors.

The OHIP-Edent scores in some domains also deteriorated during the 3rd year of function, showing that the patients' satisfaction with the IMO treatment began to decrease. The global score, functional limitation, psychological discomfort, and handicap domains displayed the highest increases between 2 and 3 years. A systematic review (Boven et al., 2015) previously concluded that the effects of IMO on OHRQoL are still uncertain, as some studies show that the improvements achieved in the first year remained stable over 5 (Martínez-González, Martín-Ares, Cortés-Bretón Brinkmann, Calvo- Guirado, & Barona-Dorado, 2013) to 10 years (Cune et al., 2009). However, these authors argued that improvements in satisfaction do not necessarily lead to improvements in OHRQoL and that the questionnaires used may contribute to these uncertain findings, because they may address outcomes from different viewpoints and different foci of self-perception. The systematic review by Emami, Heydecke, Rompré, de Grandmont, and Feine. (2009) also compiled studies that analyzed OHRQoL in individuals with IMO, but only 2 of these evaluated for a period longer than 2 years (Kapur et al., 1999; Meijer et al., 2003). These authors also found that individuals treated with IMO show better OHRQoL than those rehabilitated with CD. So far, few studies (Cune et al., 2009; Martínez-González et al., 2013; Meijer et al., 2003) have analyzed OHRQoL for periods greater than 1 year and few addressed the evolution of OHRQoL of the same individuals as IMO wearers, inhibiting direct comparison with our results. Our study results show that progressive improvements in OHRQoL occur up to 2 years. However, the subsequent deteriorating during the third year can be attributed to the mucosal support of the 2 unconnected implants in the posterior region. This study observed bone changes in this region, which may decrease the local stability. Instability generated by gradual wear combined with posterior bone remodeling may negatively contribute to the patients' OHRQoL, especially in the functional, psychological, and handicap domains.

The progressive increase of PAI over time indicates that the normally progressive bone resorption in this region was reversed in our sample. A previous 6-year study of found that IMO users had significantly reduced mandibular bone resorption (by approximately 76.4%) compared to the CD user group, in accordance with our results (López-Roldán, Abad, Bertomeu, Castillo, & Otaolaurruchi, 2009). Another study (Kordatzis, Wright, Meijer, & a., 2003) with a similar methodology also found that during 5 years of function, individuals rehabilitated with IMO gained bone in the posterior mandible. This study also showed that patients diagnosed with mandibular bone atrophy gain more bone (+0.12 mm) in the posterior mandible than non-atrophic ones. Treatment with IMO was able to reverse bone resorption, with mean bone gains of 0.03 mm in the posterior mandible over 5 years in non-atrophic patients (Kordatzis et al., 2003), consistent with our results. In addition, Kimoto and Garrett (2003) showed that individuals with prominent mandibular bone resorption prior to implant placement benefited more from IMO use than those with lower bone resorption, as MF and satisfaction outcomes were better in this group. Other authors also showed that age may influence posterior bone loss in patients rehabilitated with IMO (Elsyad et al., 2017; Kordatzis et al., 2003): as the age of individuals increases, lower resorption rates are found in the posterior mandible. Since more than half of our sample had bone increase in posterior mandible region (62.5%), and the majority of our sample comprises atrophic individuals with advanced age, these factors may account for the observed small average bone gains in the posterior mandible in this population.

The multivariate model that aimed to evaluate whether BF and PAI could correlate with MF and OHRQoL during the third year of function showed that BF continues to be positively correlated with MF via the number of chewing cycles. According to Van der Bilt (2011), BF directly influences the variation in size reduction of food particle and the swallowing threshold. Moreover, longer chewing time ensures more uniform trituration and softening of foods. The BF of IMO patients are 2 times higher than the BF of CD users (Fontijn-Tekampl et al., 1998), and IMO users' BF could still increase by around 123% after one year (Enkling et al., 2017). However, the studies included in the review by Boven et al. (2015) indicate that this improvement generally occurs in the first year of function and that the BF stabilizes over the years, and that the final BF is still lower than in dentate individuals.

Our results show that the time needed to complete the ST cycles reduces since the 1st year of IMO function. The BF may have been responsible for this reduction in time, because the masticatory muscles may still be adapting to the rehabilitation until the 3rd year of function. The BF increased after transition to IMO in the study by Al-Magaleh et al. (2016), but there was a statistically significant gradual variation in muscle activity throughout the follow-up period and a shorter duration of cycles was recorded for the IMO group, corroborating our results. This finding implies that the time required to chew also depends on the retention and especially on the support of the IMO. Higher retention improves the support of the prosthesis, and consequently BF, because the muscles act exclusively in accordance with their main role, and thus, the patient achieves adequate trituration in less time.

The multivariate model also showed a correlation between the PAI and some of the MF parameters, such as ST_X50 and the percentage retention in the 2.8 mm sieve (ME_2.8). After 3 years, there was a slight worsening in food comminution and a lower retention in this sieve and this may have correlation with the PAI. In addition, the bone area in the posterior region of the mandible increased after 3 years, and this bone remodeling may influence these variables. This bone increase in the posterior region of the mandible can lead to IMO instability in this region and may con- tribute to a deteriorating food comminution and decreasing retention in the fine 2.8 mm sieve.Kimoto and Garrett (2003) discussed the influence of retention and stability of the IMO based on chewing capacity and found that, although IMO treatment provided improvements in prosthesis retention regardless of bone height, this advantage was not directly related to an increased chewing capacity.

This study was able to reliably demonstrate radiographic, functional, and OHRQoL changes that occur during the first 3 years of IMO function. Clinically speaking, the use of IMO retained by 2 non-splinted implants is strongly indicated in cases of total edentulous elderly patients with atrophic mandibles, as they contribute to the reduction of posterior mandibular bone loss and BF improvements. Both the BF and the PAI are related to MF, and possible posterior bone remodeling can affect the IMO stability and retention and, consequently the OHRQoL. Thus, it was found that 2 non-splinted implants are sufficient to reverse bone loss in the posterior region of the mandible; however, this remodeling may increase the IMO’s instability. The use of a third implant in the medial region of the mandible can contribute to continue reversing posterior bone loss, while increasing the IMO retention. In addition, periodic evaluations to assess bone parameters, IMO retention and stability, should be performed routinely to ensure the success and predictability of rehabilitation through improvements in MF and OHRQoL. Furthermore, comparative clinical studies that demonstrate the clinical superiority of the use of 3 implants to retained IMO are still scarce and few results are reported to support the adoption of this rehabilitation option. Regarding the retention systems, there is not enough evidence to determine the clinical effectiveness of the different systems. Thus, future studies analyzing long-term changes in radiographic, functional, and OHRQoL parameters using 2 or 3 implants and different retention systems are desirable to understand the influence of various treatment options on the IMO's long-term behavior. Finally, the limitations of this study include the scarcity of similar studies to guide comparisons, the lack of measurements of masticatory muscle activity during the evaluation period, and that the PAI was investigated only using 2D analysis, because the 3D methodology is not yet standardized and not extensively used in IMO studies.

## 5 CONCLUSION

Masticatory function, OHRQoL, and bone area in the posterior region of the mandible still vary significantly over time. The bite force and the posterior area index were closely correlated and significantly influenced the masticatory function of totally edentulous elderly patients with atrophic mandibles rehabilitated with IMO during the third year of IMO function.

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## CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

## AUTHOR CONTRIBUTION

**Anna Paula da Rosa Possebon:** Conceptualization (equal), Investigation (equal); Methodology (equal); Writing-original draft (equal); Writing-review & editing (equal). **Alessandra Julie Schuster:** Investigation (equal); Methodology (equal); Writing-original draft (equal); Writing-review & editing (equal). **Samille Biasi Miranda:** Investigation (equal); Methodology (equal). **Raissa Micaella Marcello- Machado:** Conceptualization (equal); Formal analysis (equal); Writing-original draft (equal); Writing-review & editing (equal). **Otacilio Luiz Chagas Junior:** Conceptualization (equal); Investigation (equal); Methodology (equal); Writing-original draft (equal); Writing- review & editing (equal). **Fernanda Faot:** Conceptualization (lead); Data curation (equal); Formal analysis (lead); Funding acquisition (lead); Methodology (equal); Supervision (lead); Visualization (lead); Writing-original draft (equal); Writing-review & editing (lead).

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**2.4ARTIGO 4:Influence of facial morphology on masticatory function and quality of life in elders using mandibular overdentures: 3-year results.**

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**Abstract**

**Background:** Facial types may interfere in the oral health-related quality of life (OHRQoL) and masticatory performance of implant-retained mandibular overdenture (IMO) wearers. **Purpose:** Investigate the medium-term changes in the masticatory function (MF) and OHRQoL parameters of IMO users, as a function of facial pattern, anteroposterior skeletal discrepancy, and sex. **Methods:** Forty IMO users, most of them Caucasian (90%) with average age of 69.17 years were classified according to their facial pattern and antero-posterior discrepancy prior to rehabilitation. MF was evaluated by the multiple sieves method to determine the average particle size (X50), heterogeneity (B) and masticatory efficiency (ME, calculated as the percentage of material retained in the 5.6 and 2.8 mm sieves), using Masticatory performance (MP) and swallowing threshold (ST) tests. OHRQoL was measured by applying the dental impact on daily life (DIDL) questionnaire. The data were analyzed by Wilcoxon-paired tests to analyze changes in MF parameters over time, and mixed-effect multilevel regression models were employed to verify differences between groups. **Results:** Significant changes were still observed in the 3rd year for the ST test with improvements in B for Mesofacial and in time for Dolichofacial individuals, while ME_2.8 deteriorated for Brachyfacial participants. B values of Class I and male individuals improved and brachyfacial individuals still presented worse homogenization (B) than Mesofacial participants in both masticatory tests. Class II and III participants still showed improvements in ME_5.6 and time compared to Class I despite increases in X50. Class II individuals needed less cycles than Class I in the 3rd year. Brachyfacial participants scored lower in the Appearance domain than Mesofacial ones in the 3rd year. Dolichofacial participants and Class III patients scored lower in the

Oral Comfort domain than Mesofacial and Class I, respectively. In addition, age influenced the Pain, Oral Comfort and General Performance domains in the 3rd year. **Conclusions:** Differences in facial morphology continue to influence the MF and OHRQoL outcomes in the 3rd year, and age influenced some OHRQoL domains. Brachyfacial individuals continue to benefit least from rehabilitation with IMO according to masticatory parameters.

**Keywords:** mandibular overdentures, facial profile, oral health-related quality of life, facial morphology, anteroposterior skeletal discrepancy, masticatory function

**Introduction**

The masticatory function (MF) of total edentulous individuals can be directly affected by the facial pattern (FP), by the anteroposterior discrepancy (ASD), and the type of prosthetic rehabilitation (1). According to the specialized literature, facial morphology shows cephalometric differences between ethnic groups (2–4). As an example, studies have shown that black and female individuals have a greater depth of the maxilla, whereas white individuals and men have a greater tendency for cranial deflection. Meanwhile, angular cephalometric measurements show no difference between these groups. The facial type is genetically established, and gender influences facial type, mainly through muscle pattern (3, 4). In terms of FP, Mesofacial individuals present a balanced bone profile and facial musculature, thus having a more predictable prognosis during prosthetic rehabilitation with conventional complete dentures (CCD), and consequently, they are considered the standard for comparisons (5, 6). Meanwhile, Brachyfacial individuals may present a greater bite force due to the biomechanical changes resulting from a compressed lower third of their face combined with strong muscle activity, which can contribute to a greater displacement of CCD during function (7, 8). Finally, Dolichofacial individuals present a greater bone height of the residual ridges in both jaws than Brachyfacial individuals (9), which would contribute to a greater stability of this type of rehabilitation with CCD and consequently a superior masticatory performance is expected. Thus, the bone and muscle characteristics of the different FP must be taken into account when planning treatment with complete dentures, to ensure a good prognosis of prosthetic rehabilitation in addition to ensuring the quality of MF (8, 10).

Another important factor capable of influencing the prognosis of totally edentulous rehabilitation is the anteroposterior discrepancy. In this framework, Class I individuals have balanced horizontal bone growth, resulting in have more predictable prosthetic rehabilitation than for Class II and Class III individuals, and thus are considered the standard for comparison (8, 10, 11). The mandibular protrusion of Class III individuals may result in a decreased vertical dimension of occlusion (VDO) (8), while the greater height of the residual bone crest in Class II individuals may enlarge VDO, which can inhibit reestablishment of the adequate maxillomandibular relationship (1, 7). The ASD deviations can often be compensated during prosthetic rehabilitation to improve MF. However, a previous study (9) found that Class III individuals had a reduced capacity to homogenize the bolus even after rehabilitation with new CCDs, suggesting that reestablishment of an effective masticatory pattern is extremely challenging in patients with this profile, and that they need a longer period to adapt to the prostheses.

Rehabilitation with implant mandibular overdentures (IMO) is preferable to the use of CCD, especially when patients experience difficulties adapting to CCD (12). IMO increase the retention and stability of the prostheses, and improve the comfort, speech and masticatory function of individuals, generating greater satisfaction with the treatment and an increase in self-reported oral health-related quality of life (OHRQoL) in the first 3 months of use (13). However, studies have shown that FP and ASD can affect the masticatory pattern that individuals develop even after the transition from CCD to IMO (1, 10, 11). Brachyfacial patients showed only a small short- term improvement in the test food trituration (10) and the FP no longer influenced the quality of chewing already after 1 year of IMO usage (11). Meanwhile, ASD negatively influenced the masticatory function, since Class II patients continued to present difficulties homogenizing the food compared to Class I individuals, both short term (10) and after 1 year of IMO use (11).

Presently, little is known about the medium-term influence of the facial morphology on OHRQoL of IMO users. In a clinical study with a 3-month follow-up time, the authors found that Dolichofacial individuals reported better scores in the Appearance and General Performance domains than Mesofacial individuals, while Class II Individuals reported higher Oral Comfort scores than Class I individuals (10). Despite the observed OHRQoL improvements of these individuals, the benefits of using IMO are perceived differently by the individuals in the short term. Thus, given the gap in the literature regarding the impact of factors such as facial pattern and the anteroposterior discrepancy may still have on MF and OHRQoL of IMO users, the objective of the present study was to investigate the medium-term changes in MF and OHRQoL parameters of IMO wearers as a function of FP, ASD, and sex. The null hypothesis of the study is that these parameters do not vary over time and that differences in the aspects PF, ASD, sex, and age are not able to influence MF and OHRQoL in the 3rd year of function.

**Materials and methods**

This longitudinal clinical study reports 3 year follow-up results of a previous study (10) performed with totally edentulous individuals assessed before transition from CCD to IMO and after 3 months. Initially, all volunteers were rehabilitated with new CCD, which were made with thermo-polymerizable acrylic resin (VIPICRIL plus - VIPI), artificial acrylic resin teeth (Trilux - VIPI) assembled in bilateral occlusion. The new protheses were fabricated in the Complete Denture Clinic by undergraduate students under the supervision of two specialized professors (FF, LRP). Panoramic and lateral radiographs for all participants were performed on a Rotograph Apparatus Plus instrument by a single trained and calibrated technician. The facial pattern (FP) and anteroposterior skeletal discrepancy (ASD) classifications were performed with cephalometric analysis software (CefX version 4.5.10), using cephalometric tracings as described in the previous clinical study (9, 10). Thus, individuals were classified as Mesofacial, Brachyfacial or Dolichofacial through Rickets' analysis, based on 5 angles (14). The ASD classification into class I, II or III was based on 3 angles (15).

The original study recruited completely edentulous elderly participants of both sexes with good general and oral health according to the following inclusion criteria: users of conventional complete dentures with difficulties adapting to a mandibular complete denture, adequate oral hygiene, without self-reported systemic impairments, and with bone heights ≥ 10mm in the anterior region of the mandible. Participants presenting serious systemic diseases that compromised bone healing were excluded, along with uncontrolled diabetes, history of radiotherapy in the head or neck region, previous history of oral implants installation, and participants who underwent treatment with bisphosphonates in the preceding 12 months. At the moment of the 3-year follow-up visit, all participants were ≥65 years and all prostheses were of good quality [category 0 according to the criteria of Vigild (16)].

After 3 months of the adaptation to the new CCD, two narrow diameter implants (Facility implant: 2.9 × 10mm; Ti grade V, NeoPoros surface -Neodent) were installed in the region between mental foramina and immediately connected to healing caps. After a 3-month osseointegration period, the healing caps were replaced by Equator attachments, and the IMO were installed. All implant surgeries were performed by a specialized surgeon (OLCJ) and the IMO were made by prosthodontists. In the previous short-term study, 56 individuals were evaluated; 42 of them (29 women and 13 men) met the inclusion criteria, signed the informed consent form, and participated in the study. Volunteers who presented decompensated diabetes, uncontrolled hypertension, hemorrhagic disorders, severe systemic diseases, compromised immune system, or a history of radiotherapy in the head or neck region were excluded. The participants in the aforementioned study had an average age of 66.31 years, an average time since mandibular edentulism of 24.14 years. Most individuals are Caucasian/white (90%), 1 is of Asian origin (2.5%) and 3 are brown/black (7.5%). The sample comprised 33% Dolichofacial (8 women and 6 men), 31% Brachyfacial (9 women and 4 men), and 36% Mesofacial participants (12 women and 3 men). In terms of ASD, the sample consisted of 26% of Class I (6 women and 5 men), 29% Class II (7 women and 5 men) and 45% Class III participants (16 women and 3 men). This report follows the STROBE guidelines (17), was conducted in accordance with the Declaration of Helsinki 2008, and was approved by the Research Ethics Committee of the Faculty of Dentistry UFPel, protocol (No. 69/2013). The 42 volunteers were contacted via telephone for annual assessments 1–3 years after occlusal IMO loading for evaluation of masticatory function and oral health-related quality of life (OHRQoL) would be carried out.

To assess masticatory performance (MP), individuals were instructed to chew 17 cubes with sides of 5.6 mm (≈3.7 g) of "Optocal" test material for 40 cycles (18). During the swallowing threshold (ST) test, participants chewed another 17 cubes until they felt like swallowing, and the number of cycles and the time to execute the cycles were recorded (19). After both tests, the crushed material was expelled on a paper filter, dried at room temperature for 7 days and passed through multiple sieves. The material retained in each sieve was then weighed, and the average sieve opening through which 50% of the masticated material would pass (X50) and the homogeneity of the chewed particle distribution (B) were calculated. The masticatory efficiency parameters (ME_5.6 and ME_2.8) were calculated as the percentage of material retained in the 5.6 and 2.8mm sieves (20, 21).

The OHRQoL was assessed through the DIDL questionnaire that assesses self-reported satisfaction through 36 questions divided into 5 domains: Appearance, Pain, Oral Comfort, General Performance, and Chewing (22, 23). The possible answers are agreed, neutral or disagreed, scored as +1, 0, and −1, respectively. All annual evaluations were performed by a single evaluator. Multilevel mixed effect regression models were used to estimate the effect of time on masticatory outcomes (MP, ST, and ME) and OHRQoL according to FP, ASD, sex and age, using Mesofacial and Class I patients as the reference groups. Regression coefficients and 95% confidence intervals were estimated, and $p$-values $\leq 0.05$ were considered statistically significant. Intra-group changes in the masticatory parameters between the evaluation periods, as indicated by a significant time effect in the regression analysis, were assessed through the Wilcoxon-paired test using Bonferroni correction of the $P$-values ($P$-value required for significance = 0.05/3 = 0.0166). For the OHRQoL analyses, the effect size (ES) was calculated as the difference in the mean scores of the DIDL domains divided by the standard deviation of the previous evaluation period. The effect size was classified as small ($ES < 0.5$), moderate ($0.5 < ES < 0.8$) or large ($ES \geq 0.8$) (24). All analyses were performed using the Stata 14.1 software (StataCorp).

**Results**

Of the 42 individuals included in the initial study, 40 returned for evaluation at 1 and 3 years. The two follow-up losses were 2 women (1 Brachyfacial and Class III, and 1 Dolichofacial and Class I) and occurred due to loss of contact between 3 months and 1 year. The average age of the individuals evaluated in this period was 69.17 ± 3.93 years.

The mixed-effect multilevel regression models showed significant differences in B values between Brachyfacial and Mesofacial individuals in the

**TABLE 1 |** Mixed-effects regression model of the masticatory performance outcomes (MP- 40 cycles) according to facial pattern (FP), anteroposterior skeletal discrepancy (ASD), sex, and age.

| | Masticatory performance test | | | |
|---|---|---|---|---|
| **Outcomes** | **MP_X50, coefficient (95%CI)** | **MP_B, coefficient (95% CI)** | **MP_ME _5.6, coefficient (95% CI)** | **MP_ME_ 2.8, coefficient (95% CI)** |
| **Time** | | | | |
| 3 months | Ref. | Ref. | Ref. | Ref. |
| 1 year | **0.51 (0.14; 0.89)** | 0.55 (−0.18; 1.28) | 0.28 (−0.11; 0.69) | **0.46 (0.16; 0.76)** |
| 3 years | 0.27 (−0.07; 0.62) | 0.36 (−0.34; 1.07) | **0.53 (0.12; 0.94)** | 0.31 (−0.04; 0.67) |
| 1–3 years | **0.58 (0.33; 0.82)** | **0.65 (0.42; 0.89)** | **0.66 (0.40; 0.92)** | **0.58 (0.22; 0.93)** |
| **FP** | | | | |
| Mesofacial | Ref. | Ref. | Ref. | Ref. |
| Brachyfacial | 0.58 (−0.72; 1.88) | **0.25 (0.04; 0.45)** | 0.49 (−0.24; 1.22) | 0.60 (−0.27; 1.48) |
| Dolichofacial | 0.45 (−0.84; 1.79) | 0.28 (−0.95; 1.52) | 1.06 (−0.61; 2.73) | 0.93 (−0.74; 2.60) |
| **ASD** | | | | |
| Class I | Ref. | Ref. | Ref. | Ref. |
| Class II | 0.80 (−1.10; 2.70) | 0.02 (−2.02; 2.08) | 1.44 (−3.04; 5.94) | 1.42 (−0.75; 3.60) |
| Class III | 0.11 (−0.79; 1.01) | −0.15 (−0.59; 0.27) | −0.00 (−1.30; 1.29) | −0.26 (−0.97; 0.44) |
| **Sex** | | | | |
| Male | Ref. | Ref. | Ref. | Ref. |
| Female | 0.15 (−0.29; 0.61) | −0.17 (−0.43; 0.07) | 0.01 (−0.29; 0.31) | 0.08 (−0.47; 0.65) |
| **Age (years)** | −0.01 (−0.05; 0.04) | −0.01 (−0.09; 0.06) | 0.22 (−0.74; 1.19) | 0.06 (−0.34; 0.48) |

*MP_X50, particles trituration; MPB, chewing homogenization; MP_ME_5.6, % material retained in the 5.6 mm sieve; MP_ME_2.8, % material retained in the 2.8 mm sieve. Bold font indicates statistically significant differences.*

3rd year, both in the MP ($p \leq 0.01$, **Table 1**) and in the ST test ($p \leq 0.01$, **Table 2**). Brachyfacial individuals showed worse food homogenization, as indicated by B values that are 28.78% higher in the ST test and 39.23% higher the MP test. The ST outcomes of Class II and Class III individuals also differed from those of Class I individuals in the third year, with X50 values that were 3.03 and 13.37% higher for Class II and Class III individuals, respectively ($p \leq 0.01$; $p \leq 0.01$, respectively), and 48% and 2.49% higher ME_5.6 values for Class II and Class III individuals ($p = 0.04$; $p = 0.03$, respectively). In addition, the cycle time in Class II and Class III individuals was also 14.74 and 2.47% lower than for Class I individuals ($p = 0.02$; $p = 0.04$, respectively). Meanwhile, significant differences in the number of cycles were only found between Class II and Class I individuals ($p \leq 0.01$), with a 6.09% reduction in the number of cycles at the end of the 3rd year.

**Table 3** lists the coefficients and confidence intervals obtained for OHRQoL domain scores and shows that Brachyfacial and Mesofacial individuals reported differences in the Appearance domain ($p \leq 0.01$). Dolichofacial and Mesofacial individuals experienced different Oral Comfort ($p \leq 0.01$), while Class III and Class I individuals experienced a reduction in this same domain ($p \leq 0.01$). After the 3rd year, age resulted in differences in the

**TABLE 3 |** Mixed-effects regression model of DIDL domain scores according to facial pattern (FP), anteroposterior skeletal discrepancy (ASD), sex, and age.

| | DIDL | | | | |
|---|---|---|---|---|---|
| | **Appearance, coefficient (95%CI)** | **Pain, coefficient (95%CI)** | **Oral comfort, coefficient (95%CI)** | **General performance, coefficient (95%CI)** | **Eating and chewing, coefficient (95%CI)** |
| **Time** | | | | | |
| 3 months | Ref. | Ref. | Ref. | Ref. | Ref. |
| 1 year | * | −0.26 (−0.67; 0.14) | 0.20 (−0.11; 0.52) | **1.61 (0.99; 2.22)** | **0.84 (0.63; 1.06)** |
| 3 years | −0.26 (−0.16; 0.11) | **1.63 (0.89; 2.37)** | 0.27 (−0.17; 0.73) | −0.12 (−0.38; 0.14) | 0.21 (−0.07; 0.49) |
| 1–3 years | * | **0.77 (0.24; 1.31)** | 0.14 (−0.31; 0.61) | 0.01 (−0.12; 0.16) | **0.78 (0.43; 1.14)** |
| **FP** | | | | | |
| Mesofacial | Ref. | Ref. | Ref. | Ref. | Ref. |
| Brachyfacial | **0.49 (0.40; 0.59)** | −0.40 (−1.85; 1.05) | 0.05 (−0.57; 0.62) | −0.55 (−1.79; 0.69) | −0.16 (−0.85; 0.52) |
| Dolichofacial | 0.03 (−0.76; 0.15) | 2.59 (−1.87; 1.87) | **−0.77 (−1.12; 0.68)** | −0.65 (−2.55; 1.24) | −0.14 (−0.74; 0.45) |
| **ASD** | | | | | |
| Class I | Ref. | Ref. | Ref. | Ref. | Ref. |
| Class II | −0.05 (−0.22; 0.11) | * | 0.08 (−0.10; 0.27) | * | * |
| Class III | −0.92 (−3.62; 1.76) | −0.10 (−0.49; 0.29) | **0.49 (0.26; 0.72)** | * | * |
| **Sex** | | | | | |
| Male | Ref. | Ref. | Ref. | Ref. | Ref. |
| Female | 0.02 (−0.14; 0.19) | −0.06 (−0.38; 0.26) | −0.00 (−0.54; 0.53) | −0.05 (−0.21; 0.11) | −0.32 (−1.40; 0.77) |
| **Age (years)** | 0.00 (−0.014; 0.023) | **0.00 (0.00; 0.01)** | **0.01 (0.00; 0.02)** | **0.00 (0.00; 0.01)** | 0.01 (−0.00; 0.02) |

*Bold font indicates statistically significant differences. *Variables show collinearity: constant variables.*

| | | | | | | |
|---|---|---|---|---|---|---|
| Class I | Ref. | Ref. | Ref. | Ref. | Ref. | Ref. |
| Class II | **1.17 (0.40; 1.93)** | 1.59 (−0.01; 3.20) | **2.97 (0.08; 5.86)** | 0.92 (−0.31; 2.17) | **−1.79 (−3.27; −0.32)** | **−0.75 (−1.39; −0.11)** |
| Class III | **−0.59 (−0.86; −0.32)** | 0.02 (−0.01; 0.07) | **−0.60 (−1.17; −0.04)** | −0.04 (−0.72; 0.63) | 1.25 (−0.35; 2.88) | **1.21 (0.04; 2.39)** |
| **Sex** | | | | | | |
| Male | Ref. | Ref. | Ref. | Ref. | Ref. | Ref. |
| Female | −0.15 (−0.49; 0.19) | −0.04 (−0.22; 0.14) | −0.10 (−0.22; 0.01) | −0.01 (−0.31; 0.27) | 0.04 (−0.84; 0.93) | 0.04 (−0.52; 0.61) |
| **Age (years)** | −0.00 (−0.05; 0.04) | −0.13 (−0.52; 0.24) | 0.22 (−0.63; 1.07) | 0.02 (−0.45; 0.50) | 0.82 (−0.26; 1.91) | 0.67 (−0.23; 1.58) |

*MP_X50, particles trituration; MPB, chewing homogenization; MP_ME_5.6, % material retained in the 5.6 mm sieve; MP_ME_2.8, % material retained in the 2.8 mm sieve.*
*Bold font indicates statistically significant differences.*

Pain ($p \leq 0.01$), Oral Confort ($p \leq 0.01$) and General Performance ($p \leq 0.01$).

**Figures 1–3** illustrate the changes in DIDL scores over time within each group. The Pain domain scores of dolichofacial individuals reduced by 12.50% between 3 months and year 1 (ES 0.8). For Mesofacial individuals, there was a 4.04% reduction in the average General Performance domain score between 3 months and 3 years and between 1 and 3 years (ES 0.9 and ES 1.2, respectively). Finally, Class III individuals reported a 6.06% reduction in the General Performance domain score between 1 and 3 years old (ES 2.2). Finally, women reported a reduction of 14.58% in the Appearance domain between 3 months and 3 years (ES 1.05), while their General Performance (ES 2.06) and Eating and Chewing (ES 2.20) domain scores reduced by 5.10% and 7.07%, respectively, between 1 and 3 years.

**Figure 1:** Evolution of average DIDL scores according to facial pattern. Periods with large effect size are indicated.

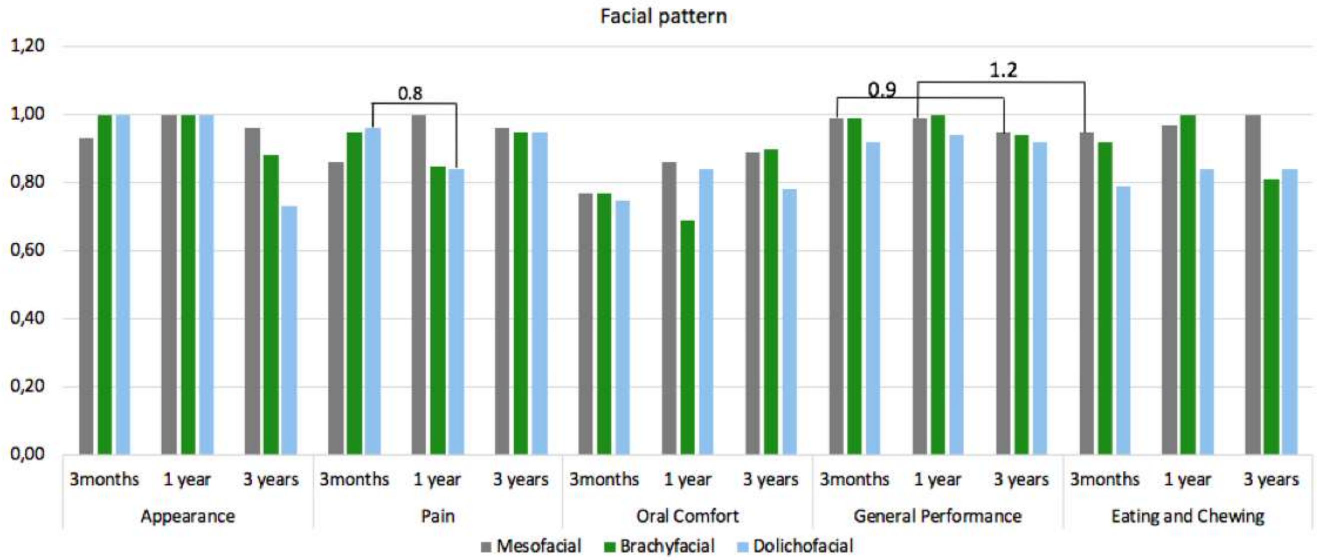


**Figure 2**: Evolution of average DIDL scores according to anteroposterior skeletal discrepancy. Periods with large effect size are indicated.

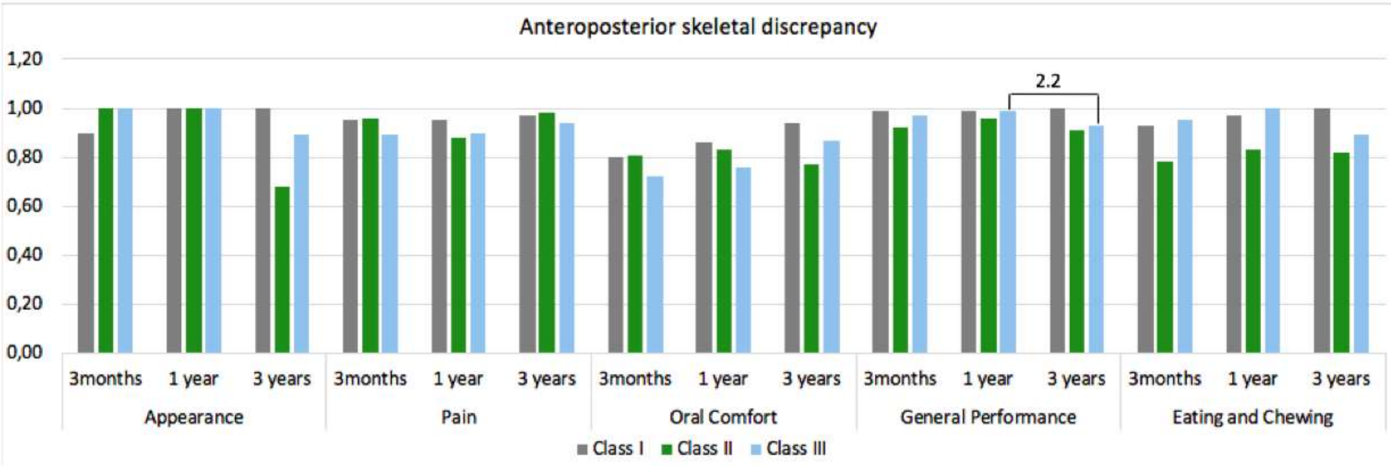
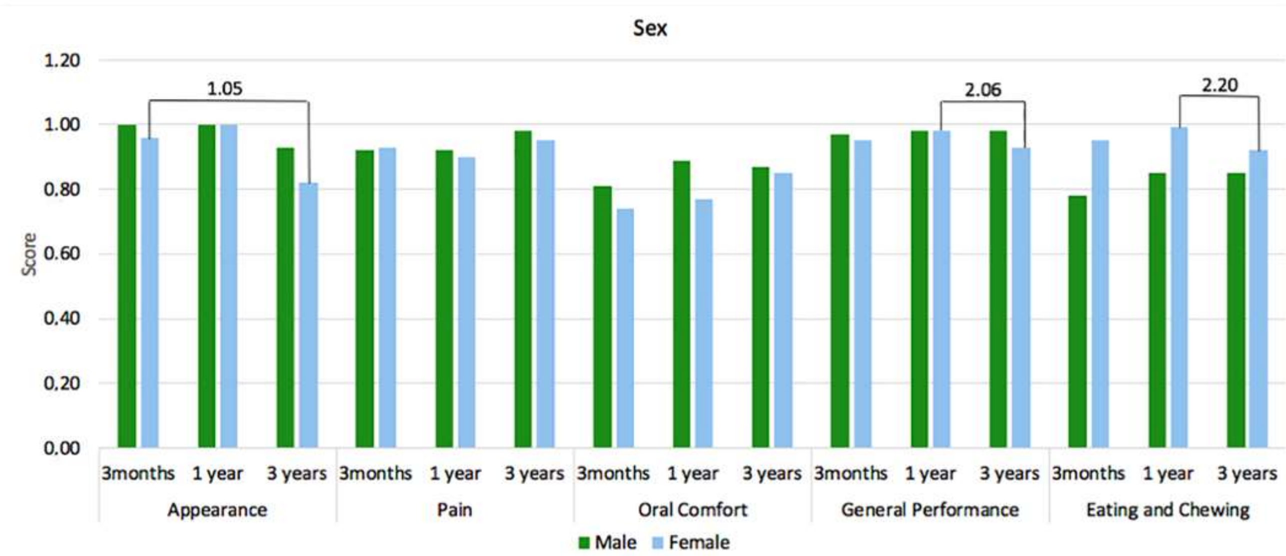



**Figure 3.** Evolution of average DIDL scores according to sex. Periods with large effect size are indicated.

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The masticatory outcomes at all evaluation periods are listed in the **Tables 4**, **5** and show that significant differences were observed only for the swallowing threshold tests. **Table 5** shows that the ST_X50 values only reduced significantly in male individuals between 3 months and 1 year by 7.83% ($p \leq 0.01$).

**TABLE 4 |** Masticatory Performance (MP) outcomes (mean ± standard deviation) over time according to facial pattern, anteroposterior skeletal discrepancy and sex (Wilcoxon-paired test).

| | | Facial pattern | | | Anteroposterior skeletal discrepancy | | | Sex | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Mesofacial** | **Brachyfacial** | **Dolichofacial** | **Class I** | **Class II** | **Class III** | **Male** | **Female** |
| MP_X50: (mm) | 3 months | 4.23 (1.10) | 4.78 (1.44) | 4.17 (1.26) | 4.28 (1.15) | 4.20 (1.28) | 4.55 (1.36) | 3.62 (1.18) | 4.72 (1.17) |
| | 1 year | 3.94 (1.00) | 4.73 (1.22) | 3.94 (1.01) | 4.42 (1.18) | 3.84 (0.96) | 4.29 (1.17) | 3.54 (0.92) | 4.46 (1.08) |
| | 3 years | 3.43(1.24) | 4.64 (1.15) | 3.99 (0.70) | 3.92 (1.37) | 3.90 (0.83) | 4.04 (1.23) | 3.72 (0.91) | 4.08 (1.23) |
| MP_B | 3 months | 3.27 (1.35) | 4.77 (2.69) | 3.99 (3.87) | 3.34 (0.70) | 4.16 (4.19) | 4.23 (2.57) | 3.11 (0.68) | 4.36 (3.29) |
| | 1 year | 3.53 (2.24) | 4.42 (2.06) | 3.10 (0.38) | 3.48 (1.85) | 3.05 (0.39) | 4.16 (1.17) | 2.86 (0.46) | 4.02 (2.07) |
| | 3 years | 3.11 (1.00) | 4.33(2.85) | 3.10 (0.46) | 3.13 (1.12) | 3.02 (0.54) | 3.91 (2.30) | 2.99 (0.51) | 3.67 (2.00) |
| MP_ME_5.6: (%) | 3 months | 26.05 (20.97) | 38.38 (28.32) | 25.23 (25.54) | 25.12 (19.97) | 23.63 (17.31) | 34.33 (27.01) | 17.03 (19.43) | 34.17 (22.59) |
| | 1 year | 23.39 (19.54) | 34.82 (25.22) | 17.92 (18.33) | 31.26 (18.08) | 19.32 (19.02) | 25.83 (24.85) | 12.15 (14.47) | 30.83 (22.05) |
| | 3 years | 15.81 (21.07) | 34.66 (24.75) | 15.63 (10.48) | 23.85 (24.66) | 15.72 (11.45) | 23.00 (23.31) | 14.32 (11.70) | 24.26 (23.31) |
| MP_ME_2.8: (%) | 3 months | 22.81 (8.54) | 17.28 (12.97) | 21.40 (9.49) | 21.45 (10.16) | 21.54 (9.11) | 19.34 (11.34) | 25.63 (8.74) | 18.23 (10.18) |
| | 1 year | 22.19 (10.70) | 16.81 (12.96) | 26.17 (7.97) | 17.57 (9.26) | 25.45 (7.82) | 21.61 (13.21) | 26.64 (7.20) | 19.73 (11.90) |
| | 3 years | 24.89 (9.19) | 17.23 (10.06) | 24.32 (5.51) | 22.49 (10.32) | 24.13 (5.84) | 21.50 (9.83) | 25.02 (7.18) | 21.35 (9.40) |

*Statistically significant differences were not found.*

**TABLE 5 |** Swallowing threshold outcomes (mean ± standard deviation) over time according to facial pattern, anteroposterior skeletal discrepancy, and sex (Wilcoxon-paired test).

| | | Facial pattern | | | Anteroposterior skeletal discrepancy | | | Sex | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Mesofacial** | **Brachyfacial** | **Dolichofacial** | **Class I** | **Class II** | **Class III** | **Male** | **Female** |
| ST_X50: (mm) | 3 months | 3.81 (0.98) | 4.53 (0.98) | 3.65 (0.89) | 3.72 (1.15) | 3.70 (0.98) | 4.24 (0.99) | **3.32 (0.93)*** | 4.23 (0.97) |
| | 1 year | 3.47 (1.33) | 4.21 (1.34) | 3.49 (0.94) | 3.91 (1.29) | 3.33 (0.94) | 3.85 (1.37) | **3.06 (0.72)*** | 3.99 (1.31) |
| | 3 years | 3.07 (1.06) | 4.34 (1.35) | 3.41 (0.60) | 3.29 (1.23) | 3.39 (0.66) | 3.73 (1.29) | 2.92 (0.67) | 3.78 (1.17) |
| ST_B | 3 months | 2.88 (0.93) | 4.93 (4.83) | 3.12 (1.21) | 3.17 (1.78) | 3.19 (1.33) | 4.05 (4.00) | 3.05 (1.74) | 3.81 (3.31) |
| | 1 year | 3.43 (1.92)# | 3.68 (2.21) | 2.93 (0.61) | 3.70 (2.36)# | 2.97 (0.52) | 3.41 (1.87) | 2.87 (0.60)# | 3.55 (1.98) |
| | 3 years | 2.64 (0.80)# | 3.40 (1.99) | 2.83 (0.37) | 2.70 (0.89)# | 2.79 (0.44) | 3.11 (1.58) | 2.52 (0.44)# | 3.10 (1.34) |
| ST_ME_5.6: (%) | 3 months | 18.11 (14.64) | 32.34 (19.29) | 13.69 (14.04) | 17.58 (16.58) | 15.40 (15.01)# | 26.61 (18.63) | 11.66 (12.25)# | 25.25 (18.04) |
| | 1 year | 14.88 (24.05) | 31.01 (24.85) | 12.14 (17.06) | 26.87 (29.00) | 9.72 (15.88)# | 21.10 (23.28) | 7.15 (11.16)# | 24.16 (25.28) |
| | 3 years | 9.66 (15.06) | 26.07 (21.85) | 13.75 (15.51) | 18.50 (21.67) | 9.62 (9.35) | 18.04 (20.31) | 6.49 (4.90) | 20.00 (20.48) |
| ST_ME_2.8: (%) | 3 months | 22.88 (7.88) | 18.26 (11.39) | 24.30 (7.98) | 21.94 (8.61) | 25.75 (8.61) | 19.50 (9.65) | 25.76 (8.15) | 20.21 (9.35) |
| | 1 year | 22.85 (11.53) | 20.63 (11.01)# | 27.50 (10.95) | 24.37 (14.65) | 27.76 (9.28) | 20.69 (10.24) | 29.27 (9.44) | 21.25 (11.26) |
| | 3 years | 25.00 (9.59) | 16.33 (10.49)# | 28.54 (7.46) | 21.35 (9.86) | 28.94 (6.62) | 21.83 (11.55) | 26.12 (5.78) | 22.65 (11.66) |
| Time: (sec) | 3 months | 59.48 (31.03) | 56.14 (23.59) | 62.98 (19.09)# | 57.05 (23.28) | 62.04 (15.64) | 60.83 (30.08) | 62.40 (25.07) | 59.19 (24.58) |
| | 1 year | 60.40 (36.86) | 56.95 (22.96) | 56.18 (13.24) | 47.32 (12.79) | 53.82 (12.71) | 65.98 (34.50) | 55.05 (13.70) | 59.22 (30.06) |
| | 3 years | 56.37 (14.02) | 60.37 (26.13) | 47.46 (19.25)# | 57.53 (24.67) | 49.05 (20.49) | 56.11 (17.31) | 63.97 (18.13) | 50.10 (19.59) |
| Cycles | 3 months | 69.73 (37.73) | 60.31 (23.61) | 73.71 (29.36) | 70.64 (35.62) | 73.33 (28.61)# | 63.42 (30.35) | 79.46 (36.74) | 63.07 (27.04) |
| | 1 year | 65.71 (37.09) | 62.25 (16.28) | 56.62 (15.31) | 51.78 (14.96) | 57.67 (15.50)# | 69.17 (32.23) | 61.83 (14.66) | 61.52 (28.96) |
| | 3 years | 63.31 (25.93) | 67.40 (28.10) | 57.08 (18.18) | 63.89 (31.82) | 60.00 (18.38) | 62.94 (23.36) | 74.18 (24.31) | 56.92 (22.12) |

# *Shows statistically significant difference according to Wilcoxon-paired ($p = 0.05$).*

* *Shows statistically significant difference according to Wilcoxon-paired test using Bonferroni correction of the P-values ($p = 0.0166$).*

*Exact p values found according to the intragroup comparisons: Mesofacial= ST_B (1–3 y, $p = 0.023$); Brachyfacial = ST_ME_2.8 (1–3 y, $p = 0.022$); Dolichofacial = Time (3 m–3 y, $p = 0.050$); Class I = ST_B (1–3 y, $p = 0.036$); Class II = ST_ME_5.6 (3 m–1 y, $p = 0.034$), Cycles (3 m–1 y, $p = 0.041$);* ***Male = ST_X50 (3 m–1 y, $p = 0.015$)****, ST_B (1–3 y, $p = 0.028$), ST_ME_5.6 (3 m–1 y, $p = 0.019$).*

**Discussion**

In our study population, a robust regression analysis indicated important changes in the mean values of the MF and OHRQoL variables over the 3-year follow-up period. Brachyfacial individuals continue to show worse food homogenization than Meso- and Dolichofacial individuals in year 3 for both masticatory function tests. Meanwhile, food trituration abilities of Class II and Class III individuals deteriorated slightly, while their masticatory efficiency (ME_5.6) improved and Class II individuals needed fewer masticatory cycles after 3 years. The improvements in masticatory efficiency are clinically insignificant for Class III individuals, but fairly large for Class II individuals. Finally, the various OHRQoL, domains continue to be influenced by both FP, ASD and age, in the same period.

Mesofacial individuals showed improvements over time after transition to IMO, as indicated by a reduction in their B values between the 1st and the 3rd year that reflects an improvement in particle homogenization. This continuous improvement can be explained by the vertical growth (1) and balanced facial musculature activity, added to the continued long-term improvement in retention and stability promoted by IMO. Conversely, Brachyfacial individuals showed changes in the monitored parameters both over time and in relation to Mesofacial individuals. The ME_2.8 percentage in these individuals reduced by 20.84% between 1st and the 3rd year of function from 20.63 to 16.33%, showing that the medium-term use of IMO did not improve the fine particle trituration capacity of brachyfacial individuals. This worsening of the trituration ability can be attributed to reduced growth and height of the lower third of the face (8), which lowers the amplitude of mandibular movement during chewing, resulting in reduced mobility of the bolus in the oral cavity. Thus, the mandibular kinematics of edentulous brachyfacial individuals may have contributed to a smaller number of chewed particles that reached the 2.8 mm sieve. In this sense, these results support the idea that a larger intra-oral space favors more efficient breakdown of food particles during chewing (10).

In addition, Brachyfacial individuals also obtained less homogenous food boluses than Mesofacial individuals in the third year for both masticatory tests. This shows that the rehabilitation with IMO did not promote the expected improvement of all outcomes related to masticatory capacity, the most sensitive being the particle homogenization, followed by ME_2.8, as both outcomes started to worsen in the third year compared with the reference group (Mesofacial individuals). For Dolichofacial individuals, the masticatory cycles needed to complete the ST test reduced over time, which can be explained by the greater intraoral space that facilitates handling the food bolus and pulverization of the particles, reducing the time needed to perform the masticatory cycles (10).

In terms of ASD, only Class I individuals still showed changes in some masticatory variables in the 3rd year, as their particle homogenization capabilities improved between the 1st and 3rd year. As the homogenization capabilities of Mesofacial individuals also improved, it seems likely that the improved retention and stability provided by IMO, added to the fact that these patients feel safer when chewing, are factors that contribute to medium-term improvements in particle homogenization capabilities. Furthermore, Classes II and III showed differences in relation to Class I for various ST parameters, including X50, ME_5.6, and cycle time. Class II individuals showed slightly worse average particle crushing capacity in the 3rd year, however, the ability to triturate coarse particles, and the time and number of cycles simultaneously showed improvements. The slightly worse crushing ability of Classes II and III may be related to the reduced time taken for chewing, as this can directly interfere with particle crushing (25, 26). In this context, the study by Van der Bilt (27) showed that subjects with good masticatory function, do not necessarily swallow food after a smaller number of cycles, as the ST is directly influenced by the physiology of the individual aside from the social context wherein the individual is included, as the social context can induce the patient to chew more quickly. In addition, the mandibular protrusion in Class III and maxillary protrusion in Class II individuals may also be responsible for these differences in MF in the 3rd year of IMO function.

It is well-known that sex can influence MF even after rehabilitation with IMO. In our study population, males still showed changes in particle homogenization capacity after 3 years. Hatch et al. (28) found that sex was the factor that most influenced the bite force, mainly due to the larger thickness of the masseter which is the main contributing factor to a greater bite force. Thus, the improvement in the particle homogenization for male individuals may be related to development of the masseter during medium-term IMO use. In this context, the literature showed that the bite force and the MF continue to improve over 3 years of IMO use (29), and show that after treatment with implants there is a long-term neuromuscular adaptation, and report an increase in myodynamic parameters and electromyography, approximating the values of dentate individuals (30), corroborating our results.

Presently, little is known about the influence of facial morphology on OHRQoL and patient satisfaction. Faot et al. (10) observed that treatment with IMO positively impacts OHRQoL after 3 months of rehabilitation, especially in the Oral Comfort domain. In the present study, however it was observed that FP can still influence OHRQoL medium-term, since individuals with Dolichofacial and Brachyfacial features reported distinct scores in various domains in the 3rd year, where Dolichofacial individuals reported a worse score (11%) in the Oral Comfort domain and Brachyfacial individuals reported a worse score (8%) in the Appearance domain compared to the reference group (Mesofacial individuals). In terms of ASD, only Class III still shows significantly lower scores (7%) than Class I individuals in the Oral Comfort domain after 3 years. While Faot et al. (10) found no differences in subjective perception in both types of PF and ASD 3 months after loading the IMO our results indicate that on the mediumto long-term, OHRQoL is influenced by different facial patterns and anteroposterior discrepancies. Moreover, age influenced the OHRQoL regardless of facial patterns, mainly in the Pain, Oral Comfort and General Performance domains. These results are in accordance with Schuster et al. (31) wherein the authors observed that individuals aged ≥65 years reported worse domain scores than individuals aged <65 years, reflecting a decrease in OHRQoL with increasing age. The effect size analysis reveals that Mesofacial and Class III individuals reported a reduction in the General Performance domain in the 3rd year compared to the first. However, in general facial patterns had limited influence on the OHRQoL outcomes, as most domains maintained an average score > 0.7, reflecting overall satisfaction with the treatment.

The limitations of this study include the lack myographs, especially of the masseter, and bite force measurements, as these directly influence MF. Another limitation relates to the lack of studies available for direct comparison of these results, due to the scarcity of studies in literature assessing medium-term effects of MF and OHRQoL as a function of facial morphology (FP and ASD). The present study assessed a relatively small number of patients ($n$ = 40) given theamount of parameters needed to describe these relationships. Extrapolation of our results to different populations should be done with caution. More studies with larger sample sizes, more diverse sample populations, and assessment of more parameters related to mastication are required to understand the medium-term relationships between oral health-related quality of life, mastication, and facial morphology.

## Conclusion

The masticatory performance and oral health-related quality of life parameters of implant mandibular overdenture users change over time as a function of facial pattern, anteroposterior skeletal discrepancies, and sex. In our study population, the differences in facial morphology continued to influence the masticatory function and oral health-related quality of life in the 3rd year of implant mandibular overdenture function, and age can influence some OHRQoL domains; brachyfacial individuals benefited least from rehabilitation with IMO, as several masticatory outcomes deteriorated, such as particle homogenization and masticatory efficiency (ME_2.8).

## DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article and further inquiries can be directed to the corresponding author.

## ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Research Ethics Committee of the Faculty of Dentistry UFPel, protocol (No. 69/2013). The patients/participants provided their written informed consent to participate in this study.

## AUTHOR CONTRIBUTIONS

FF, AP, and AM: conceptualization and project administration. AP, AS, RM-M, AM, LP, and OC-J: methodology, patient's treatment, and clinical follow-ups. AP, AS, RM-M, and AM: writing—original draft preparation, software, data curation, and visualization. FF, LP, OC-J, and AD: investigation. FF, LP, and OC-J: formal analysis, resources, and supervision. FF, AP, AS, RM-M, and AD: writing—review and editing. All authors contributed to the article and approved the submitted version.

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**Conflict of Interest:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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**2.5 ARTIGO 5: Performance of clinical, functional, and OHRQoL parameters in mandibular overdentures retained by the Facility-Equator System: 3-year follow-up.**

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Running title: *Facility-Equator System: 3-year follow-up results*

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**Abstract**

**Objective:** Investigating the clinical, functional, and oral health-related quality of life (OHRQoL) outcomes, and complications and maintenance occurrences in mandibular overdenture (MO) wearers during 3 years.**Materials and methods:** The following parameters were recorded: Probing depth (PD), Bleeding on Probing (BOP), Plaque index (PI), Gingival Inflammation (GI), Calculus presence (CP), secondary stability (ISQ) and marginal bone loss (MBL), masticatory performance (MP), masticatory efficiency (ME), and DIDL questionnaire domains. Multilevel mixed-effects linear regression was performed to analyze changes over time. Chi-square tests were performed to analyze the differences in prosthetic complication and maintenance occurrences. The impact of MO use on OHRQoL was assessed via the effect size. The survival rate was calculated using the Kaplan-Meier.**Results:** Between 1 and 3 years the survival rate was 100%. There were significant differences for PD between 1 and 3 years ($p \leq 0.01$), and between 2 and 3 years, for ISQ ($p=0.02$), PI ($p \leq 0.01$), GI ($p \leq 0.01$) and MBL ($p \leq 0.01$). Furthermore, significant differences were observed in MP_X50 ($p \leq 0.01$), EM5.6 ($p \leq 0.01$) and EM2.8 ($p \leq 0.01$) and in MPB ($p \leq 0.01$). The number of complications and maintenance events decreased significantly over time. High OHRQoL effect sizes were found in the Appearance, General Performance, and Eating and chewing domains.**Conclusion:** Continuedchanges were observed in the clinical parameters of MO wearers over years. In addition, most functional parameters, except for particle homogenization, improved significantly over time. **Clinical Relevance:** Periodic returns to assess peri-implant tissues and the MO maintenance should be performed, to ensure the success of rehabilitation to assure improvements in the MF and OHRQoL

**Key words:** peri-implant health; masticatory performance; oral health-related quality of life; mandibular overdentures

**INTRODUCTION**

Dental implants have become a viable rehabilitation option for totally edentulous individuals even in highly complex cases where the patient has pronounced mandibular atrophy. After the wide dissemination and implementation of the McGill (2002) and York (2009) consensuses, treatment with mandibular overdentures (MO) has become the norm for treatment of totally edentulous patients due to its proven effectiveness. This type of rehabilitation has undergone modifications over the years and has trended towards becoming a minimally invasive, low-cost, and fast treatment option [1].

The expansion of indications for treatment with MO and their high clinical predictability is directly linked to four factors: i) implant-related factors: the development of surfaces that favor immediate loading [2–4] and high-strength titanium alloys that provide greater resistance for narrow dental implants (NDI) [5–8] and simplified prosthetic connections [9–11] ii) no requirement for rigid splinting as a prerequisite for clinical success [12–18] iii) wide implementation of versatile stud abutment systems that can be used in situations with atrophic alveolar edges and with reduced interocclusal space [19–23] and iv) possibility of working with implants in a non-ideal position with compromised parallelism to retain MO [24–26]: currently button-type systems are available that can compensate for angles of up to 60 degrees between the implants (e.g., Locator R-Tx). Furthermore, NDI were designed to enable predictable MO treatment with high success rates in cases with compromised bone availability [5, 27–29]. A systematic review [30] found that NDI have a success survival rate of around 98%, that the peri-implant bone tissue reacts favorably to this treatment option, and results in small marginal bone loss (-0.32mm) up to the 3rd year, and thus shows excellent predictability and success throughout of the years.

However, there is currently insufficient evidence to compare and evaluate the effectiveness of the many different retention systems available on the market and their influence on the success rates of MO treatment, prosthetic maintenance events and associated costs, and on patient satisfaction [31]. In mid-2013, the Facility-Equator System (FES, Neodent) was made available on the Brazilian market as a MO retainer. This system consists of a 2.9 mm diameter implant with a 5-degree angled morse connection available with 3 lengths (Facility implant; 10,12 and 14mm); and prosthetic component retention

(Equator attachment) through a screwless friction system activated by the use of a hammer. The prosthetic mechanism is performed by means of a button fitting and allows correction of up to 30º of divergence between implants.

Studies available in the literature with a follow-up time of up to 1 year report on the behavior of MO retained by the FES, and describe its clinical and functional performance and the impact on users' oral health-related quality of life (OHRQoL) [10, 32–35]. In MO retained by FES with conventional loading [10], the probing depth index (PD) decreased significantly between 8 and 12 weeks after implant installation, ensuring good biological sealing of peri-implant tissues, in addition to the immediate increase in ISQ value, after occlusal loading. In addition, this system showed no marginal bone loss (MBL) in the first year of follow-up, proving its short-term predictability and clinical success [10]. Regarding functional performance, the masticatory function of MO users retained by FES improved already in the first month of using MO and kept stable during the first year of usage markedly in the homogenization of the chewed particles and in the capacity to reduce the particles size expressed by the ME 2.8. In addition, OHRQoL improvements are found as early as the 3$^{rd}$ month after transition from conventional complete dentures (CCD) to MO, eliminating problems related to functional limitations such as lack of retention and stability [32, 34]. Finally, a recent 1-year study that compared conventional and immediate loading of MO retained by FES observed that the MBL and the ISQ values were identical between the groups and that the probing depth was around 30.8% greater in the conventional loading group (2.19 mm) after 12 months [35].

However, evidence for the medium and long-term behavior of MO retained by this system and by NDI in general is still scarce, especially in cases of individuals with different levels of mandibular height, long time since edentulism, and compromised bone thickness. Very few studies that investigated MO retained by NDI have a follow-up time of more than 2 years [6, 7, 28, 36], and most of them focus on differences between NDI and conventional diameter implants or with mini-implants or differences between the materials used to manufacture the implants. Still, some evidence provided by studies with a follow-up time greater than 2 years [29, 37] suggests that NDI may present a comparatively higher risk for fatigue after a long follow-up period.

Therefore, the aim of this follow-up study was to investigate the clinical, functional, and OHRQoL-related performance of NDI-retained MO (Facility Equator System) in a group of totally edentulous individuals during 3 years of follow-up, after loading. In addition to monitoring the number of prosthetic complications and maintenance events. The null hypothesis is that there are no significant changes between the analyzed time periods for any parameter.

## MATERIALS AND METHOS

### Study design

This is a 3 years follow-up of a previous clinical study approved by the UFPeL research ethics committee (protocol nr. 1267086/2015). The study was conducted in accordance with the declaration of Helsinki (2008) and the description of the results follows the STROBE guidelines [38].  A total of 30 patients from a previous studythat assessed MO performance during the 1$^{st}$ year of function [10] were contacted by phone to return for the 2 and 3 year follow-up examinations. During these examinations, the following parameters were monitored: i) clinical parameters: peri-implant health parameters, implant stability (ISQ) and marginal bone loss (MBL); ii) functional parameters: masticatory performance (MP, ME); iii) patient-reported outcomes related to OHRQoL were assessed via the Dental Impact in the Daily Living (DIDL) questionnaire. In addition, the number of complications and prosthetic maintenance events over the years was recorded and the survival rate of NDIs was calculated, and sociodemographic and clinical characteristics of the sample population were recorded. All collections and evaluations were performed by a single calibrated evaluator.

### Clinical peri-implant health parameters

The peri-implant health was assessed through clinical examination of the mesial, distal, buccal, and lingual sides the implant through the probing depth (PD), Bleeding on Probing (BOP), plaque index (PI), Gingival inflammation (GI) and calculus presence (CP) indices. The implant stability coefficient (ISQ) was measured using resonance frequency analysis by manually connecting an A3 smartpeg to the internal connection of the Equator component. The ISQ measurements were performed in triplicate using an Ostell device (Integration Diagnostics AB, Göteborg, Sweden) on the 4 faces of the implants. The marginal bone loss (MBL) around the implants was analyzed using digital panoramic radiographs with the linear measurement tools available in the DBSWIN software (Dürr Dental, Bietigheim-Bissingen, Germany). Measurements were made at the mesial and distal faces of each implant and the implant length was used as a reference to correct for distortions [10, 39].

**Functional parameters**

The masticatory function was assessed via the Masticatory Performance (MP) test, in which individuals chew a standardized portion (3.7g) of Optocal test food for a fixed amount of cycles (n = 40) as counted by a calibrated evaluator (APRP). The chewed material was expelled in a paper filter and dried at room temperature for 7 days and subsequently processed through a stack of 9 sieves with openings ranging from 5.6 mm to 0.5 mm coupled to a shaker. The material retained in each sieve was weighed, and the MP_X50 and MPB outcomes were calculated using the Rosin-Rammler formula. The MP_X50 value reflects the average particle size and corresponds to the sieve opening through which 50% of the crushed particles would pass and the MPB reflects the homogenization of the triturated particles, with lower MPB values corresponding to more homogeneous particle size distributions [40]. In addition, the masticatory efficiency (ME) was calculated as the percentage of retention in the 5.6 and 2.8 sieves (ME5.6 and ME2.8).

**Patient-reported parameters:**

The OHRQoL was assessed by application of the DIDL questionnaire [41]. This questionnaire contains 36 questions divided into 5 domains that map patient satisfaction: Appearance, Pain, Oral Comfort, General Performance and Eating and chewing.

**Prosthetic complications and maintenance events**

Data from prosthetic complications and maintenance events during the second and third year after MO loading were also collected. These data include prosthodontic complications related to prosthetic component dislodgement

(Equator Attachment, Matrix/female), prosthesis fracture, new prosthesis/ overdenture, Equator Attachment change (transmucosal length), matrix (female) recapture, teeth fractures, matrix (female) change, reopening for attachment replacement, vestibular deepening surgery, removal of keratinized mucosa and prosthesis rebasing. Events related to the prosthesis maintenance included Pink nylon O-ring replacement and prosthesis adjustments. The type of complication, number of events (NE) and number of patients (NP) experiencing these events were recorded.

**Success and survival rate**

The criteria proposed by Misch et al. (2008) [42] were used to evaluate implant success: no pain or tenderness during function, no implant clinical mobility, radiographic marginal bone loss from initial surgery <1.5 mm, 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 [43].

**Statistical analysis**

For data analysis, the BOP, PI, GI and CP indices were dichotomized using scores (0 and 1: absence and scores of 2 and 3: presence). For PD, ISQ and MBL, the mean values of the four implant faces were used as the final value. All outcomes were assessed by multilevel mixed-effects linear regressionanalysis and were used to test trends in change in outcome variables over time (1-baseline, 2, and 3 years). The time points were established as the fixed effect to test this trend and the individuals' time since edentulism was selected as the random effect. To verify differences between times for complications, the chi-square test was used. Values of $p \leq 0.05$ were considered significant. The effect size (ES) for the DIDL data was calculated based on the final scores for each domain. The effect sizes were classified as follows: small (0.2 ≥ ES < 0.5), moderate (0.5 ≥ ES < 0.8), or large (0.8 ≥ ES) [44]. Survival rate were visualized though the Kaplan-Meier curve. All data were analyzed using the statistical software Stata 14.1 (StataCorp., College Station, TX, USA).

**RESULTS**

At the end of the 3rd year, 26 individuals were included in the sample for this study. There was a total of 4 follow-up losses over the follow-up period, two dues to death and two dues to loss of contact by phone call. All 4 losses occurred between the 1st and 2nd year of evaluation. Figure 1 shows the Kaplan-Meier implant survival curve: In the 1st year the survival rate was 83.3%; but in 3 years, after replacement of lost implants by larger diameter implants (3.5 x 9mm, Titamax Cone Morse implant, Neodent), showed a survival of 100% over the entire period of follow-up (95%CI:27.46;33.64). Thus, a total of 43 NDIs (Facility implant) were evaluated in the second and third year. The sample population consisted of 8 men (30.77%) and 18 women (69.23%) with a mean age of 69.23 ± 7.30 years and a mean mandibular time since edentulism of 28.04 ± 12.92 years. In addition, 14 were classified as having of the mandibular ridge atrophy (53.84%), according Cawood and Howell [45].

**Figure 1:** Kaplan-Meier survival curve during the 3-years follow-up period.

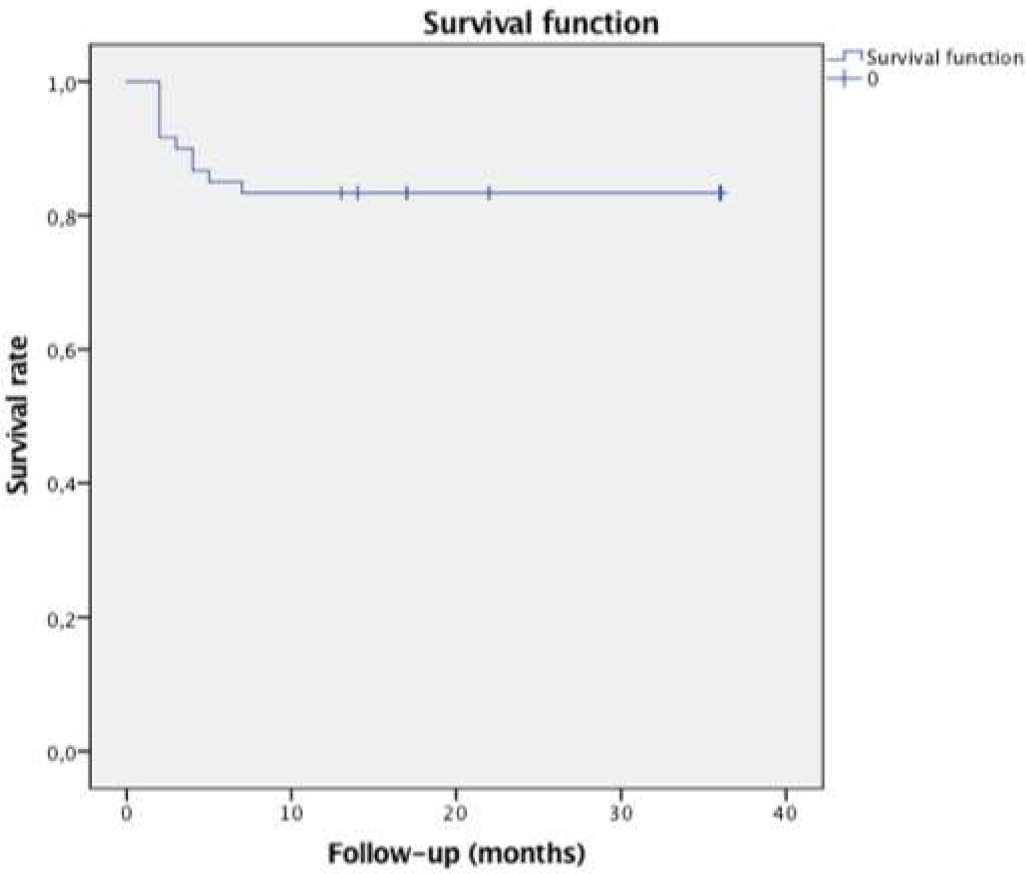

Table 1 lists the data of peri-implant health, masticatory function, and patient-reported (DIDL) outcomes at each evaluation time.

**Table 1:** Mean/ standard deviation values of clinical, functional, and OHRQoL outcomes; and number of patients (n) and % presence for the respective peri-implant health proxies.

| Outcomes | 1 year | 2 years | 3 years |
|---|---|---|---|
| **Peri-implant health (mean/ SD)** | | | |
| PD | 1.93/ 0.51 | 1.78/ 0.67 | 2.16/ 0.67 |
| ISQ | 54.88/ 5.19 | 56.60/ 4.50 | 54.88/ 6.05 |
| MBL | -0.18/ 0.54 | -0.20/ 0.60 | -0.12/ 0.57 |
| **Peri-implant health (N/ % presence)** | | | |
| BOP | 0/ 0.00% | 0/ 0.00% | 0/ 0.00% |
| PI | 13/ 26.00% | 8/ 18.60% | 10/ 23.25% |
| GI | 1/ 2.00% | 1/ 2.33% | 0/ 0.00% |
| CP | 0/ 0.00% | 1/ 2.33% | 0/ 0.00% |
| **Masticatory function (mean/ SD)** | | | |
| MP_X50 | 4.35/ 1.16 | 4.23/ 1.17 | 4.02/ 1.23 |
| MPB | 3.90/ 2.04 | 3.55/ 1.59 | 3.68/ 1.90 |
| ME5.6 (%) | 27.62/ 22.62 | 26.38/ 23.95 | 23.63/ 22.35 |
| ME2.8 (%) | 20.06 / 11.26 | 18.71/ 11.58 | 22.18/ 9.70 |
| **DIDL (mean/ SD)** | | | |
| Appearance | 1.00/ 0.00 | 0.98/ 0.10 | 0.86/ 0.44 |
| Pain | 0.87/ 0.22 | 0.96/ 0.14 | 0.92/ 0.15 |
| Oral comfort | 0.79/ 0.31 | 0.88/ 0.19 | 0.88/ 0.14 |
| General performance | 0.97/ 0.08 | 0.99/ 0.04 | 0.95/ 0.15 |
| Eating and chewing | 0.91/ 0.39 | 0.98/ 0.10 | 0.84/ 0.30 |

Table S1 lists the clinical parameters and shows a significant increase in the mean value of the PD between the 1st and the 3rd year (1.93–2.16 mm; $p \leq 0.01$). The ISQ increased significantly between the first and the second years (54.88–56.60; $p \leq 0.01$), followed by a significant decrease in the 3rd year (56.60–54.88; $p = 0.02$). The MBL values decreased significantly between the 1st and 3rd year evaluations (-0.18; -0.12: $p \leq 0.01$) and between the 2nd and the 3rd year (-0.20; -0.12: $p \leq 0.01$), showing the lowest mean value in the third year. The % presence of PI significantly increased (18.60– 23.25%; $p \leq 0.01$) and GI significantly decreased (2.33–0.00%; $p \leq 0.01$) between the 2nd and the 3rd year.

The results for the functional parameters over time are listed in Table S2 and graphically presented in the Figure 2. The mean particle size (MP_X50) reduced gradually and significantly between the 1st and the 2nd year (4.35–4.23; $p \leq 0.01$) year and between the 2nd and the 3rd year (4.23–4.02; $p \leq 0.01$). The mean MPB reduced significantly between the 1st year and the two subsequent evaluation periods (1-2 years and 1-3 years; both with $p \leq 0.01$), yet mean MPB increased significantly slightly (3.66%; 3.55– 3.68; $p \leq 0.01$) between the 2nd and the 3rd year. The percentage of material retained in the 5.6 mm sieve (ME5.6) reduced significantly between the 1st and the 2nd year (27.62–26.38; $p \leq 0.01$) and between the 2nd and the 3rd year (26.38–23.63; $p \leq 0.01$). A significant increase in retention in the 2.8 mm sieve (ME2.8) (18.71–22.18; $p \leq 0.01$) was only apparent in the last two evaluation periods (2-3 years).

**Figure 2:** Box plots show the masticatory function outcomes. A) Masticatory Performance; b) Masticatory efficiency. Significant difference between times: values $p \leq 0.05$ (multilevel regression of mixed effects).

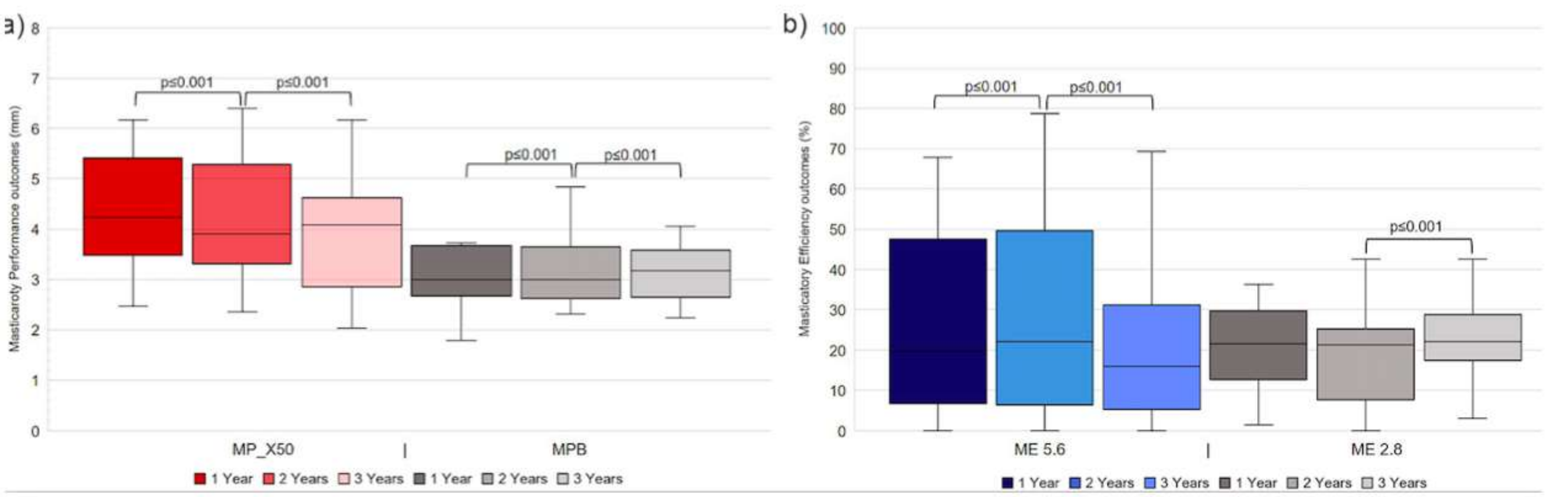

Table S3 and Figure 3 shows the changes in the domains of the DIDL questionnaire between the evaluation periods as well as the effect size values obtained in all domains according to each time comparison. It was found that, for the pain domain, there was a significant increase of the scores between the first and the third year (0.87–0.92; $p \leq 0.01$). For the domains oral comfort, general performance and eating and chewing, the positive changes were significantly noted early, between the first and the second year ($p \leq 0.01$ for all domains). Higher effect sizes were present between years 2 and 3 for the Appearance (ES 1.33), the General Performance (ES 1.16) and Eating and chewing domains (ES 1.50), with a reduction in the scores mean values of all domains.

**Figure 3:** DIDL domain means and effect size values between times. (*) indicate significant difference between times (multilevel regression of mixed effects)

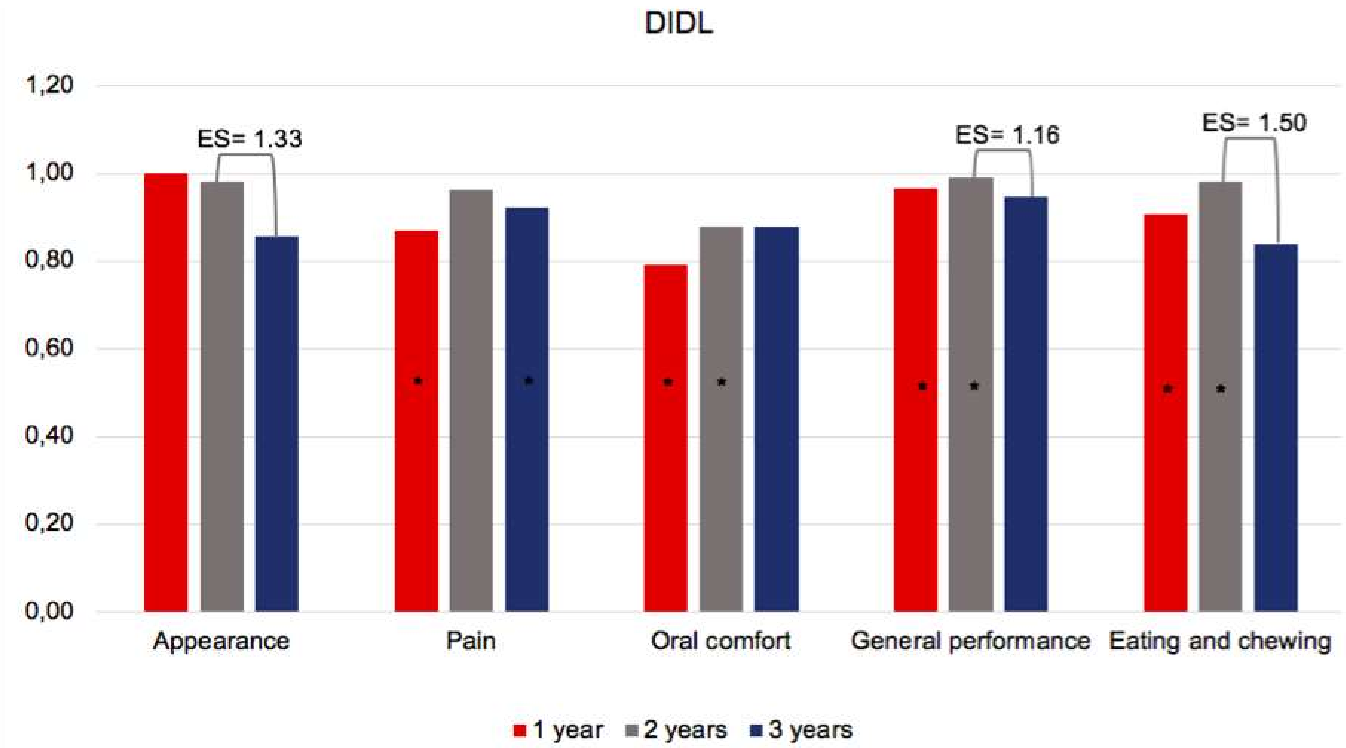

Table 2 lists the prosthetic complications, the type of maintenance events, and statistical differences in occurrence rates over time. The number of complications reduced successively and significantly between all evaluation periods; the third year showed the lowest number of maintenance events. The chi-square tests further indicate significant reductions in the frequency of Equator dislodgement (years 1-2, years 1-3; $p \leq 0.01$), new prosthesis/overdenture (years 1-2, $p = 0.03$), prosthesis adjustment (years 2 -3, $p \leq 0.01$), pink nylon O-Ring replacement (years 1-2, years 1-3, years 2-3, $p \leq 0.01$), reopening for attachment replacement (years 1-3, $p = 0.04$) and prothesis rebasing (years 1-3, $p = 0.03$; years 2-3, $p = 0.04$)

**Table 2:** Type, number of patients (NP), number of events (NE) and % of prosthetic intercurrences during the first, second and third year of occlusal loading. Different letters indicate significant difference (chi-square test).

| | 1 year | | | 2 years | | | 3 years | | |
|---|---|---|---|---|---|---|---|---|---|
| **Type of intercurrences** | **NP** | **NE** | **%** | **NP** | **NE** | **%** | **NP** | **NE** | **%** |
| Healing abutment dislodgement | 4 | 6A | 3,45 | 0 | 0A | 0,00 | 0 | 0A | 0,00 |
| Equator dislodgement | **6** | **20A** | **11,49** | **2** | **3B** | **2,86** | **1** | **1B** | **1,49** |
| Matrix (female) dislodgement | 1 | 1A | 0,57 | 1 | 1A | 0,95 | 0 | 0A | 0,00 |
| Prothesis fracture | 5 | 5A | 2,87 | 3 | 3A | 2,86 | 0 | 0A | 0,00 |
| New prosthesis/ overdenture | **5** | **5A** | **2,87** | **9** | **9B** | **8,57** | 5 | 5AB | 7,46 |
| Prosthesis adjustment | 14 | 32AB | 18,39 | **11** | **27A** | **25,71** | **5** | **6B** | **8,96** |
| Equator change (transmucosal lenght) | 4 | 8A | 4,60 | 3 | 5A | 4,76 | 4 | 6A | 8,96 |
| Matrix (female) recapture | 13 | 26A | 14,94 | 7 | 13A | 12,38 | 7 | 13A | 19,40 |
| Teeth fracture | 4 | 8A | 4,60 | 3 | 3A | 2,86 | 0 | 0A | 0,00 |
| Pink nylon O-ring replacement | **13** | **24A** | **13,79** | **14** | **28B** | **26,67** | **11** | **35C** | **52,24** |
| Matrix (female) change | 6 | 8A | 4,60 | 3 | 4A | 3,81 | 0 | 0A | 0,00 |
| Reopening for attachment replacement | **4** | **10A** | **5,75** | 2 | 2AB | 1,90 | **0** | **0B** | **0,00** |
| Vestibular deepening surgery | 1 | 1A | 0,57 | 0 | 0A | 0,00 | 0 | 0A | 0,00 |
| Removal of keratinized mucosa | 7 | 9A | 5,17 | 1 | 1A | 0,95 | 1 | 0A | 1,49 |
| Prosthesis rebasing | **10** | **11A** | **6,32** | **4** | **6A** | **5,71** | **0** | **0B** | **0,00** |
| | **total** | **174** | 100.0% | | **105** | 100.0% | | **67** | 100.0% |

## DISCUSSION

The null hypothesis was rejected since the clinical, functional and patient-reported outcomes of our sample of MO users changed significantly over 3 years, after loading. Existing doubts regarding the clinical, functional and OHRQoL behavior in the medium time, of OM retained by NDI, due to the scarcity of data and available longitudinal studies, can be clarified through our results. A robust statistical analysis showed that during 3 years of function, there are still significant changes in peri-implant tissues, in masticatory function and in the OHRQoL of MO users. The 100% survival rate between 1 and 3 years is in line with the literature that reports survival rates of 94–100% after 2 years [28, 46, 47]. Thus, rehabilitation of patients with atrophic mandibles and with low bone availability with NDI-retained MO is adequate and predictable.

Our results indicate a 11.92% increase in PD in the 3rd year and a concomitant 3.04% decrease in ISQ. Elsyad et al., 2016 [48]during the first year, found a decrease in the ISQ after loading the MO, and this decrease was attributed to an increase in stress around the implants that negatively affected the secondary stability of the implants.The increase in PD values over time may indicate less bone tissue around the implants, but does not necessarily indicate unhealthy peri-implant tissues [42]. However, the available literature reports diverging results for the long-term behavior of the peri-implant health indices. A 3-year retrospective study [36] found a reduction in PD between 1 and 3 years, while another clinical study found that the PD and VPI remained stable after the first 12 months of occlusal loading [49]. Finally, Miyamoto et al., 2005 [50] found that a reduction in ISQ is more closely related to loss of bone thickness than to changes in bone height. Consequently, the reduction in the ISQ may be related to the PD increase found in the 3rd year, because of the reduction in bone-implant contact due to circumferential remodeling.

Our sample population presented MBL reduction of about 0.06 mm (33.33%) between years 1 and 3 and of 0.08 mm (40%) between years 2 and 3, indicating that bone remodeling of peri-implant tissues continues in the 3rd year after loading. The MBL values found in this study are consistent with those in literature. For instance, Vercruyssen & Quirynen 2010 [51] found an average MBL difference of 0.08 mm between the 1st and 3rd year after loading, showing that the annual MBL is on average 0.04mm, starting from the first year. Still, it is important to emphasize that a systematic review [30] demonstrated that the MBL of similar studies with a follow-up period of ≥ 3 years varies greatly from −1.29 to +0.64 mm, showing that the treatment with NDI-retained MO in this study achieved predictable results. The concomitant reduction in mean GI values and the increase of PI between years 2 and 3 reflects a slight increase in the accumulation of visible plaque and a lower degree of inflammation. It is known that the health of peri-implant tissues is directly related to the hygiene habits of patients [52, 53], and non-splinting prosthetic systems with smooth components such as FES facilitate the cleaning and maintenance of peri-implant health. The accumulation of visible plaque observed after the third year of follow-up does not reflect a worsening in peri-implant tissue inflammation, as the GI value simultaneously decreased. Instead, this may reflect progressive accumulation that does not reflect the patients' daily hygiene habits. The host's response, the time of exposure of the tissues to bacterial plaque, and the etiopathogenesis of this plaque directly interfere with peri-implant health [54], which may justify a higher % of PI presence and a concomitant lower GI. Furthermore, recent findings by Salvi et al. 2015 [55] indicated that 21 days of experimental plaque accumulation in humans elicited an inflammatory response in the peri-implant mucosa, showing that the time of exposure is important to inflammation development.

Implant-supported removable prostheses like MO still have a mucous support and consequently may present a greater amount of prosthetic complications and maintenance requirements over the years. Different types of complications are reported, depending on the type of retention system, but all systems are susceptible to maintenance [19]. The number of complications and maintenance events decreased progressively from the 1$^{st}$ to the 3$^{rd}$ year. In the 3$^{rd}$ year, 52.24% of the maintenance events consist of Pink nylon O-ring replacement and 8.96% of prosthesis adjustments, all with significant differences over years. The persistent high rates of Pink nylon O-ring replacements and prosthesis adjustments may be related to instability of the MO, reflecting their loss of retention over the years. These results are consistent with those from similar studies that followed clinical cases of MO retained by Locator attachments [19, 56, 57], which showed that the most frequent reason for maintenance in 5 years of follow-up was loss of retention due to the wear of the nylon O-rings. In addition, Mackie et al., 2001 [57], found that the nylon O-rings of the Locator system often lose their retention over the course of 3 years, but replacing them is simple and requires minimal clinical time. The wear of the pink O-rings is thought to be caused by continuous remodeling of the residual ridge, causing loss of retention of the MO.  Since the MO are mucosal supported in the posterior region of the mandible, any bone alteration in the residual ridge may cause instability and consequently loss of retention.

The functional parameters presented significant changes for all variables in this study. Considerable improvements in the MP_X50, ME5.6 and ME2.8 values indicate that the masticatory function continues to improve between the 2$^{nd}$ and the 3$^{rd}$ year. However, this was accompanied by a concomitant significant but slight (3.66%) worsening in the particle homogenization, which may reflect the complications and maintenance in that period. Even though there was a decrease in the absolute number of maintenance events between 2 and 3 years, there was a significant relative increase in the number of pink nylon O-ring replacements, corresponding to more than 50% of the existing maintenance events in the 3rd year, which can be explained by an increase in instability and consequently a loss of MO retention. Clinically speaking, the peri-oral musculature contributes to both the crushing and the homogenization of the particles, however when the MO present retention and stability problems, the muscles are recruited to promote MO stability, and in this way contributing to impairing the homogenization of the particles.

Regarding the changes in the OHRQoL of MO users, this study showed that the patients perceived better the functional benefits in second year of usage, while the complains related to the pain domain were significantly reduced only after 3 years. Although the use of MO for 3 years has negatively impacted on appearance, general performance and eating and chewing, no major effect was seen in pain on use, showing that MOs guarantee comfort and satisfaction to the patients. Finally, the reduction in the ability to homogenize food, and the high rate of maintenance events related to loss of MO retention may have resulted in the worsening of DIDL scores in the 3rd year for the general performance and eating and chewing domains, which showed high effect size values. The score of the appearance domain also worsened in this period, likely due the progressive wear and color changes of artificial teeth, and the occasional requirements to confect new CD or MO.

The main limitations of the present study are the absence of muscle myograph data, analysis of the degree of retention and stability of MO, and the difficulty of direct comparison with similar studies due to the relative scarcity of longitudinal studies that analyze changes in clinical, functional, and OHRQoL parameters in atrophic patients treated with NDI-retained MO.

## CONCLUSION

Over 3 years of NDI-retained MO function, various clinical parameters still changed significantly in our sample population, and this reflects continued remodeling of peri-implant tissues. Changes in the functional parameters and OHRQoL demonstrated that the masticatory capacity of MO users is still evolving over 3 years, after loading. The slight deterioration in particle homogenization capacity can be attributed to instability and wear of the prostheses.

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## Supplementary Tables:

**Supplementary Table 1:** Results of the multilevel regression of mixed effects of clinical outcomes. Bold variables indicate significant difference between times (p≤0.05).

| | PD | | | BOP | | | ISQ | | | PI | | | GI | | | CP | | | MBL | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | coef. | 95%CI | P value | coef. | 95%CI | P value | coef. | 95%CI | P value | coef. | 95%CI | P value | coef. | 95%CI | P value | coef. | 95%CI | P value | coef. | 95%CI | P value |
| **Time** | | | | | | | | | | | | | | | | | | | | | |
| **1 year** | | 1.00 | | | 1.00 | | | 1.00 | | | 1.00 | | | 1.00 | | | 1.00 | | | 1.00 | |
| **2 years** | 0.09 | 0.09;0.27 | 0.34 | -0.22 | -1.04;0.58 | 0.58 | **0.50** | **0.23;0.76** | **≤0.01** | 0.23 | -0.01;0.47 | 0.06 | 0.07 | -0.14;0.28 | 0.51 | -0.01 | -0.16;0.13 | 0.87 | 0.07 | 0.22;0.37 | 0.62 |
| **3 years** | **0.44** | **0.25;0.62** | **≤0.01** | -0.20 | -1.01;0.60 | 0.62 | 0.30 | 0.10;0.48 | 0.10 | -0.03 | -0.28;0.20 | 0.76 | -0.14 | -0.54;0.25 | 0.47 | | ** | | **0.63** | **0.30;0.95** | **≤0.01** |
| **2-3 years** | 0.04 | 0.26;0.34 | 0.78 | -0.02 | -0.33;0.28 | 0.87 | **0.23** | **0.02;0.43** | **0.02** | **0.52** | **0.27;0.76** | **≤0.01** | **0.86** | **0.33;1.39** | **≤0.01** | 0.04 | -0.04;0.14 | 0.31 | **0.73** | **0.49;0.97** | **≤0.01** |

** variables: collinearity.

**Supplementary Table 2:** Results of the multilevel regression of mixed effects of masticatory function. Bold variables indicate significant difference between times (p≤0.05).

| | MP_X50 | | | MPB | | | ME5.6 (%) | | | ME2.8 (%) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | coef. | 95%CI | p value | coef. | 95%CI | p value | coef. | 95%CI | p value | coef. | 95%CI | p value |
| **Time** | | | | | | | | | | | | |
| **1 year** | | 1.00 | | | 1.00 | | | 1.00 | | | 1.00 | |
| **2 years** | **0.67** | **0.40;0.94** | **≤0.01** | **0.70** | **0.44;0.97** | **≤0.01** | **0.71** | **0.45;0.97** | **≤0.01** | 0.29 | -0.07;0.66 | 0.12 |
| **3 years** | 0.09 | -0.16;0.35 | 0.46 | **0.29** | **0.06;0.52** | **≤0.01** | 0.10 | -0.17;0.38 | 0.45 | 0.36 | -0.07;0.81 | 0.10 |
| **2-3 years** | **0.60** | **0.30;0.90** | **≤0.01** | **0.44** | **0.15;0.73** | **≤0.01** | **0.70** | **0.38;1.02** | **≤0.01** | **0.64** | **0.23;1.04** | **≤0.01** |

**Supplementary table 3:** Results of the multilevel regression of mixed effects of OHRQoL (DIDL). Bolt variables indicate significant difference between times (p≤0.05) and high effect size value.

| | Appearance | | | | Pain | | | | Oral comfort | | | | General Performance | | | | Eating and chewing | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | coef. | 95%CI | p value | ES | coef. | 95%CI | p value | ES | coef. | 95%CI | p value | ES | coef. | 95%CI | p value | ES | coef. | 95%CI | p value | ES |
| **1 year** | | 1.00 | | . | | 1.00 | | . | | 1.00 | | . | | 1.00 | | . | | 1.00 | | |
| **2 years** | | ** | | 0.00 | 0.14 | -0.39;0.69 | 0.58 | 0.51 | **1.01** | **0.48;1.54** | **≤0.01** | 0.38 | **1.27** | **0.65;1.90** | **≤0.01** | 0.31 | **3.97** | **3.45;4.50** | **≤0.01** | 0.22 |
| **3 years** | | ** | | 0.00 | **0.76** | **0.28;1.23** | **≤0.01** | 0.32 | 0.06 | -0.64;0.78 | 0.84 | 0.44 | -0.04 | -0.21;0.11 | 0.57 | 0.27 | -0.04 | -0.22;0.12 | 0.59 | 0.15 |
| **2-3 years** | 0.03 | -0.04;0.12 | 0.39 | **1.33** | 0.08 | -0.25;0.41 | 0.63 | 0.29 | 0.42 | -0.06;0.91 | 0.08 | 0.09 | 0.05 | -0.04;0.15 | 0.27 | **1.16** | 0.07 | -0.04;0.20 | 0.22 | **1.50** |

** variables: collinearity

## 2.6 ARTIGO 6:Diferenças de desfechos clínicos, funcionais e centrados no paciente entre carregamento convencional e imediato de ovedentures mandibulares retidas por 2 implantes de diâmetro reduzido: 3 anos de acompanhamento de um estudo clinico randomizado

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### Resumo

**Objetivo:** Avaliar a diferença entre os tipos de carregamento oclusal, convencional e imediato, recebido por overdentures mandibulares retidas por dois implantes de diâmetro reduzido durante 3 anos de função. Nesse estudo, avaliou-se a evolução de preditores clínicos, radiográficos, qualidade de vida e função mastigatória entre os 2 tipos diferentes de carregamento. **Materiais e Métodos:** Pacientes de um ensaio clínico randomizado controlado, tratados com carga imediata ou convencional, foram convocados para avaliação de 2 e 3 anos. Os pacientes foram avaliados quanto a parâmetros clínicos,

radiográficos, funcionais e centrados no paciente, através de instrumentos de qualidade de vida relacionada a saúde bucal (QVRSB). Intercorrências e manutençõesprotéticas além de complicações biológicas, sucesso e sobrevivência também foram registradas. Os dados foram testados para normalidade através de Shapiro- Wilk e posteriormente pela análise de regressão linear multinível de efeitos mistos para testar as tendências de mudança das variáveis de resultado ao longo do tempo e entre grupos em cada período de tempo. Para verificar diferenças entre os tempos para as manutenções e intercorrências utilizou- se o teste qui-quadrado. Valores de $p \leq 0.05$ foram considerados significativos. **Resultados:** Durante o período de acompanhamento houve 3 perdas de acompanhamento, 2 do grupo CC e 1 do grupo CI. Assim, a amostra do grupo CC foi composta por 8 indivíduos e o grupo de CI por 9. A taxa de sobrevivência foi de 100% ao longo do $2^0$ e $3^0$ ano para ambos os grupos. Clinicamente, para o grupo CC, mudanças como aumento nos valores médios de ISQ ($p \leq 0.01$), placa visível ($p \leq 0.01$) e perda óssea marginal ($p \leq 0.01$), no $3^0$ ano foram encontradas. Redução no valor da área óssea posterior ($p \leq 0.01$) também foi encontrada nesse período, assim como piora no PMX50 ($p \leq 0.01$), PMB ($p \leq 0.01$) e EM5.6 ($p \leq 0.01$), além de mudanças positivas para o domínio conforto oral ($p \leq 0.01$). Já o grupo CI mostrou, ainda no $3^0$ ano mudanças nos desfechos, com aumento nos valores médios de ISQ ($p=0.04$), profundidade de sondagem ($p \leq 0.01$) e radiograficamente com aumento na perda óssea marginal ($p \leq 0.01$) e perda óssea contínua na área óssea posterior de mandíbula entre os períodos analisados ($p \leq 0.01$). Funcionalmente houve melhorias na função mastigatória para o PMX50 ($p=0.04$), e na % retenção na EM 5.6 ($p=0.04$). Melhoria para QVRSB para parâmetro dor ($p=0.02$) também foi observada. Somente uma diferença entre os grupos foi verificada no $3^0$ ano, para a POM, com menor perda para o grupo CI (-0.04; $p \leq 0.01$). **Conclusão:** Ao fim do $3^0$ ano, o CI foi semelhante ao CC em todos os desfechos, tanto clínicos quanto funcionais e de QVRSB, somente apresentando uma significativa menor perda óssea marginal nesse período, mostrando assim ser um tipo de carregamento bastante viável, garantindo um processo reabilitador previsível e viável, a longo prazo, quando bem indicado.

**Key words:** overdentures mandibulares, carregamento convencional, carregamento imediato, desfechos clínicos, função mastigatória, qualidade de vida relacionada a saúde bucal

## INTRODUÇÃO

Com o envelhecimento da população em geral, principalmente de indivíduos desdentados totais, um quadro de atrofia óssea do rebordo residual é comumente diagnosticado [1,2] e agravado pelo tempo de edentulismo, independente do grau e severidade da reabsorção óssea [3]. Assim, a qualidade do rebordo residual e da base de uma prótese total (PTC), também podem ser considerados preditores para o não uso ou até mesmo o abandono do uso da PTCs, principalmente da mandibular [4,5]. Diante do alto índice de sucesso e sobrevivência dos implantes osseointegrados, overdentures mandibulares implanto-retidas (OMI) tem se tornado um tratamento mais popular e previsível nos últimos 20 anos, e atualmente tornou-se a primeira escolha para reabilitação de pacientes edêntulos com comprometimento da altura do rebordo alveolar. Evidências substanciais demostradas através de ensaios clínicos randomizados [6] tem comprovado melhorias da satisfação e qualidade de vida dos pacientes portadores de OMI, quando comparados com o tratamento com PTCs [7]. Do ponto de vista funcional, estudos acerca da força de mordida [8,9], da habilidade e performance mastigatória [10] e do controle de coordenação neuromuscular [11] tem mostrado que o aumento da retenção e estabilidade de próteses mandibulares promove o fechamento voluntário máximo da boca com força e biomecânica equilibrada [9] capaz de reproduzir uma mastigação normal e ativar diversas áreas do córtex cerebral [12]. Adicionalmente, a presença de implantes também tem resultado em redução da reabsorção óssea [13,14] e no aumento significativo do índice de área posterior da mandíbula [15].

Comumente, a severidade da atrofia óssea tem impossibilitado o uso de implantes convencionais, e nestes casos, implantes de diâmetro reduzido (IDR) e mini-implantes tem se tornado uma modalidade cirúrgica atrativa como retentores para OMI, pois são instalados por meio técnica cirúrgica simplificada e minimamente invasiva[16–19]. Consequentemente, IDRs podem proporcionar ao paciente um tempo menor de tratamento, menor tempo de recuperação e menor custo[18] possibilitando reabilitação de pacientes com comprometimento sistêmico ou idade avançada com contraindicação de um procedimento cirúrgico mais invasivo, extenso e com tempo de cicatrização prolongado[20]. Comparações de desempenho clínico entre IDRs e mini-implantes mostram que ambos possuem alta taxa de sucesso e sobrevivência (93-98%), perda óssea peri-implantar aceitável em acompanhamentos de 12, 24 e 36 meses (MI= 0,89, 1,18 e 1,02 mm; IDR= 0,18, 0,12 e -0,32 mm), entretanto IDRs apresentaram melhor previsibilidade a longo prazo para reter OM apenas quando o carregamento convencional foi adotado [21]. Outra revisão sistemática mais recente descreveu índice de sobrevivência entre 94.7 a 97.7% para IDRs entretanto, a respeito de protocolo cirúrgico e do protocolo de carregamento, dados disponíveis na literatura foram insuficientes para recomendar a superioridade de um dos os protocolos de carregamento [22].

A maioria das evidências robustas atuais permitem que muitos clínicos recomendem o uso de OMI com 2 implantes, independentemente do diâmetro, em regime de carregamento convencional (CC) no tratamento de indivíduos completamente edêntulos [23]. Entretanto, este tratamento apesar de rentável em termos de custo-benefício e de resultar em satisfação para alguns pacientes, em curto período de tempo [24], para outros, a consequência da ausência de prótese por pelo menos 3 meses ou uma inadequada prótese total provisória pode ser inaceitável. Muitos pacientes, durante o período de espera pela reabilitação definitiva ou pelo carregamento oclusal das OM tem relatado o período como traumático e desconfortável, pois as próteses totais provisórias não fornecem adequada função e estética [25]. Além disso, durante o período de espera, os pacientes não só sofrem de função mastigatória insuficiente, mas às vezes também de pressão social [26]. Neste sentido, alguns estudos demonstram que o carregamento imediato (CI) é capaz de melhorar a qualidade de vida relacionada à saúde bucal (QVRSB) mais rapidamente que o CC [26,27]e que em geral, a satisfação com a OMI aumenta progressivamente desde os primeiros meses até o segundo ano, assim como o conforto, estética e capacidade de mastigar e falar [28].

Neste sentido poucos estudos têm mensurado o desempenho das OMI retidas por implantes de diâmetro reduzido em pacientes portadores de atrofia óssea severa e moderada [29–32] diferenciando sua previsibilidade no que se refere ao tipo de carregamento adotado. Schuster et al, (2020) [33] relataram resultados promissores em termos biológicos, clínicos e funcionais ao comparar pacientes submetidos tanto ao CC quanto CI, quando reabilitados por IDRs que preconizam plataformas protéticas tipo cone Morse sem aparafusamento (Sistema Facility-Equator). Quanto à função mastigatória, os autores encontraram melhorias estatisticamente significativas para todos os desfechos funcionais avaliados imediatamente após a instalação OMI, cerca de 48% para CC e 44% para CI. Entretanto, durante o primeiro ano de função o grupo CI precisou de mais tempo para alcançar função mastigatória similar aos indivíduos do grupo CC, pois comparações intragrupo mostraram que após 1 mês, somente a EM2.8 (% de partículas trituradas retida na peneira 2.8) melhorou significativamente no grupo CI. Melhorias para o X50, EM2.8 e EM5.6 somente melhoraram significativamente em relação ao baseline, após 12 meses (melhorias de 28%; 54%; 64%, respectivamente). Já no grupo CC, melhorias foram vistas em mais desfechos no $1^0$ mês, porém em 12 meses mudanças significativas também foram observadas para o X50 = 23%, EM 2,8 = 51%, EM 5,6 = 60%). Diferença estatística entre os grupos, nesse mesmo período, não foram visualizados.

Ainda, apesar do encorajamento para a implementação do CI na prática clínica para OMI, dados provenientes de revisões sistemáticas recentes dos últimos 5 anos ainda são contraditórios ou demonstram a equivalência em entre o CC e o CI apontando que: I) a preferência pela adoção de protocolos de carregamento precoce ou tardio após análise da influência de fatores biomecânicos e dos desfechos clínicos preditivos para o sucesso do CI [34]; II) que meta-análises não mostraram nenhuma diferença estatisticamente significativa em relação à falha do implante ou perda óssea marginal para implantes de suporte mandibular, entre protocolos de CC e CI, em OMI retidas por sistemas não esplintados [35]; III) que quando estudos clínicos randomizados são avaliados, o período de cicatrização após a implantação é um período de risco e requer cuidado e monitoramento no CI, uma vez que poucos estudos monitoraram o ISQ-coeficiente de estabilidade e PTV-periotest value [36]; IV) estudos clínicos prospectivos apresentam taxas de sucesso e sobrevivência e perda óssea marginal ssemelhante entre CC e CI, profundidade de sondagem e índice de placa mais baixos no CC, ISQ com valores favoráveis para o CC (3 meses), e semelhantes para CI nos períodos de acompanhamento, bem como para perda óssea marginal [37]; V) efeito similar para saúde peri-implantar e perda óssea marginal em sistemas de retenção não esplintados, taxa de sobrevivência do implante de 100% e 94.7% para encaixes do tipo Locator em CI e CC, respectivamente [38] e resultados inconclusivos para alguns desfechos peri-implantares e complicações protéticas e VI) apesar de maior profundidade de sondagem observado no CI, nenhum tipo de attachment, número de implante ou protocolo de carregamento apresentou ter uma vantagem clara sobre o outro [39].

Por fim, todas as revisões sistemáticas recentes sobre CI em OMI apontam a persistência de problemas relacionados ao desenho dos estudos clínicos analisados, como tamanho amostral e diferentes desfechos, com tempos de acompanhamentos diversos, potencial desvantagem de sua adoção devido a falta de resultados de tratamento de médio e longo prazo de ensaios clínicos [40]. Além disso, poucos estudos têm avaliado desfechos centrados nos pacientes, e ao investigarem o impacto de OMI na QVRSB e satisfação empregam diversos instrumentos resultando em dificuldade de comparação entre os estudos. Devido a escassez de ensaios clínicos randomizados que relatem resultados em médio e longo prazo e de consenso na literatura sobre a previsibilidade da adoção do CI na reabilitação de pacientes usuários de OMI, o objetivo do presente estudo foi avaliar a diferença entre os tipos de carregamento oclusal, convencional e imediato, recebido por overdentures mandibulares retidas por dois implantes de diâmetro reduzido durante 3 anos de função. Nesse estudo, avaliou-se a evolução de preditores clínicos, radiográficos, qualidade de vida e função mastigatória entre 2 tipos diferentes de carregamentos de implantes, para reabilitações do tipo overdentures mandibulares. A hipótese é de que não há diferença entre os grupos em nenhum dos desfechos avaliados.

## METODOLOGIA

## 1. ***População e Desenho do estudo***

O presente estudo observacional é um acompanhamento de 3 anos de indivíduos participantes de em um estudo clínico controlado randomizado (RCT) que comparou o carregamento imediato versus convencional de dois IDRs não esplintados que suportam OMI retidas pelo sistema Facility-Equator [33]. O RCT original foi conduzido entre 2014 e 2016. O acompanhamento de 3 anos foi realizado no Serviço de Manutenção de Próteses Totais, Clinica de Pós-Graduação de Prótese Total, de Setembro de 2017 a Outubro de 2019. O protocolo do estudo foi aprovado pelo CEP (protocolo 1.267.086). Cada paciente forneceu um formulário informado por escrito consentir em participar do estudo. A maior ênfase do presente estudo foi relatar os novos resultados encontrados em 2 e 3 anos.

## 2. ***Seleção do paciente***

Pacientes tratados com carregamento imediato ou convencional de dois implantes que suportam OMI foram convocados para avaliação de 2 e 3 anos. Inicialmente um total de 20 pacientes foram selecionados e através da randomização foram alocados aleatoriamente 10 pacientes em cada grupo Os critérios de inclusão e exclusão de pacientes foram descritos em detalhes anteriormente [33,41]. Em resumo, os critérios de inclusão foram pacientes totalmente desdentados usando PTC em ambos os arcos com pelo menos 3 meses de adaptação, pouca disponibilidade óssea na região anterior da mandíbula, estabilidade reduzida da prótese mandibular e retenção insuficiente da prótese total mandibular suporte ósseo adequado para receber implante de diâmetro reduzido sem necessidade de procedimentos de aumento ósseo. Os pacientes foram excluídos história de radioterapia na região da cabeça ou pescoço, história prévia de inserção de implante oral, pacientes que fizeram tratamento com bifosfonatos nos últimos 12 meses, fumantes, diabetes grave (hiperglicemia ou controle glicêmico inadequado), distúrbios hemorrágicos (diatese hemorrágica, anticoagulação induzida por drogas), doenças sistêmicas graves (artrite reumatóide, osteogênese imperfeita) e sistemas imunológicos comprometidos (HIV, medicamentos imunossupressores).

## 3. ***Procedimento cirúrgico***

Os procedimentos cirúrgicos foram descritos em detalhes anteriormente [33,41]. O mesmo operador experiente (OLCJ) realizou todas as cirurgias. Dois NDI (ø = 2,9 × 10 mm Facility, Neodent) foram inseridos na região entre forame mentual mandibular sob anestesia local. Para o grupo de CC, cicatrizadores não submersos foram instalados, já para o grupo CI os attachment Equator foram fixados no implante usando martelete e os retalhos mucoperiostais foram suturados.

### 4. ***Tratamento protético***

Os pacientes do grupo CC receberam reembasamento macio na base da PTC mandibular (Trusoft®, Bossworth Company, USA), que foi substituído mensalmente até o período de cicatrização dos implantes (3 meses). Os pacientes do grupo CI tiveram suas OMI carregadas imediatamente por um dentista experiente (AMB) através da matriz do Equator, via oral, usando resina acrílica autopolimerizavel (VIPI Flash®, VIPI industry, São Paulo, Brazil) para encaixe do sistema de retenção interno (cápsula de retenção oring rosa) na base da prótese.

### 5. ***Parâmetros clínicos***

A saúde periimplantar foi avaliada através de exame clínico das 4 faces do implante para monitorar: profundidade de sondagem (IPS), índice de sangramento gengival a sondagem (ISG), índice de placa visível (IPV), grau de inflamação (GI) e presença de cálculo (PC). A análise de estabilidade do implante foi realizada através da análise de frequência ressonância pela aferição do coeficiente de estabilidade do implante (ISQ) por meio da conexão de um smartpeg A3 conectado manualmente na conexão interna do componente (Equator). As medidas foram realizadas em triplicata através do aparelho Ostell (Integration Diagnostics AB, Göteborg, Suécia) também nas 4 faces dos implantes.

### 6. ***Avaliação radiográficas: perda óssea marginal e reabsorção óssea posterior***

A perda óssea marginal dos implantes (POM) e o índice de área posterior (IAP) foram analisados através de radiografias panorâmicas digitais, utilizando ferramentas de mensuração. As mensurações para POM foram feitas na mesial e na distal de cada implante e o comprimento do implante foi utilizado como referências para evitar distorções utilizando o software DBSwin, já para determinação da do índice de área posterior (IAP) utilizou- se a metodologia proposta por ELSYAD et al. (2017)[42] baseada na delimitação de áreas de referência e experimentais traçadas em radiografias panorâmicas digitais utilizando o software Photoshop, para posterior mensuração no software ImageJ.

### 7. ***<u>Parâmetros funcionais e centrados no paciente</u>***

Para análise da função mastigatória utilizou -se a Performance mastigatória (PM), que utiliza 40 ciclos fixos de mastigação. Para a PM os pacientes foram orientados a mastigar uma porção de 3,7 g de Optocal e após a mastigação, o material de teste foi expulso em papel de filtro, enxaguado com água e seco à temperatura ambiente durante 7 dias. Em seguida, o material passou por um conjunto de peneiras compostas por peneiras com tamanhos de abertura decrescentes (5,6-0,5mm) por 20 minutos. O material retido em cada peneira foi pesado e inserido na equação de Rosin-Rammler para calcular os valores de X50 e B. O PMX50 refere-se a abertura teórica por onde passariam 50% do material retido (trituração das partículas) e o PMB a homogeneidade da mastigação. A eficiência mastigatória (EM) foi calculada utilizando-se a porcentagem do peso do material retido nas peneiras 5.6 e 2.8 [43]. Dados centrados no paciente foram analisados através da análise do impacto do uso das OM na QVRSB através da aplicação do questionário DIDL [44]. Este é um instrumento com 36 questões dividido em 5 domínios que mapeiam a satisfação do paciente referente a aparência da prótese, dor ao uso, conforto oral, performance geral e mastigação. As pontuações finais para cada domínio representam a pontuação média das questões relacionadas a cada domínio e são classificadas como insatisfeito (<0), relativamente satisfeito (0–0,69) ou satisfeito (0,7–1,0) [45].

### 8. ***<u>Intercorrências e manutenções protéticas</u>***

Os dados referentes a complicações das próteses relacionadas ao deslocamento do componente protético (queda do cicatrizador, queda do

Equador ou da matriz), fratura da prótese mandibular, confecção de novos overdenture, troca do pilar Equator pela necessidade de alterar a altura do transmucoso, recaptura da matriz, fratura do dente artificial, troca da matriz, reabertura do tecido para substituição do pilar, cirurgia de aprofundamento vestibular e remoção da mucosa queratinizada periimplantar e necessidade de reembasmento da prótese foram coletados. Eventos relacionados à manutenção da prótese, como troca de O-ring rosa (cápsula retentiva de nylon) e ajustes da prótese, também foram registrados. Essas informações foram relatadas como tipo de complicação, número de eventos e número de pacientes.

## 9. ***Complicações biológicas e Índices de sucesso e sobrevivência***

Complicações biológicas, como mucosite ou periimplantite, foram relatadas no recente Workshop Mundial sobre a classificação de doenças e condições periodontais e periiimplantar [46]. A mucosite é diagnosticada com base nos seguintes critérios: I) a presença de sinais de inflamação periimplantar como vermelhidão, inchaço, linha ou queda de sangramento e ou supuração após sondagem, combinada com II) nenhuma perda óssea adicional pós a remodelação inicial. Já a definição de periimplantite é baseada nos seguintes critérios: I) presença de sinais de inflamação periiimplantar, II) perda óssea progressiva comparada ao nível ósseo radiográfico do $1^0$ ano após carregamento da OMI e III) aumento da profundidade de sondagem baseado nos valores de profundidade de sondagem coletados após carregamento das OMI. É considerado falha ou sucesso do implante quando uma das condições como radioluscência ao redor do implante; mobilidade; supuração, dor ou processo patológico que exigiu a remoção do implante; ou o implante não está mais na boca estivesse presente ou ausente. Quando os implantes ainda estão em função no acompanhamento são considerados como sobrevivência, e uma taxa de sobrevivência foi calculada em 2 e 3 anos.

## 10. **Análise estatística**

Todos os dados foram analisados em 2 e 3 anos. Os índices IPV, PC, GI e ISG foram dicotomizados; os escores 0 e 1 correspondem à ausência dos respectivos sintomas (0) e os escores 2 e 3 correspondem à sua presença (1).

Para o ISQ e IPS utilizou- se a média das 4 faces analisadas. A taxa de sobrevivência dos grupos foi calculada por meio da análise de sobrevivência de Kaplan-Meier. Inicialmente testou os dados com relação a sua normalidade usando o teste Shapiro- Wilk e posteriormente todos os desfechos foram avaliados pela análise de regressão linear multinível de efeitos mistos foram usados para testar as tendências de mudança das variáveis de resultado ao longo do tempo. O primeiro ano foi utilizado como referência na análise intragrupo assim como a carga convencional na análise entre grupos. Devido a normalidade dos dados, para verificar diferenças entre os tempos para as manutenções e intercorrências utilizou- se o teste qui-quadrado. Valores de $p \leq 0.05$ foram considerados significativos.

**RESULTADOS**

Durante o período de acompanhamento houve 3 perdas de acompanhamento, 2 do grupo CC (1 homem e 1 mulher) e 1 do grupo CI (1 homem). Assim, a amostra do grupo CC foi composta por 6 mulheres e 2 homens, com idade média de 68.9 anos, tempo médio de edentulismo mandibular de 25 anos. Já o grupo de CI foi composto por 5 mulheres e 4 homens com idade média de 70 anos, tempo médio de edentulismo mandibular de 27.4 anos. Quanto a perda de implantes 5 foram perdidos (3 CI e 2 CC) durante o primeiro ano do estudo e após a substituição por novos implantes cone morse (ø=3,5×10 mm, Neodent) a taxa de sobrevivência foi de 100% ao longo do $2^0$ e $3^0$ ano (Figura 1). No grupo CC, 1 paciente apresentou mucosite no implante direito, ao fim do $3^0$ ano que foi tratado e o quadro revertido.

Figura 1: Curva de sobrevivência (Kaplen-Meier).

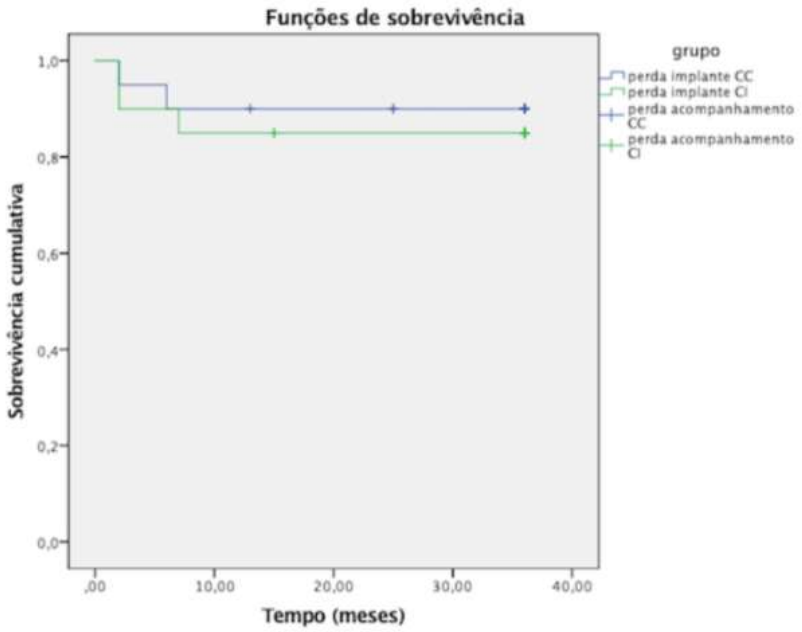



Tabela [illegible] ɔo.

| D | | | | | | ediata f. (IC95%) |
|---|---|---|---|---|---|---|
| IP | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | (-0.06;0.95) |
| IS | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | (-4.76;2.98) |
| IS | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | ** |
| IP | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | -0.14;3.94) |
| GI | 1.00 | ** | 1.00 | ** | 1.00 | ** |
| **Desfechos Ósseos** | | | | | | |
| POM | 1.00 | -0.13 (-0.68;0.40) | 1.00 | -0.23 (-1.07;0.60) | 1.00 | **-0.28 (-0.42;-0.15)*** |
| IAP | 1.00 | -0.16 (-0.87;0.55) | 1.00 | -0.41 (-1.14;0.32) | 1.00 | -0.21 (-1.10;0.67) |
| **Performance Mastigatória** | | | | | | |
| PMX50 | 1.00 | -0.09 (-0.74;0.54) | 1.0 | 0.09 (-0.21;0.40) | 1.0 | -0.11 (-1.09;0.86) |
| PMB | 1.00 | -2.47 (-6.78;1.84) | 1.00 | **-0.19 (-0.29;-0.08)*** | 1.00 | 0.33 (-0.25;0.92) |
| EM5.6 | 1.00 | -0.13 (-0.77;0.50) | 1.00 | 0.10 (-0.03;0.23) | 1.00 | -0.71 (-1.70;0.28) |
| EM2.8 | 1.00 | -0.38 (-1.27;0.50) | 1.00 | -0.46 (-0.94;0.01) | 1.00 | -0.08 (-0.86;0.69) |

*variáveis com diferença estatística significativa. **colinearidade; variáveis constantes

Os dados brutos coletados de todos os desfechos estão listados na tabela S1. De acordo com a Tabela 1, que descreve a análise das diferenças entre os grupos ao longo de 3 anos, observa-se que o CI diferiu do CC no segundo ano, apresentando valores significativamente inferiores para IPS ($p \leq 0.01$) e para IPV ($p=0.03$) e PMB ($p \leq 0.01$). No $3^0$ ano, diferença entre os carregamentos foi visualizado somente na POM ($p \leq 0.01$), tendo o grupo CI uma pequena redução da perda óssea na região periimplantar em relação ao grupo CC (diferença de -0.04).

Com relação as complicações e manutenções referentes à prótese (Tabela 2), não houve nenhuma diferença entre os grupos CC e CI em 2 e 3 anos.

Tabela 2: Intercorrências e manutenções ocorridas durante os 3 anos de acompanhamento (teste qui-quadrado)

| | Carga convencional | | | | | | Carga imediata | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Intercorrências** | **Durante segundo ano** | | | **Durante terceiro ano** | | | **Durante segundo ano** | | | **Durante terceiro ano** | | |
| | N (pacientes) | N (casos) | % | N (pacientes) | N (casos) | % | N (pacientes) | N (casos) | % | N (pacientes) | N (casos) | % |
| Complicações | | | | | | | | | | | | |
| Queda do Equator | 1 | 1 | 1,90% | 0 | 0 | 0% | 0 | 0 | 0,00% | 0 | 0 | 0,00% |
| Queda da matrix (Fêmea) | 0 | 0 | 0% | 0 | 0 | 0% | 0 | 0 | 0,00% | 0 | 0 | 0,00% |
| Fratura da prótese | 0 | 0 | 0% | 0 | 0 | 0% | 1 | 1 | 2,08% | 0 | 0 | 0,00% |
| Confecção de prótese nova | 3 | 3 | 5,80% | 1 | 1 | 6,60% | 2 | 2 | 4,17% | 2 | 2 | 5,56% |
| Troca do encaixe Equator (Transmucoso maior/menor) | 2 | 3 | 5,80% | 1 | 1 | 6,60% | 2 | 4 | 8,33% | 2 | 3 | 8,33% |
| Recaptura da matrix (Fêmea) | 5 | 10 | 19,60% | 2 | 2 | 13,30% | 5 | 9 | 18,75% | 3 | 7 | 19,44% |
| Fratura de dente artificial da prótese | 1 | 1 | 1,90% | 0 | 0 | 0% | 1 | 1 | 2,08% | 0 | 0 | 0,00% |
| Troca da matrix (Fêmea) | 1 | 2 | 3,90% | 0 | 0 | 0% | 1 | 1 | 2,08% | 0 | 0 | 0,00% |
| Reabertura para recolocação do componente | 0 | 0 | 0% | 0 | 0 | 0%* | 1 | 1 | 2,08% | 0 | 0 | 0,00% |
| Aprofundamento de vestíbulo | 1 | 1 | 1,90% | 0 | 0 | 0% | 0 | 0 | 0,00% | 0 | 0 | 0,00% |
| Remoção de mucosa ceratinizada | 1 | 1 | 1,90% | 1 | 1 | 6,60% | 0 | 0 | 0,00% | 0 | 0 | 0,00% |
| Reembasamento da prótese | 2 | 2 | 3,90% | 0 | 0 | 0% | 4 | 5 | 10,42% | 1 | 1 | 2,78% |
| Total | 12 | 24 | 47% | 6 | 6 | 40% | 17 | 24 | 50,00% | 8 | 13 | 36,11% |
| **Manutenção** | | | | | | | | | | | | |
| Ajuste da prótese | 4 | 10 | 19,60% | 1 | 1 | 6,60% | 4 | 12 | 25,00% | 1 | 1 | 2,78% |
| Troca de O-ring (cápsula retententiva de nylon) | 6 | 17 | 33,30% | 3 | 8 | 53,30% | 6 | 12 | 25,00% | 6 | 22 | 61,11% |
| Total | 10 | 27 | 52,94 | 4 | 9 | 60% | 10 | 24 | 50,00% | 7 | 23 | 63,89% |

Quando analisadas as mudanças ao longo do tempo (Tabela 3) para o grupo CC verificou- se mudança significativa para o ISQ no $3^0$ ano em relação ao $1^0$ ano ($p \leq 0.01$), com aumento dos valores médios entre esses dois períodos de 5.47%. Para o IPV a mudança foi significativa entre o $2^0$ e o $3^0$ ano ($p \leq 0.01$), com aumento de 2x na presença de placa visível. Para a POM, a variação entre o $2^0$e o $3^0$ ano ($p \leq 0.01$) resultou em leve aumento de 4.17%. Para a área óssea da região posterior da mandíbula, alterações significativas ($p \leq 0.01$) foram observadas no IAP ao longo dos 3 anos, com aumento de 5.83% entre o $1^0$ e o $2^0$ ano e subsequente redução de 0.79% no terceiro ano. Do total de indivíduos do grupo CC, somente 2 tiveram perda real de área óssea posterior (25.00%) ao fim do $3^0$ ano, o restante ganhou ou manteve a área óssea nessa região. Com relação aos desfechos funcionais, mudanças significativas entre o $1^0$ e o $2^0$ ano foram encontradas para o PMX50 ($p=0.04$), com redução nos valores de 11.25%, porém entre o $2^0$ e o $3^0$ ano ($p \leq 0.01$), um leve aumento dos valores médios de 5.19% foi encontrado para esse período. Para a variável PMB, mudanças foram visualizadas entre todos os períodos (1-2 anos, $p \leq 0.01$; 1-3 anos, $p \leq 0.01$; 2-3 anos, $p \leq 0.01$), com aumento de 9.56% dos valores médios entre os dois últimos anos. Para a eficiência mastigatória, apesar do aumento significativo ($p \leq 0.01$) de 46.47% de retenção na peneira 5.6

(EM5.6) entre o $2^0$ e o $3^0$, observou-se que, a comparação entre o $1^0$ e o $3^0$ ano, evidenciou que a piora deste parâmetro de fato resultou em aumento de 3.35% (p=0.02). Já para EM2.8, um leve aumento significativo (p=0.02) de 5.10% na % de retenção foi observado apenas na comparação entre 1-3 anos.

Com relação ao grupo CI (Tabela 3), mudanças nos desfechos clínicos ao longo de todo o período de acompanhamento foram visualizados para o IPS entre o $1^0$ e o $3^0$ ano ($p \leq 0.01$), com aumento de 13.16% na profundidade de sondagem, assim como um aumento de 12.20% no ISQ nesse mesmo período (p=0.04). Já em relação a POM, mudanças foram encontradas entre o $1^0$ e o $3^0$ ano ($p \leq 0.01$), com aumento de 16.66% da perda óssea na região periimplantar e uma redução progressiva da área óssea posterior (IAP) entre o $1^0$ e o $2^0$ ano ($p \leq 0.01$) e entre o $2^0$ e o $3^0$ ($p \leq 0.01$), com uma redução mais acentuada de 5.26% entre os dois primeiros anos, seguido de uma leve redução ainda de 0.93% entre 2 e 3 anos de função das OM carregadas imediatamente. Do total de indivíduos do grupo CI, 5 tiveram perda óssea na área posterior (55.55%) e o restante teve ganho ou mantiveram área nessa região. ao fim do $3^0$ ano. Na análise dos desfechos mastigatórios, mudanças no PMX50 foram encontradas entre o $1^0$ e o $2^0$ ano (p=0.03) e entre o $2^0$ e o $3^0$ ano (p=0.04), com aumento de 7.18% entre o primeiro período, seguido de redução de 6.44% ao fim do $3^0$ ano. Na peneira 5.6 a mudança significativa ocorreu entre o $2^0$ e o $3^0$ ano (p=0.04), com redução na % de retenção das partículas de 43.75% enquanto que para a peneira 2.8, a mudança ocorreu entre o $1^0$ e o $2^0$ ($p \leq 0.01$) com leve redução de 0.32% na retenção nessa peneira.

Tabela 3: Regressão linear multinível de efeitos mistos dos desfechos clínicos, ósseos e mastigatórios ao longo do tempo, para cada grupo.

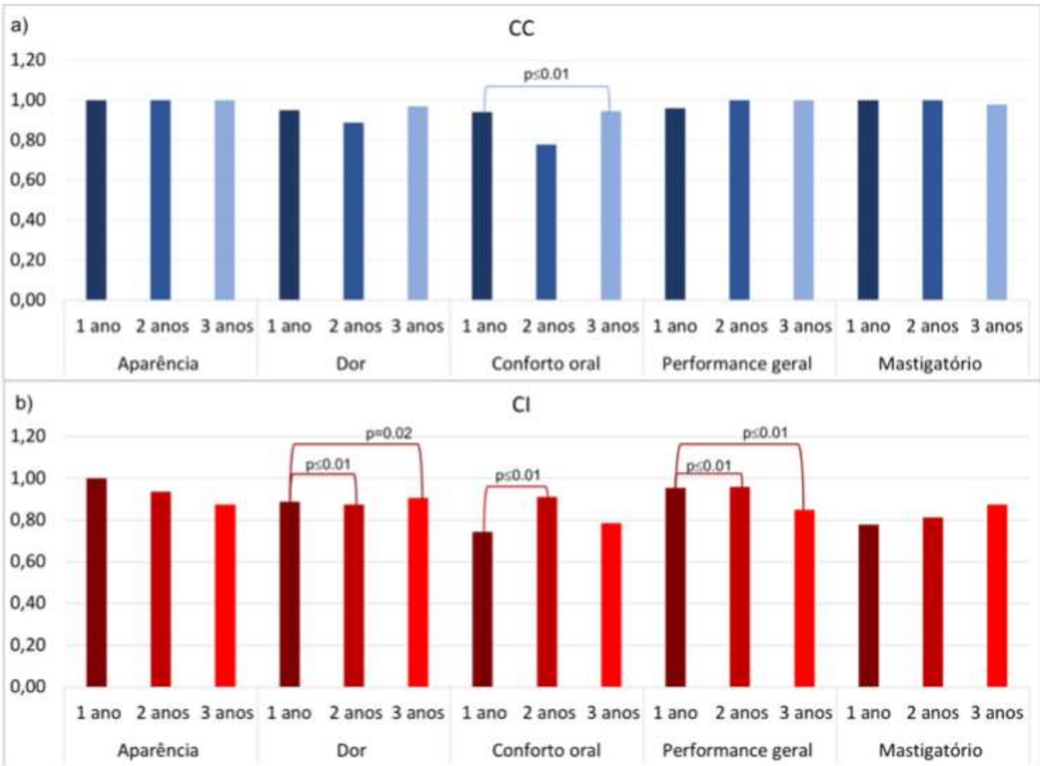
| | **Carga Convencional** | | | | **Carga Imediata** | | | |
|---|---|---|---|---|---|---|---|---|
| | **1 ano** | **2 anos** | **3 anos** | **2- 3 anos** | **1 ano** | **2 anos** | **3 anos** | **2- 3 anos** |
| **Desfechos Clínicos** | **Ref.** | **coef. (IC95%)** | **coef. (IC95%)** | **coef. (IC95%)** | **Ref.** | **coef. (IC95%)** | **coef. (IC95%)** | **coef. (IC95%)** |
| IPS | 1.00 | 0.07 (-0.13;0.28) | -0.11 (-0.53;0.30) | -0.16 (-1.20;0.86) | 1.00 | 0.07 (-0.34;0.50) | **0.49 (0.08;0.90)*** | 0.40 (-0.04;0.85) |
| ISQ | 1.00 | 0.18 (-0.23;0.61) | **0.51 (0.16;0.86)*** | 0.30 (0-0.10;0.70) | 1.00 | -0.00 (-0.02;0.00) | **0.64 (0.01;1.27)*** | -6.89 (-36.38;22.58) |
| ISG | 1.00 | ** | ** | ** | 1.00 | -0.33 (-1.00;0.32) | 0.19 (-0.21;0.61) | -0.09 (-0.40;0.22) |
| IPV | 1.00 | -0.06 (-0.71;0.58) | -0.17 (-0.63;0.29) | **0.49 (0.21;0.76)*** | 1.00 | -0.12 (-1.01;0.77) | -0.45 (-1.89;0.98) | -0.21 (-1.01;0.58) |
| GI | 1.00 | ** | ** | ** | 1.00 | ** | ** | ** |
| **Desfechos Ósseos** | | | | | | | | |
| POM | 1.00 | 1.00 (-0.08;2.10) | -0.20 (-1.78;1.37) | **1.34 (1.07;1.62)*** | 1.00 | -0.46 (-1.10;0.18) | **0.55 (0.23;0.87)*** | 0.06 (-0.17;0.31) |
| IAP | 1.00 | **1.16 (0.69;1.63)*** | 0.00 (-0.40;0.42) | **0.82 (0.61;1.02)*** | 1.00 | **0.94 (0.28;1.60)*** | -0.02 (-0.69;0.64) | **0.96 (0.73;1.19)*** |
| **Performance Mastigatória** | | | | | | | | |
| PMX50 | 1.00 | **0.52 (0.01;1.02)*** | 0.29 (-0.08;0.67) | **0.66 (0.40;0.91)*** | 1.00 | **0.69 (0.04;1.34)*** | -0.76 (-1.58;0.05) | **0.73 (0.01;1.44)*** |
| PMB | 1.00 | **0.61 (0.12;1.09)*** | **1.36 (1.00;1.72)*** | **0.61 (0.33;0.89)*** | 1.00 | 0.13 (-0.02;0.30) | -0.05 (-0.41;0.30) | -0.27 (-1.74;1.19) |
| EM 5.6 | 1.00 | 0.40 (-0.03;0.83) | **0.42 (0.05;0.79)*** | **0.73 (0.44;1.03)*** | 1.00 | 0.58 (-0.12;1.29) | -0.81 (-2.33;0.70) | **1.22 (0.00;2.43)*** |
| EM 2.8 | 1.00 | 0.06 (-0.50;0.63) | **0.76 (0.12;1.40)*** | 0.39 (-0.33;1.12) | 1.00 | **0.55 (0.17;0.93)*** | -0.60 (-1.22;0.01) | 0.82 (-0.16;1.81) |

*variáveis com diferença estatística significativa. **colinearidade; variáveis constantes

Quando analisados os dados de QVRSB, a única diferença entre os grupos ocorreu no primeiro ano para o domínio dor (coef: 0.50; IC 95%: 0.12;0.87; $p \leq 0.01$). De acordo com a Figura 2, que apresenta os resultados da regressão linear multinível de efeitos mistos, verificou- se que ao longo dos 3 anos de função das OM, os escores dos domínios do DIDL apenas variaram ao longo do tempo, dentro de cada grupo. Para o grupo CC, houve mudança no domínio conforto oral entre o $1^0$ e o $3^0$ ano (coef: 1.21; IC 95%: 0.26;2.17; $p \leq 0.01$), com um leve aumento médio de 1.06% nos escores entre os períodos. Já para o grupo CI, as variações dos escores médios foram para o domínio dor, entre o $1^0$ e o $2^0$ ano (coef: 1.83; IC95%: 0.39;3.27; $p \leq 0.01$), com leve redução nos escores (1.12%), seguido de um leve aumento de 2.24% dos valores médios, entre o $1^0$ e o $3^0$ (coef:-2.00; IC 95%: -3.78;-0.21; $p=0.02$). Já no domínio conforto oral, a mudança foi entre o $1^0$ e o $2^0$ ano (coef:2.10; IC 95%: 0.65;3.56; $p \leq 0.01$), com aumento médio dos valores de 22.97% e para a performance geral as mudanças foram entre o $1^0$ e o $2^0$ ano (coef: 1.45; IC 95%: 0.91;1.99; $p \leq 0.01$), e entre o $1^0$ e o $3^0$ (coef: -0.23; IC 95%: -0.36;-0.10; $p \leq 0.01$), com pequeno aumento de 1.05% entre o primeiro período, seguido de redução de 10.52% nos escores médios no último período. Em relação a satisfação com suas OM, todos os indivíduos, tiveram escore final superior a

0.7, mostrando que independentemente da carga adotada todos estavam satisfeitos com a sua reabilitação, ao longo do tempo.

Figura 2: Gráfico DIDL (Regressão linear multinível de efeitos mistos intra grupo ao longo do tempo).




## DISCUSSÃO

Levando em consideração a robustez dos resultados pela análise estatística utilizada, a hipótese nula de que não haveria diferenças entre CC e CI e também de mudanças nos desfechos ao longo do tempo para cada um dos grupos de carregamento, foi rejeitada. Dessa forma, pôde- se verificar que mudanças nos desfechos clínicos como ISQ, POM e IAP variaram ao longo do tempo para ambos os grupos, mostrando que ainda há remodelação dos tecidos periimplantares e de região posterior de mandíbula ao fim do $3^0$ ano, independentemente da carga adotada. Porém, com relação aos desfechos ósseos, embora ambos tenham aumentado os valores médios de perda óssea periimplantar com o passar dos anos, o grupo CI quando comparado ao CC, apresentou menor perda. Ainda, o grupo CI funcionalmente ainda respondeu positivamente em relação a função mastigatória e no domínio dor ao fim do $3^0$ ano. Após 2 anos, a taxa de sobrevivência dos implantes de 100% de ambos os grupos está de acordo com a literatura [47,48].

Com relação ao ISQ, verificou- se que, no $3^0$ ano, ambos os tipos de carregamento tiveram aumento dos valores médios, refletindo em maior contato entre tecido ósseo e a superfície do implante. Como visto, a partir da análise estatística, não houve diferença no ISQ entre os dois grupos, no $3^0$ ano, percebendo- se assim que a estabilidade secundária dos implantes e a quantidade de tecido ósseo ao redor dos implantes não é afetada, a longo prazo, pelo tipo de carregamento adotado, resultado também encontrado por Emami et al., 2016 [28]. Percebe- se assim, que o tipo de carregamento pode influenciar no coeficiente de estabilidade do implante somente no período inicial, e pode ser explicado que devido a adoção de uma carga precoce pode existir uma maior remodelação óssea circunferencial inicial. Tal evidência foi verificada nos estudos de Elsyad et al., 2016 [49] e Miyamoto et al., 2005 [50], onde os autores encontraram variações no ISQ logo após o carregamento das OM. Assim, com o passar dos anos, o tipo de carregamento adotado deixa de ter influência direta sobre o ISQ, visto que houve aumento médio nos valores de ISQ em ambos os grupos. O que pode justificar esse achado é que devido a existência de implantes osseointegráveis, as forças mastigatórias, provenientes do tipo de reabilitação utilizada, são transmitidas diretamente ao osso periimplantar e as tensões provenientes da função da OM, refletem em mudanças no ISQ nos dois grupos. Isso pode explicar assim, que o fato de existir uma reabilitação retida por implantes já é suficiente para influenciar o osso a responder de forma positiva ao estimulo mecânico da prótese, garantindo boa quantidade de tecido ósseo circunferencial ao redor dos implantes.

Ainda, levando em consideração a região periimplantar, em ambos os grupos, houve aumento da perda óssea ao longo dos anos. Para o grupo CC o a perda entre 2 e 3 anos foi de -0.01mm, enquanto que para o grupo CI a perda ao longo dos anos foi de -0.03 (1-3 anos). No estudo de Vercruyssen & Quirynen 2010 [51], os autores mostram que a perda óssea em altura anual é em média 0.01mm, a partir do primeiro ano, mostrando assim que nossos resultados estão de acordo com a literatura. Esse fato mostra que ambos os carregamentos apresentam resultados a longo prazo coerentes com a literatura, evidenciando que em 3 anos de função das OM, ainda se faz presente um processo de remodelação óssea periimplantar. Ainda, embora a POM pareça ser maior, ao longo dos anos para o grupo CI, quando analisado diferença entre eles, esse grupo teve menor perda óssea no $3^0$ ano que o grupo CC, sendo esta a única diferença encontrada entre os dois tipos de carregamento durante todo o período de acompanhamento desse estudo. Quando analisado os valores médios de POM do grupo CC, mesmo não existindo mudanças significativas entre todos os períodos, se vê uma tendência de maior perda óssea periimplantar e com pouca variação entre os anos, com valores mais altos em todos os períodos, do que o grupo CI. Esse resultado é corroborado pelo estudo de Salman et al. 2019 [48], que durante 5 anos de acompanhamento de OM também encontrou médias maiores de perda óssea para o grupo CC e médias menores para o CI. A longo prazo também verificou-se diferença entre os grupos para o POM, com menor perda óssea para o grupo CI. Assim, a menor perda óssea em altura no CI pode ser uma consequência longeva dos reflexos da adoção de uma carga precoce, que pode ter gerado uma resposta, do tecido periimplantar, às forças transmitidas ao tecido ósseo através dos implantes, que de forma positiva pode ainda refletir na remodelação óssea tardia em altura no grupo CI [52,53].

Ao interpretarmos nossos achados referentes ao rebordo residual na região posterior de mandíbula, verificou- se que o IAP reduziu, para ambos os grupos, entre 2 e 3 anos, porém para o grupo CI essa redução de área posterior de mandíbula foi progressiva, diferentemente do CC que houve ganho inicial e posterior redução, mostrando que a CI foi responsável por uma remodelação contínua da área óssea na região posterior da mandíbula. Embora não se tenha encontrado diferença no IAP entre os grupos, o grupo CI teve menor número de pacientes com ganho ou manutenção de tecido ósseo nessa região e maior número de indivíduos com perda óssea, mostrando assim que o CI, assim como o CC, nessa amostra de indivíduos, não foi capaz de reverter o quadro de remodelação óssea do rebordo residual. Além disso, embora não se tenha encontrado diferença entre os grupos para as frequências de manutenções e intercorrências protéticas no $3^0$ ano, percebe-se que o grupo CI apresentou maior número de trocas de cápsulas retentivas nesse período (22 casos CI e 8 do CC). Esse resultado é corroborado por Salmam et al., 2019 [48] que também não encontrou diferenças entre os grupos a longo prazo para manutenção das próteses. Sugere- se assim que o grupo CI apresentou maior perda de retenção no $3^0$ ano, gerando maior instabilidade das OM e isso pode estar associado à remodelação contínua do rebordo residual, pois na região posterior de mandíbula as OM seguem sendo mucossuportadas, e que esses resultados podem ser um reflexo tardio de um maior tempo de função das OM desse grupo devido ao carregamento precoce, sendo assim uma consequência, a longo prazo, da adoção desse tipo de carregamento.

Já em relação aos dados funcionais, verificou- se que durante o período de acompanhamento não houve diferenças significativas entre os grupos para os desfechos mastigatórios, evidenciando que funcionalmente os protocolos de carregamento, a longo prazo, se equiparam. Esse resultado foi corroborado por Komagamine et al., 2019 [54], que após o primeiro ano também não encontrou nenhuma diferença estatística significativa para a função mastigatória entre os grupos. Porém, quando analisado as mudanças durante todo o período de acompanhamento, verificou- se que cada um dos grupos respondeu de forma distinta e que mudanças foram perceptíveis em ambos os tipos de carregamentos. O grupo CI entre o $2^0$ e o $3^0$ ano, teve melhorias no PMX50 e na % de retenção na peneira 5.6, enquanto o CC teve piora no PMX50, no PMB e na peneira 5.6 nesse mesmo intervalo de tempo. Assim, percebe-se que o grupo CI seguiu melhorando a função mastigatória a longo prazo, evidenciando que a adoção dessa carga precoce, que consequentemente representa em um maior tempo de função das OM, nesses indivíduos, reflete ainda no $3^0$ ano em melhorias funcionais. A literatura aponta sobre melhorias funcionais iniciais do CI [33,54], nos primeiros meses pós carregamento, porém ainda se tem escassez de resultados do comportamento a longo prazo. Em um estudo de 5 anos de acompanhamento de OM carregadas de forma imediata, os autores também verificaram melhorias na função mastigatória, a longo prazo, nos indivíduos com carregamento precoce. Essa melhoria significativa entre 2 e 5 anos, após o carregamento, pode ser consequência da adoção da carga imediata das OM com 2 implantes, que reproduz uma melhoria prolongada, que iniciada de forma precoce, segue sendo positiva a longo prazo [55].

Por fim, sobre o impacto dos tipos de carregamento na QVRSB, verificou -se que também não houve diferença entre os grupos em nenhum dos períodos de acompanhamento, mas que ao longo dos anos, o grupo CI teve melhorias nos scores de dor, mas piora nos scores de performance geral. Já o CC teve mudanças no conforto oral no $3^0$ ano com pequena melhoria no conforto oral. Ao interpretarmos esses resultados, sugere- se que a melhoria na dor para o grupo CI, torna-se claro, visto que a OM é instalada imediatamente após a cirurgia, o que implica em aumento da dor nesses primeiros meses de função e que a percepção do paciente em relação a dor foi melhorando com o passar dos anos, demostrando que no primeiro ano o score era menor e a percepção de dor era presente, reduzindo esse impacto no $3^0$ ano. Já em relação ao domínio performance geral, acredita- se que pelo mesmo motivo de existir uma remodelação contínua do rebordo residual e existir um maior número de casos de redução de retenção da prótese devido ao maior número de trocas de cápsulas de retenção, essa possível associação pode estar refletindo nessa percepção de piora da performance geral com o maior tempo de uso das OM. A maioria dos estudos que relatam dados de qualidade de vida, que levam em consideração os diferentes tipos de carregamento, são de curto prazo mostrando melhorias de qualidade de vida e satisfação dos pacientes que tiveram suas OM carregados de forma imediata [27,56]. A longo prazo estudos mostram que melhorias visualizadas inicialmente para o CI seguem sendo vistas após 2 anos [57,58] até 5 anos [59], diferentemente do visto no nosso estudo que encontrou piora na performance geral para o grupo CI.

Dessa forma, nosso estudo contribui com a literatura existente e extrapolando nossos resultados para a prática clínica sugere-se que a carga imediata traz consequências positivas para os tecidos periimplantares. Porém, a adoção da carga precoce pode não ser capaz de reverter processo de reabsorção continua do rebordo residual mandibular (IAP) e que isso pode refletir, mesmo que não significativamente, a longo prazo, em maior número de manutenções e trocas de cápsulas retentivas, que podem levar em uma piora na percepção do paciente em relação a performance geral das OM. Porém, mesmo com essa percepção de piora, funcionalmente segue havendo melhorias na função mastigatória. Limitações desse estudo são referentes a ausência de avaliações de força de mordida que está fortemente associada a mastigação e pela dificuldade de comparação direta de resultados com estudos de maior tempo de acompanhamento. Para melhor compreensão do comportamento a longo prazo dos dois tipos de carregamento mais estudos são necessários, com maior número amostral e maior tempo de acompanhamento.

## CONCLUSÃO

Clinicamente o carregamento imediato mostrou, ainda no $3^0$ ano, tendência de remodelação óssea periimplantar, por ainda apresentar mudanças nos desfechos como ISQ, IPS e POM e progressiva redução na área óssea posterior de mandíbula, podendo ser reflexo do carreamento precoce que ainda repercute sobre o tecido periimplantar e rebordo residual mandibular. Ainda funcionalmente, o CI segue apresentando melhorias na função mastigatória ao longo dos anos, principalmente na trituração (PMX50) e na % de retenção na peineira 5.6 (EM5.6) e com melhorias na percepção para o domínio dor. Porém, quando analisado ao fim do $3^0$ ano, diferenças entre os grupos, o CI se igualou ao CC em todos os desfechos, tanto clínicos quanto funcionais e de QVRSB, somente apresentando diferença na POM nesse período, com uma menor perda óssea periimplantar, mostrando assim ser um tipo de carregamento bastante viável ainda a longo prazo, garantindo um processo reabilitador previsível e viável a longo prazo quando bem indicado.

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## Tabela Suplementar

Tabela S1: Valores médios e desvio padrão dos desfechos clínicos, ósseos, mastigatórios e de QVRSB (suplementar).

| | Carga Convencional | | | Carga Imediata | | |
|---|---|---|---|---|---|---|
| **Desfechos Clínicos (média/DP)** | **1 ano** | **2 anos** | **3 anos** | **1 ano** | **2 anos** | **3 anos** |
| IPS (mm) | 2.16/ 0.44 | 1.89/ 0.89 | 2.08/ 0.45 | 1.52/ 0.37 | 1.88/ 0.41 | 1.72/ 0.42 |
| ISQ | 54.29/ 5.02 | 57.83/ 4.25 | 57.26/ 5.17 | 52.70/ 13.99 | 55.03/ 6.54) | 59.13/ 2.91 |
| **Desfechos Clínicos (n/ % presença)** | | | | | | |
| ISG | 1.00/ 5.55% | 0.00/ 0.00% | 0.00/ 0.00% | 0.00/ 0.00% | 0.00/ 0.00% | 1.00/ 6.66% |
| IPV | 4.00/ 22.22% | 3.00/ 21.43% | 6.00/ 42.86% | 3.00/ 17.65% | 0.00/ 0.00% | 0.00/ 0.00% |
| GI | 0.00/ 0.00% | 3.00/ 21.43% | 0.00/ 0.00 % | 0.00/ 0.00% | 0.00/ 0.00% | 0.00/ 0.00% |
| **Desfechos Ósseos (média/DP)** | | | | | | |
| POM (mm) | -0.34/ 0.68 | -0.24/ 0.56 | -0.25/ 0.39 | -0.18/ 0.54 | -0.07/ 0.34 | -0.21/ 0.68 |
| IAP | 1.20/ 0.22 | 1.27/ 0.17 | 1.26/ 0.20 | 1.14/ 0.21 | 1.08/ 0.16 | 1.07/ 0.16 |
| **Performance Mastigatória (média/DP)** | | | | | | |
| PMX50 | 3.91/ 1.12 | 3.47/ 1.06 | 3.65/ 1.41 | 3.62/ 0.95 | 3.88/ 0.93 | 3.63/ 0.73 |
| PMB | 3.97/ 2.56 | 2.93/ 0.81 | 3.21/ 1.10 | 2.87/ 0.32 | 2.64/ 1.09 | 3.12/ 0.51 |
| EM 5.6 ( %) | 18.51/ 21.15 | 13.06/ 20.11 | 19.13/ 23.61 | 13.58/ 16.74 | 18.79/ 17.60 | 10.57/ 8.25 |
| EM 2.8 (%) | 22.74/ 12.33 | 19.40/ 10.28 | 23.90/ 9.12 | 27.44/ 7.38 | 27.35/ 11.64 | 27.52/ 7.08 |
| **QVRSB- DIDL – Escores dos Domínios** | | | | | | |
| Aparência | 1.00/ 0.00 | 1.00/0.00 | 1.00/0.00 | 1.00/0.00 | 0.94/0.17 | 0.88/0.22 |
| Dor | 0.95/015 | 0.89/0.21 | 0.97/0.08 | 0.89/0.21 | 0.88/0.22 | 0.91/0.17 |
| Conforto Oral | 0.94/0.12 | 0.78/0.37 | 0.95/0.10 | 0.74/0.37 | 0.91/0.14 | 0.79/0.20 |
| Performance Geral | 0.96/0.09 | 1.00/0.00 | 1.00/0.00 | 0.95/0.09 | 0.96/0.07 | 0.85/0.30 |
| Mastigação | 1.00/0.00 | 1.00/0.00 | 0.98/0.06 | 0.78/0.63 | 0.81/0.35 | 0.88/0.33 |

# 3 CONCLUSÃO GERAL

De acordo com o acompanhamento de usuários de OM, ao longo de 3 anos,foi possível concluirapós o desenho de 6 estudos clínicos que:

i) A retenção e estabilidade são os principais fatores que influenciam em uma limitada função mastigatória de usuários de prótese total convencional e que a reabilitação com overdentures mandibuares elimina amplamente esses dois problemas. Porém, que mesmo com o uso de overdentures por 1 ano, não houve melhora significativa na homogeneização dos alimentos para indivíduosClasse II e que essa baixa capacidade de homogeneizar os alimentos apresentada por esses pacientes não deve ser subestimada durante a reabilitação e acompanhamento de overdentures no primeiro ano;

ii) Usuários de OM alcançam maior força de mordida e melhor desempenho mastigatório do que usuários de prótese total convencional, e equalizam a diferença de força de mordida entre os lados dominante e não dominante. O desempenho mastigatório nos usuários de overdentures se correlaciona com uma força de mordida mais alta, através da capacidade aprimorada de trituração das partículas;

iii) A função mastigatória, qualidade de vida relacionada a saúde bucal e a área óssea na região posterior da mandíbula ainda variam significativamente ao longo do tempo em usuários de overdentures mandibulares. A força de mordida e o índice de área posterior foram intimamente correlacionados e influenciaram significativamente a função mastigatória de pacientes idosos totalmente desdentados com mandíbulas atróficas reabilitadas com overdentures mandibulares durante o terceiro ano de função;

iv) O desempenho mastigatório e os parâmetros de qualidade de vida relacionados à saúde bucal de usuárias de overdenture mandibular ainda mudam ao longo do tempo quando levado em consideração o padrão facial, discrepâncias esqueléticas ântero-posteriores e sexo. Em nossa população de estudo, as diferenças na morfologia facial continuaram a influenciar a função mastigatória e a qualidade de vida relacionada à saúde bucal no 3º ano de função e a idade pode influenciar alguns domínios da qualidade de vida relacionada à saúde bucal. A longo prazo, indivíduos braquifaciais foram os que menos se beneficiaram da reabilitação com as overdentures mandibulares, pois vários resultados mastigatórios se deterioraram, como homogeneização de partículas e eficiência mastigatória (EM_2.8);

v) Ao longo de 3 anos de função de overdentures retida por implantes de diâmetro reduzido, vários parâmetros clínicos ainda mudaram significativamente refletindo em uma remodelação contínua dos tecidos periimplantares. Mudanças nos parâmetros funcionais demonstraram que a capacidade mastigatória dos usuários de overdentures mandibulares ainda está evoluindo ao longo de 3 anos, após o carregamento. Complicações protéticas que geram instabilidade das próteses ou impedem o funcionamento normal afetam negativamente a qualidade de vida. A leve deterioração na capacidade de homogeneização das partículas pode ser atribuída à instabilidade e ao desgaste das próteses a longo prazo;

vi) Clinicamente o carregamento imediato mostrou, ainda no $3^0$ ano, tendência de remodelação óssea periimplantar, por ainda apresentar mudanças nos desfechos como coeficiente de estabilidade secundária (ISQ), profundidade de sondagem (IPS) e perda óssea marginal (POM) e progressiva redução na área óssea posterior de mandíbula, podendo ser reflexo do carreamento precoce que ainda repercute sobre o tecido periimplantar e rebordo residual mandibular. Ainda funcionalmente, o carregamento imediato segue apresentando melhorias na função mastigatória ao longo dos anos, principalmente na trituração (PMX50) e na % de retenção na peneira 5.6 (EM5.6) e com melhorias na percepção para o domínio dor. Porém, quando analisado ao fim do $3^0$ ano, diferenças entre os grupos, o carregamento imediato se igualou ao carregamento convencinal em todos os desfechos, tanto clínicos quanto funcionais e de qualidade de vida relacionada à saúde bucal, somente apresentando diferença na perda óssea marginal nesse período, com uma menor perda óssea periimplantar. O carregamento imediato mostra assim ser bastante viável ainda a longo prazo, garantindo um processo reabilitador previsível a longo prazo, quando bem indicado.

Dessa forma, a longo prazo, através do acompanhamento das overdentures mandibulares, conclui- se de forma geral que ainda há influência de fatores intrínsecos dos indivíduos; como atrofia mandibular, padrão facial, classificação ântero-posterior e força de mordida, além do carregamento oclusal adotado, ao longo do tempo de função das OM e que variações no desempenho mastigatório, qualidade de vida relacionada à saúde bucal e das variáveis clínicas e ósseas ainda são observadas nesse período de acompanhamento. Além disso, as altas taxas de sucessoe sobrevivência e mínimas complicações biológicas e intervenções protéticas foram reportadas, mostrando que as overdentures retidas por 2 implantes de diâmetro reduzido podem ser fortemente indicadas e implementadas na rotina clínica de reabilitação de indivíduos idosos, edêntulos totais e com grau de atrofia mandibular, sendo um tratamento previsível e com sucesso clínico e funcional, a longo prazo, garantido.

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