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FÁBIO SÁ CARNEIRO SCZEPANIK

AVALIAÇÃO DA MANUTENÇÃO ÓSSEA EM IMPLANTES INSTALADOS A PARTIR DA ABORDAGEM TRIMODAL: ACOMPANHAMENTO DE 1-4 ANOS

Porto Alegre
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Dissertação apresentada como requisito para a obtenção do grau de Mestre pelo programa de Pós-Graduação da Faculdade de Odontologia da Pontifícia Universidade Católica do Rio Grande do Sul.

Orientador: Prof. Dr. Márcio Lima Grossi

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Aprovada em: _____ de _____ de _____.

BANCA EXAMINADORA:

Prof. Dr. Márcio Lima Grossi – PUCRS

Prof. Dr. Regenio Mahfuz Herbistrith Segundo – PUCRS

Profa. Dra. Vivian Chiada Maineri – UFRGS

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Dedico este trabalho à fonte de minha inspiração
diária, meus avós Lorena e Edy.

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RESUMO

Objetivos: O objetivo desta investigação retrospectiva foi avaliar, radiograficamente e clinicamente, um grupo de pacientes tratados com instalação imediata de implantes unitários, provisório imediato com um pilar protético personalizado, com uma abordagem sem descolamento de retalho mucoperiostal na região ântero superior. Nível da crista óssea marginal e crista óssea marginal a nível dos dentes adjacentes foram avaliados. **Materiais e métodos:** Uma amostra de 20 indivíduos recebeu 20 implantes cônicos com mudança de plataforma através de uma abordagem minimamente invasiva (abordagem trimodal). A média de idade foi de 55,2 anos (variando de 25 a 71 anos) e o período médio de acompanhamento foi de 2,2 anos (variando de 12 a 48 meses). **Resultados:** A taxa total de sobrevivência dos implantes e coroas definitivas foi de 100%. Não houve diferença estatisticamente significativa entre MBLN nas faces mesial e distal, comparando-se baseline ao controle final, assim como não houve entre as quatro radiografias independentemente (i.e. baseline, 6 meses, 12 meses e controle final). Houve diferença estatisticamente significativa entre MBL nas faces mesial e distal entre baseline e o controle final ($p<0,05$). **Conclusão:** Dentro das limitações deste estudo, demonstramos que a abordagem trimodal pode oferecer uma vantagem em termos de níveis de crista óssea marginal, especialmente em MBLN, durante um período médio de acompanhamento de 26 meses. Adicionalmente, reduzido tempo total de tratamento, apenas uma etapa cirúrgica e estética imediata podem ser obtidos com 100% de taxas de sobrevivência e sucesso, utilizando uma abordagem minimamente invasiva.

Palavras-chave: Implante imediato. Provisório imediato. Cirurgia sem retalho. Abordagem Trimodal. Crista óssea marginal.

ABSTRACT

Purpose: The purpose of this retrospective investigation was to evaluate, radiographically and clinically, a group of patients treated with immediate single-tooth placement, immediate restoration implants with a customized definitive abutment with a flapless approach in the area between both maxillary canines. Marginal bone level (MBL) and marginal bone level of neighboring teeth (MBLN) were assessed. **Methods:** A sample of 20 subjects received 20 tapered platform-switching implants using a minimally invasive surgery (trimodal approach). The mean age was 55.2 years (range 25 - 71 years), and the mean follow-up period was 2.2 years (range 12 - 48 months). **Results:** The overall treatment survival was 100%. There was no statistically significant difference between MBLN in both mesial and distal aspects, comparing baseline to final follow-up and between the four radiographs independently (i.e., at baseline, at 06 months, at 12 months, and at final follow-up). There was a statistically significant difference between MBL in both mesial and distal aspects at baseline and at final follow-up ($p<0.05$). **Conclusion:** Within the limitations of this study, it has demonstrated that the trimodal approach might offer an advantage in terms of marginal bone levels, especially in MBLN, in a mean follow-up time of 26 months. Additionally, reduced overall treatment time, one surgical intervention, and immediate esthetics can be obtained with 100% survival and success rates using a minimally invasive approach.

Key-words: Immediate placement. Immediate loading. Flapless approach. Trimodal approach. Peri-implant marginal bone level.

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1. INTRODUÇÃO

A atual busca pela estética em reabilitações orais modificou a forma com que abordamos os pacientes com indicação de extração e instalação de implantes osseointegrados, especialmente na região ântero superior. A instalação imediata de implantes é uma técnica consolidada na literatura e tem mostrado previsibilidade muito similar aos casos de instalação em osso cicatrizado (CABELLO et al. 2009; LANG et al. 2011), não havendo diferença estatisticamente significativa em termos de taxa de sobrevivência quando comparados os implantes imediatos *versus* tardios (CHEN et al. 2004; KAN et al 2011; LANG et al 2011).

Ao trabalharmos na região ântero superior, a altura e a espessura da parede óssea vestibular, presença de papila interdental e o biótipo gengival são considerados fatores chave para atingirmos níveis de estética satisfatórios (BUSER et al. 2004; EVANS & CHEN et al. 2007). A parede óssea vestibular dos dentes anteriores localizados na maxila geralmente apresenta-se fina ou ausente e sofre grande reabsorção após extração (BRAUT et al. 2011). A sua manutenção está diretamente ligada ao posicionamento vestíbulo-palatino desses implantes, devendo os mesmos estarem idealmente posicionados de 1-2mm palatinamente aos dentes adjacentes (BUSER et al. 2004) e de 3-4mm abaixo da margem gengival vestibular (EVANS & CHEN et al. 2007). O seu posicionamento mais vestibularizado ou ao nível dos dentes vizinhos mostrou chances três vezes maiores de perda da parede vestibular e, consequentemente, perda da arquitetura gengival (EVANS & CHEN et al. 2007). A presença de papila interdental está majoritariamente relacionada à altura óssea interproximal dos dentes adjacentes (BUSER et al. 2004; KAN et al. 2011). Deve ser respeitada a distância mínima de 1.5mm entre os dentes adjacentes no momento da instalação do implante para que não haja perda da crista alveolar (BUSER et al. 2004).

O biótipo gengival é definido pela visibilidade (fino) ou não (espesso) da sonda periodontal milimetrada através do tecido gengival quando a sondagem periodontal é realizada (KAN et al. 2003). Os indivíduos com biótipo gengival mais fino têm menores chances de formação de papila interdental (BUSER et al. 2004) e maior migração dos tecidos moles no sentido apical (45.8% *versus* 33.3%) (EVANS & CHEN et al. 2007),

apresentando maior recessão gengival quando comparados com indivíduos com biótipo espesso (85.7% versus 66.7%). Enquanto que os pacientes com maior espessura gengival apresentaram mudanças no aspecto da mucosa vestibular significativamente menores seguidas da exodontia e da instalação de implantes (KAN et al. 2003). Após a extração, a parede óssea vestibular deve apresentar ao menos 2mm de espessura para evitar a sua reabsorção, caso contrário, algum procedimento de enxertia deve ser utilizado (HOF et al. 2013; BRAUT et al. 2011). Portanto, o momento para realizar a instalação do implante seguida da exodontia pode ser importante para tirar vantagem da cicatrização de tecido mole e diminuir o risco de reabsorção óssea vestibular (CHEN et al 2004; KAN et al 2011).

O processo de cicatrização pós extração vem acompanhado de uma série de eventos biológicos (CABELLO et al 2013) que podem influenciar negativamente o resultado final de um tratamento com implantes na zona anterior. Recessão gengival, perda de papila interdental e de crista óssea marginal estão intimamente ligados (GUIRADO et al. 2009; BRAUT et al. 2011; BUSER et al. 2004) e são os principais fatores que devem ser controlados. Extrações realizadas sem o tradicional descolamento muco periostal apresentam menor perda óssea marginal quando comparadas à técnica tradicional (TSOUKAKI et al. 2013), além de reduzir o tempo de tratamento, o sangramento transoperatório e as chances de futuro desenvolvimento de periimplantite (YOU et al. 2009). Além disso, o descolamento muco periostal reduz a quantidade de mucosa queratinizada (BARONE et al. 2013), alterando a arquitetura gengival pós extração e aumentando os sinais inflamatórios clínica e histologicamente (YOU et al. 2009; BASHUTSKI et al. 2013; TSOUKAKI et al. 2013).

A instalação de um provisório imediato proporciona o acondicionamento do tecido mole periimplantar através da manutenção da arquitetura gengival (CANULLO et al. 2010; KAN et al 2003), preservando o contorno e o volume dos tecidos moles (DE CARVALHO et al. 2013). Adicionalmente, a instalação de pilares provisórios mostrou sinais inflamatórios mais exacerbados, maior migração do epitélio juncional no sentido apical e maior perda de crista óssea marginal (GRANDI et al. 2012), sugerindo que a não remoção dos pilares definitivos em titânio instalados no ato cirúrgico resultam em redução estatisticamente significativa dos níveis de perda óssea (CANULLO et al. 2010) e, consequentemente, redução na migração dos tecidos moles

no sentido apical. Além disso, estudos comparativos mostraram que as taxas de sucesso de implantes unitários instalados em zona estética com carga tardia (97%) *versus* provisório imediato (98%) são similares (KAN et al. 2003; KAN et al. 2010), fortalecendo a ideia de que a instalação de um provisório imediato é uma técnica segura e previsível. A forma dos pilares protéticos também influencia no resultado final (FREITAS et al 2011), devendo os mesmos respeitarem os princípios biomecânicos dos preparos protéticos, afim de estabelecer uma relação natural e harmônica com os tecidos moles circundantes. Coroas protéticas cimentadas na região anterior favorecem a estética e apresentam vantagens na distribuição de carga mastigatória quando comparadas com restaurações protéticas parafusadas (FREITAS et al 2011).

Tarnow e colaboradores relataram que após restauração com implantes utilizando a técnica tradicional, houve migração do tecido ósseo de 1.4 – 2.0mm a partir da união implante-pilar no primeiro ano de função (GUIRADO, 2009, HÜRZELER et al. 2007). Atieh e colaboradores (2010) vêm relatando que média de reabsorção nos anos seguintes está na casa dos 0.2mm, mais ainda não há um consenso estabelecido na literatura. Revisão sistemática da literatura realizada com estudos em humanos e com a presença de grupo controle, no período de 2007 à 2010 e com um total de 1.239 implantes, mostrou perda óssea marginal significativamente menor em implantes com mudança de plataforma, além de tecido duro substancialmente mais estável (ATIEH et al. 2010). O tempo de acompanhamento desses estudos variou de 12 aos 60 meses. Em estudo prospectivo avaliando as alterações ósseas após um ano da instalação de implantes com mudança de plataforma, a diferença entre *baseline* e follow-up foram de $-0.12\text{mm} \pm 0.40\text{mm}$ para os implantes com mudança de plataforma, contra $-0.29\text{mm} \pm 0.34\text{mm}$ ($p \leq 0.0001$) (HÜRZELER et al. 2007). A razão para essa redução na perda de quantidade óssea marginal pode estar relacionada ao posicionamento mais apical da junção implante-*abutment*, afastando o infiltrado inflamatório da crista alveolar (ATIEH et al. 2010; CANULLO et al. 2010; HÜRZELER et al. 2007). Além disso, há uma vantagem biomecânica nesse tipo de conexão, relatando que a diferença entre os diâmetros do pilar protético e da cabeça do implante reduz a concentração de stress ósseo na região cervical (MAEDA et al. 2007), reduzindo a sua migração no sentido apical. Canullo e colaboradores, em um ensaio clínico randomizado controlado duplo cego, relatam que implantes restaurados com o conceito de mudança de plataforma

apresentaram redução significativa nos níveis de perda óssea marginal e uma correlação negativa entre perda óssea e diferença de diâmetro entre implante e abutment foi encontrada (CANULLO et al. 2010). Uma redução de 0.45mm no diâmetro do pilar parece ser necessária para reduzir a perda óssea marginal (HÜRZELER et al. 2007).

Outro fator que influencia na manutenção de tecido ósseo periimplantar é o tipo de conexão. A interface implante-pilar é a região mais suscetível à contaminação bacteriana e a que mais sofre com o impacto mastigatório. Em revisão sistemática da literatura avaliando a performance de conexões do tipo *cone morse*, não foram detectados micro movimentos do abutment sob forças verticais e oblíquas. Este tipo de conexão mostrou maior resistência à perda de torque e à fratura e menor stress sobre o parafuso quando comparado com conexões não cônicas. A geometria da conexão *cone morse* distribui mais homogeneousmente o stress do impacto oclusal para o implante, melhorando o selamento, diminuindo a contaminação bacteriana e a reabsorção óssea circundante (SCHMITT et al. 2013).

O objetivo desta investigação retrospectiva foi avaliar, radiograficamente e clinicamente, um grupo de pacientes tratados com instalação imediata de implantes unitários, provisório imediato com um pilar protético personalizado, com uma abordagem sem descolamento de retalho mucoperiostal na região ântero superior. Nível da crista óssea marginal e crista óssea marginal a nível dos dentes adjacentes foram avaliados.

2. ARTIGO

EVALUATION OF BONE PRESERVATION AROUND IMPLANTS PLACED WITH THE TRIMODAL APPRACH: A 1 – 4 YEARS FOLLOW-UP

Fábio Sá Carneiro Sczepanik, DDS^a
Márcio Lima Grossi, DDS, MS, PhD^b
Eduardo Rolim Teixeira, DDS, PhD^c
José Cícero Dinato, DDS, MS, PhD^d
Thiago Revillion Dinato, DDS^e

Purpose: The purpose of this retrospective investigation was to evaluate, radiographically and clinically, a group of patients treated with immediate single-tooth placement, immediate restoration implants with a customized definitive abutment with a flapless approach in the area between both maxillary canines. Marginal bone level (MBL) and marginal bone level of neighboring teeth (MBLN) were assessed, and the final MBL and MBLN were correlated with clinical variables. **Methods:** A sample of 20 subjects received 20 tapered platform-switching implants using a minimally invasive surgery (trimodal approach). The mean age was 55.2 years (range 25 - 71 years), and the mean follow-up period was 2.2 years (range 12 - 48 months). **Results:** The overall treatment survival was 100%. There was no statistically significant difference between MBLN in both mesial and distal aspects, comparing baseline to final follow-up and between the four radiographs independently (i.e., at baseline, at 06 months, at 12 months, and at final follow-up). There was a statistically significant difference between MBL in both mesial and distal aspects at baseline and at final follow-up ($p<0.05$). **Conclusion:** Within the limitations of this study, it has demonstrated that the trimodal approach might offer an advantage in terms of marginal bone levels, especially in MBLN, in a mean follow-up time of 26 months. Additionally, reduced overall treatment time, one surgical intervention, and immediate esthetics can be obtained with 100% survival and success rates using a minimally invasive approach. Additional long-term, well-conducted, randomized-controlled trials are needed to confirm the validity of the trimodal approach.

Key-words: Immediate placement. Immediate loading. Flapless approach. Trimodal approach. Peri-implant marginal bone level.

^a Private practice, Porto Alegre, Brazil.

^b Prosthodontist; Master Of Science Restorative Dentistry-Occlusion; Doctor of Philosophy. Professor, Department of Prosthodontics, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil. Adress: Ipiranga, 6681

^c Prosthodontist; Doctor of Philosophy in Dental Sciences. Professor, Department of Prosthodontics, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil. Adress: Ipiranga, 6681

^d Implantologist; Prosthodontist; Master of Science Prosthodontics; Doctor of Philosofy in Implantology. Adress: Furriel Luiz Antônio Vargas, 250/1501

^e Implantologist; Adress: Furriel Luiz Antônio Vargas, 250/1501

Correspondence to: Dr. FSC Sczepanik, Clínica Dinato de Odontologia, CEP:90470-130, Porto Alegre, Brazil. Fax: +555133332717. Email:fabiosacarneiro@gmail.com

INTRODUCTION

As the technique of replacing missing teeth in healed edentulous sites offered a predictable and effective outcome^{1,2}. Different placement protocols have evolved to expand implant therapy applicability, starting with the first reports about immediate implant placement into extraction sites described by Schulte and colleagues² and Lazzara and colleagues⁴. Bone preservation and soft tissue stability are one of the benefits related to this approach^{5,6} as they reduce the number of surgical interventions, overall treatment time and morbidity; and they have attracted attention in recent years^{1,7}, representing a clear advantage for our day-to-day practice⁶ and patient well-being. Moreover, a recent systematic review, which have evaluated 2934 implants placed into fresh sockets in 2130 patients, have showed an annual failure rate of 0.82% and a 2-year survival rate of 98.4%¹.

Additionally, immediate loading protocols have been suggested as a way to restore aesthetic appearance², specially in the anterior maxilla, as soft tissue contour and gingival architecture can be maintained^{9,10}, adding a predictability of implant survival and papilla levels over time⁷. A systematic review have evaluated the survival rate of immediately restored implants as compared to implants conventionally restored after 1 year of implant placement, and the difference was not statistically significant (0.75% vs 0.89%)¹. Furthermore, combining a provisional crown with a definitive abutment during the healing phase may prevent bone remodeling from happening according to several authors¹⁰⁻¹³.

The elevation and advancement of a full thickness flap can cause post-operative bone resorption, reduced keratinized mucosa¹⁴, loss of gingival/papillae architecture¹⁵, higher risk of developing periimplantitis, and enhanced clinically and histologically inflammatory signs^{16,17}. Thus, the use of a minimally invasive approach, by means of a flapless protocol, may reduce bone remodeling¹⁴ and improve the esthetic result¹⁸. The complete preservation of the alveolar ridge dimension after tooth extraction is unlikely to be attainable, even with the use of a bone substitute and collagen membrane¹⁴.

Despite the high survival rate, the marginal bone level (MBL) around implants is an important factor in the success criteria for evaluating implant therapy¹⁹. Laurell and

colleagues in a 5-year of function meta-analysis have reported a mean marginal bone loss of 0.48 mm for platform-switched implants, and have suggested a revision of the existing implant success criteria²⁰. The use of a smaller diameter abutment on a larger diameter implant collar, with a conical abutment-implant attachment system, reduces de gap between both interfaces. This reduction shifts the inflammatory cell infiltrate to the central axis of the implant, which limits crestal bone resorption^{21,22}.

Additionally, a key point in maintaining interdental papillae may be the bone level to the adjacent tooth. Preserving this bone peak throughout extraction of the tooth as well as during implant placement may secure papilla height over time⁷.

Recently, few studies have been published reporting a minimally invasive approach, which consists: a) hard tissue preservation, b) peri-implant mucosal maintenance, c) reduced treatment time, and d) improved esthetic results. Primarily, an immediate placement and restoration/loading protocol have led to the introduction of a bimodal approach (BA)², which have shown similar survival rates to the conventional protocols and encouraging esthetic outcomes in a 5-year case-control study²³. Posteriorly, Cabello and colleagues added a third element to the BA: a flapless surgery, leading to a trimodal approach (TA)²⁴. This TA approach consisted of an immediate single tooth placement and an immediate provisional loading with no mucoperiostal flap raised.

Therefore, the aim of this retrospective study was twofold. First, to evaluate radiographically patients treated within TA criteria, in the area comprehended between both maxillary canines in terms of marginal bone level (MBL) and marginal bone level of neighboring teeth (MBLN). Second, to compare final MBL and MBLN with the clinical variables.

MATERIAL AND METHODS

Patients and study design

This retrospective study was based on data from 20 patients (12 females and 8 males) who were treated in a private practice in the city of Porto Alegre, in the state of Rio Grande do Sul (Brazil), who had undergone immediate placement and temporization of one single-tooth implant within the anterior maxilla (incisors and canines) using a flapless technique, and who had a definitive titanium abutment. The mean age was 55.2 ± 13.2 years (range 25 to 71 years), and the follow-up period was at least 12 months (mean = 2.2 ± 1.03 years, range 12 to 48 months). The same practitioner (J. C. D.) have treated all patients between 2010 and 2014, and he did not participate in the data collection and evaluation. The study protocol was reviewed and approved by the Research Ethics Committee (CEP, 808.513) of the Pontifical Catholic University of Rio Grande do Sul (PUCRS), Brazil.

The inclusion criteria was: a) patients with the need of a single tooth extraction in the anterior sector.

The exclusion criteria was: a) patients under 18 years of age, b) systemic diseases that would otherwise contraindicate surgery (uncontrolled diabetes, hemophilia, radiation treatment to the head and neck region, current chemotherapy, treatment with oral bisphosphonates), c) acute infection in the treatment area, d) absence of the adjacent tooth/presence of an adjacent implant, e) probing depth over 3mm, f) heavy smokers (more than 10 cigarettes a day), g) absence of opposite teeth, and h) if the principles of trimodal approach could not be followed during surgery. Patients who used less than 10 cigarettes/day were not excluded, but were instructed to stop smoking throughout the treatment. Patients with chronic endodontic pathology and/or buccal bone wall resorption were included in this study.

Surgical protocol

Before surgery, *cone beam computerized tomography* (CBCT) and periapical radiographs were requested in order to establish the indication for tooth extraction as well as the initial diagnosis and treatment planning. Patients agreed with the treatment plan and consented to be treated. They underwent professional prophylaxis and

periodontal treatment, if necessary, prior to the implant surgery. All patients received 2g of amoxicillin 1h before the procedure, and 0.12% chlorhexidine gluconate mouthwashes were given immediately before the surgery for oral disinfection.

Tooth removal was done as atraumatically as possible (Articaine 100, DFL, Rio de Janeiro, Brazil) using a specific extractor (Benex Root Extraction System, Hager and Meisinger GMbH, Neuss, Germany) without raising the mucoperiostal flap. The socket was vigorously debrided with the help of manual curettes. A roughened surface Morse tapered implant (CM Drive, Neodent, Curitiba, Brazil) was placed at 2 to 3 mm beneath the bone crest and 2 mm palatal to the buccal bone wall, with a minimum initial insertion torque of 35 N/cm verified with a digital device. The gap between the implant's shoulder and the inner wall of the buccal aspect was filled with an anorganic bovine bone in small particles (0.25 – 1 mm) (Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland).

Clinical procedures

Implant's platform impression was took immediately after surgery with a help of a rubber dam (Madeitex, São José dos Campos, SP, Brazil) in order to fabricate an acrylic provisional crown adapted to a customized definitive titanium abutment extraorally. The abutment was digitally scanned with a laboratory device (Neo Shape D700, 3Shape, Copenhagen, Denmark) to fabricate a zirconium oxide reinforced coping to be placed after the osseointegration process is completed (05 months). Within 24 hours after surgery, the abutment was tightened at 20 N/cm; and an acrylic crown cemented provisionally (Dycal, Dentsply, York, United States) with a non-functional loading (i.e., centric or eccentric contacts). A distance was left between the gingival contour and the cervical aspect of the provisional crown in order to avoid soft tissue compression. Abutments had a reduced diameter in comparison to implant's platform diameter and had a conical connection.

After surgery, patients were instructed to have a soft diet and to avoid chewing in the treated area for the remaining duration of the implant healing phase. Drug therapy consisted in antibiotics (i.e., Amoxicillin 875mg, every 12h for 7 days),

analgesic and anti-inflammatory drugs (i.e., Nimesulide 100mg, every 12h for 3 days) and mouthwashes (i.e., 0.12% chlorhexidine gluconate, twice daily for 7-10 days).

Definitive crown delivery

Five months after surgery, the provisional crown was removed, the absence of suppuration/inflammatory signs was checked, and abutment torque confirmed with a torque wrench. A CAD/CAM machined zirconium oxide coping (InLab MC XL, Sirona, Salzburg, Austria) was placed onto the abutment, and a coping pick-up silicone impression was taken (Regular Body Normal Set, Elite HD+, Zhermack, Rovigo, Italy). Feldspathic ceramic was manually applied in the final master cast and cemented definitively with a resin-modified glass ionomer cement (Relyx Luting 2, 3M ESPE, California, United States), with manual compression for 10 minutes. The cement excess was then removed with the help of a sounder and a dental floss. Patients were instructed not to chew or to floss during the first 24 hours post cementation. A periapical radiograph was taken in order to assess the presence of any residual cement remnants. All materials were handled according to the manufacturer instructions. The treatment sequence is shown in figures 1 - 5.



Fig. 1. Initial clinical aspect. Upper left central incisor with indication of extraction due to root fracture.

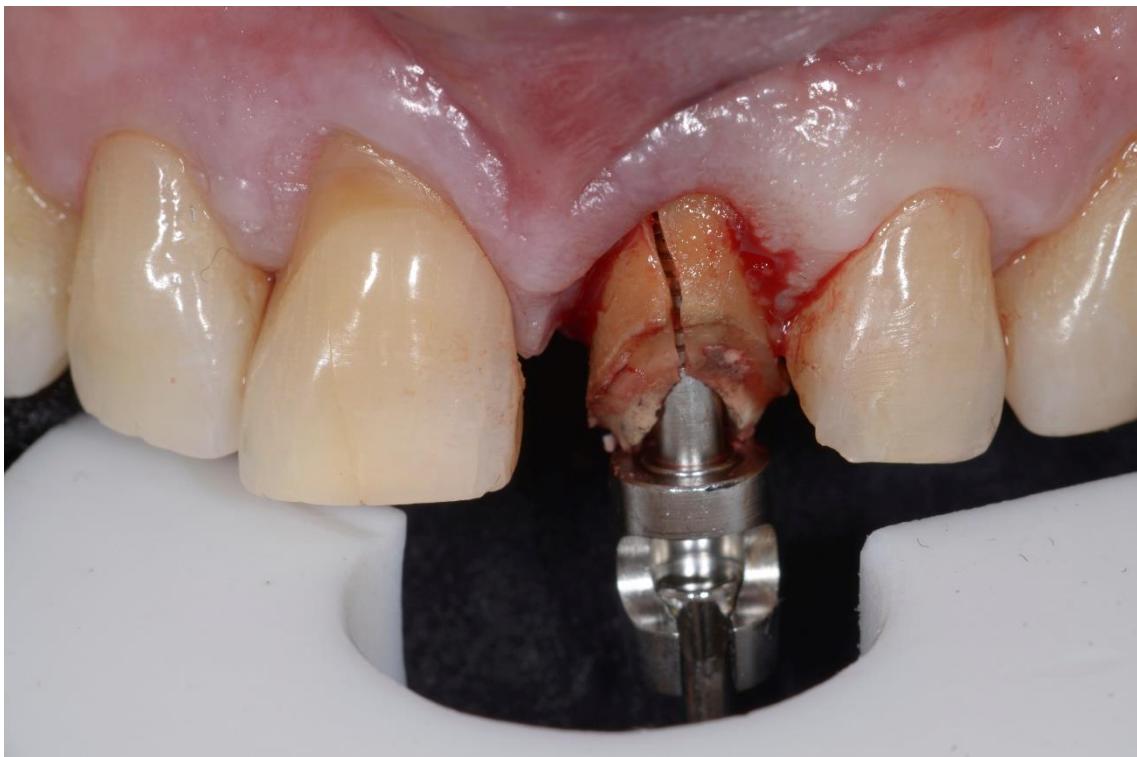


Fig. 2. Atraumatic extraction with the help of a especific extactor (Benex Root Extraction System, Hager and Meisinger GmbH, Neuss, Germany), with a flapless approach.



Fig. 3. Customized definitive titanium abutment tightened at 20 N/cm. Buccal aspect. Notice the graft material, and its intimate contact with oral environment. These anorganic bovine bone particles will unavoidably be lost, during the first 6 months.



Fig. 4. Buccal aspect of the provisional crown 7 days post-surgery. Notice the soft tissue stability, and how the gingival margin adapted to the surface of the provisional crown.



Fig. 5. Definitive crown delivery. At the 06 months follow-up.

Clinical evaluation

Patients were scheduled for follow-up visits once a month during the first 5 months of post implant placement, and then once annually after the final crown delivery. This was part of a maintenance program meant to assess clinical parameters, such as: bleeding on probing, spontaneous bleeding and plaque index. Clinical complications, such as abutment loosening/fracture and final crown chipping/fracture, were also recorded, if present.

Radiographic evaluation

For each patient, intraorally digitalized radiographs were taken with the use of both a universal radiographic positioner and the parallel technique at three different times: at baseline (up to 30 days after surgery), at 06 months (final crown delivery) and at 12 months. If the follow-up exceeded 12 months, the latest radiograph was used (follow-up time ranged from 12 to 48 months).

Measurement technique

The distance between the implant shoulder and its respective bone crest (i.e., marginal bone level or MBL) was carried out in both mesial and distal aspects, described as positive (i.e., bone crest coronal to the implant shoulder) or negative (i.e., bone crest apical to the implant shoulder). Additionally, the distance between the implant shoulder and marginal bone level of neighbouring teeth (MBLN), in both mesial and distal aspects, was performed by tracing a line perpendicularly to the implant long axis at the implant shoulder level. After that, we measured its distance to the most coronal interproximal bone crest of the neighbouring tooth, described as positive (bone crest coronal to the implant shoulder) or negative (bone crest apical to the implant shoulder). Illustrations demonstrating radiographic follow-up and its measurements are shown in Fig.6.

The radiographic implant length was measured, and compared with the true implant length (11.5 mm, 13 mm, 16 mm), for adjusting bone level and distance measurements, according to image magnification. The same equation was used to determine the distance from the implant shoulder to MBL, and the distance from the implant shoulder to MBLN. Brightness, contrast, magnification and the measurements were controlled and standardized in all radiographs with a specific imaging software (DBSWIN Imaging Software, Dürr Dental, Bietigheim-Bissingen, Germany).

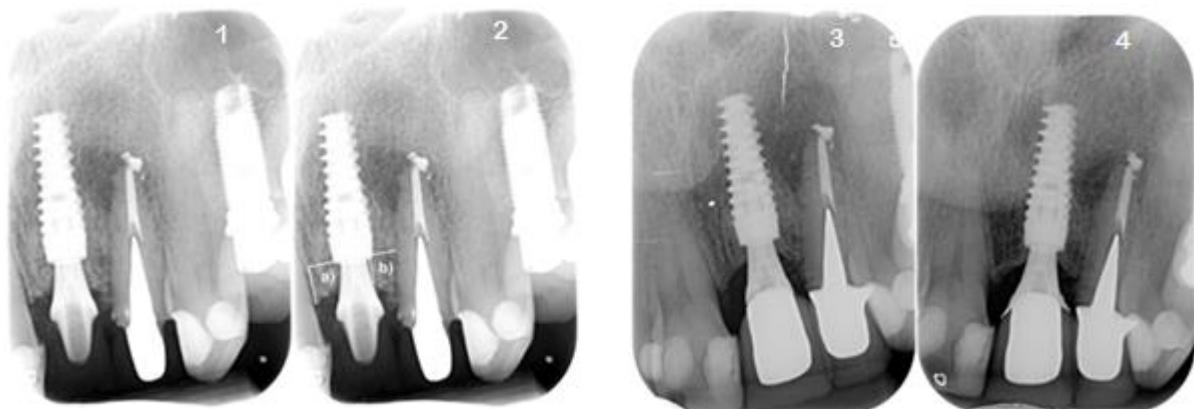


Fig. 6. Demonstrating radiographs at the baseline (1, 2), at the 6 months follow-up (3) and at the final follow-up (4). Measurement of MBLN (a) and MBL (b).

Data collection

One independent examiner performed all examinations and data collection. Evaluations were made at baseline (up to 30 days before implant placement), at 06, and at 12 months. If the follow-up exceeded 12 months, the latest radiograph was used (follow-up time ranged from 12 to 48 months). The following variables were recorded: a) age, b) gender, c) surgery site, d) implant features, e) follow-up time, f) implant success/failure, g) marginal bone level (MBL), and h) marginal bone level of neighbouring teeth (MBLN). Measurements were made in both mesial and distal aspects.

Sample size calculation and statistical analysis

For the reduction in marginal bone loss, repeated measures Analysis of Variance (ANOVA) and the Tukey-b Post-Hoc test will be used for the differences within and between groups.

The formula for the sample size calculation of hypothesis testing for population proportions is: $n = \{Z_{1-\alpha}\sqrt{[Po(1 - Po)]} + Z_{1-\beta}\sqrt{[Pa(1 - Pa)]}\}^2 / (Po - Pa)^2$; in which n = estimated sample size, Po = proportion value test of the population under the null hypothesis, Pa = anticipated value of the population proportion, $Z_{1-\alpha}$ = standard distribution value corresponding to a α level of significance (e.g. 1.96 for a one-sided test at a 0.05 level), and $Z_{1-\beta}$ = value of the normal distribution corresponding to the desired power level (e.g. 0.84 for a power of 80%). Using a success rate of 95% and an anticipated success rate of 85%, we reach a sample size of 44 individuals²⁵.

RESULTS

Patients who had received immediate placement/loading of one single-tooth tapered implant in the esthetic zone until to February 2014 were selected to this retrospective study. Twenty consecutive individuals were included for the radiographic and clinical analysis, with a mean age at implant insertion of 55.2 years (± 13.2), ranging from 25 to 71 years. Sixty per cent of the patients were female and forty per cent were male (Table I). The mean follow-up time was 2.2 years (± 1.03), ranging from 12 to 48 months (Table II). Sixty per cent of extractions were indicated because of root fracture and none was indicated because of chronic periodontal disease. Reasons for tooth extraction were in Table III.

Seventy per cent of the implants had a regular platform (4.3 mm), while a narrow platform implant (3.5 mm) was used in only 30% of the patients. The most frequent implant use had a regular diameter (4.3 mm) and was 13 mm length (45%). The upper left central incisor was the most frequent tooth restored (45%), followed by its contralateral tooth (25%). In the sample, only the upper left canine was not present. Description of surgery and implant characteristics are listed in Table III.

Table I. Social and demographic characteristics of implant patients and description of implant surgical characteristics (n = 20)

<i>Independent variables</i>	(n=24)
<u>Age (years)</u>	
Mean (\pm SD)	55.2 (13.2)
<u>Gender (%)</u>	
Women	60.0
Men	40.0

Table II. Description of surgery and implant component characteristics

<u>Implant size (%)</u>	(n=20)
3.5 x 13.0	15.0
3.5 x 16.0	15.0
4.3 x 10.0	5.0
4.3 x 13.0	45.0
4.3 x 16.0	20.0

Site of implant surgery (%) **(n=20)**

Upper right central incisor (# 11) 25.0

Upper right lateral incisor (#12) 5.0

Upper right canine (# 13)	5.0
Upper left central incisor (# 21)	45.0
Upper left left incisor (#22)	20.0

<u>Follow-up time (years)</u>	(n=20)
Mean (S.D.)	2.26 (1.03)

<u>Follow-up time (%)</u>	(n = 20)
1.0 year	10.5
1.5 years	31.6
2.0 years	21.1
2.5 years	5.3
3.0 years	10.5
3.5 years	10.5
4.0 years	5.3
4.5 years	5.3

Table III. Reasons for tooth extraction (%)

Reasons for extraction	(n=20)
Root fracture (%)	60.0
Endodontic pathology (%)	
Endo-periodontal lesion	25.0

Root resorption (%)	15.0
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Implant and definitive crown survival

All 20 implants showed an uneventful healing and integrated, presenting a survival rate of 100%. None of the 20 definitive crowns was lost and no clinical complications were recorded during the follow-up visits, such as: ceramic fracture, abutment loosening, or periimplantitis.

Radiographic marginal bone level of neighbouring tooth

Comparison of mean MBLN and MBL in both mesial and distal aspects among different follow-up time periods are shown in table IV.

The mean marginal bone level of neighbouring tooth (MBLN) in the mesial aspect at baseline was $2.9 \text{ mm} \pm 1.3 \text{ mm}$, with a variation between 1.1 to 5.9 mm. At the final follow-up, the MBLN was $3.2 \text{ mm} \pm 1.0 \text{ mm}$, ranging from 0.9 to 4.6 mm. There was no statistical significant difference between MBLN in the mesial aspect, comparing baseline to final follow-up, and between the four radiographs independently (at baseline, at 06 months, at 12 months, and at final follow-up).

The mean MBLN in the distal aspect at baseline was $2.2 \text{ mm} \pm 1.1 \text{ mm}$, with a variation between 0 to 4.2 mm. At the final follow-up, the MBLN remained $2.2 \text{ mm} \pm 1.1 \text{ mm}$, ranging from 0 to 3.9 mm. There was no statistical significant difference between MBLN in the distal aspect, comparing baseline to final follow-up, and between the four radiographs independently (at baseline, at 06 months, at 12 months, and at final follow-up).

Radiographic peri-implant marginal bone level

The mean marginal bone level (MBL) in the mesial aspect at baseline was 3.6 mm \pm 1.2, with a variation between 1.8 to 6.9 mm. At the final follow-up, the MBL was 1.0 mm \pm 1.2, ranging from 0 to 4.1 mm. There was a statistical significant difference between MBL in the mesial aspect at baseline and at the final follow-up ($p<0.05$). There was no statistical significant difference between MBL in the mesial aspect, when we compared the 06 month follow-up to the posterior radiographs.

The mean MBL in the distal aspect at baseline was 3.1 mm \pm 1.2, with a variation between 1.8 to 5.5 mm. At the final follow-up, the MBL was 1.0 mm \pm 1.2, ranging from 0 to 3.9 mm. There was a statistical significant difference between MBL in the distal aspect at baseline and at the final follow-up ($p<0.05$). There was no statistical significant difference between MBL in the distal aspect, when we compare the 06 month follow-up to the posterior radiographs.

Table IV. Comparison of mesial and distal bone / implant shoulder distances among different follow-up time periods (n = 65)

Independent variables:	1 month	6 months	12 months	+12 months
Mean (\pm SD)	(baseline)			
	(n = 20)	(n = 17)	(n = 14)	(n = 15)
<u>Mesial bone crest/implant shoulder (mm)</u>	2.9 (1.3)	3.1 (1.2)	3.2 (1.0)	3.2 (0.9) ^t
	(n = 20)	(n = 17)	(n = 14)	(n = 15)
<u>Distal bone crest/implant shoulder (mm)</u>	2.2 (1.0)	2.2 (1.3)	2.2 (1.1)	2.2 (1.0) ^t

	(n = 20)	(n = 16)	(n = 14)	(n = 15)
<u>Mesial bone insertion/implant shoulder (mm)</u>	3.6 (1.2)	1.8 (0.8)	1.0 (1.2)	1.0 (1.2) *; a,bcd
	(n = 20)	(n = 17)	(n = 14)	(n = 15)
<u>Distal bone insertion/implant shoulder (mm)</u>	3.1 (1.2)	1.7 (1.0)	1.0 (1.2)	1.2 (1.2) *; a,bcd

*Analysis of Variance (ANOVA): * p < 0.05, † NS (non-significant)*

Post-hoc Tukey-b test: a = baseline, b = 6 months, c = 12 months, and d = + 12 months

(a,bcd = value at baseline differed significantly than those at 6, 12, and + 12 months at p<0.05)

DISCUSSION

The present study has shown that immediate restorations of implants placed in fresh extraction sockets might provide successful outcomes. We focused on immediate placement and immediate loading of single-tooth implants, with a customized definitive titanium abutment, using a flapless protocol in the maxillary anterior sector. Twenty patients who underwent a trimodal approach (TA) between 2010 and 2014 were screened for radiographic analysis and clinical evaluation. The definitive crown was placed after a mean period of 6 months post-surgery. After a mean follow-up period of 26 months (range from 12 to 48 months), the survival rate of implants and definitive crowns were 100% with an overall treatment success rate of 100%.

The high success rates of endosseous implants over the years have questioned conventional placement/loading protocols. Lang and coworkers¹ in a recent systematic review on implants placed into fresh extraction sockets, with no immediate provisionalization, reported high survival rates in studies with a 2-year follow-up (98.4%, range from 97.3 to 99%) which is in line with the literature^{5,6,24,26}. Chen and

colleagues⁵, in a histological and clinical analysis, concluded that survival rates were similar for both immediate and delayed placement; but recommended the implant placement from 4 to 8 weeks after tooth extraction in order to allow soft tissue healing and removal of an inflammatory process, if present²⁷. In a prospective, controlled clinical trial, there was no statistically significant difference on survival rates as well as in clinical and radiographic parameters between immediate implant placement in sockets exhibiting periapical pathology and healthy sockets after a careful socket debridement²⁸. In terms of marginal bone loss, a systematic review on immediate placement/loading, authors have concluded that immediate loading offer more advantages in terms of bone height preservation².

Using the immediate loading protocol in the anterior maxilla is preferable in order to re-establish esthetics and to avoid the use of a temporary removable prosthesis during the healing phase^{23,29}. There are studies reporting similar high survival rates comparing delayed loading with conventional loading (97% versus 98%), respectively^{9,23,26}.

Abutment disconnection, as part of the prosthetic treatment, and its consequent disruption of the epithelial seal, may cause: a) pronounced inflammatory signs, such as bleeding and ulceration¹⁰, b) epithelial migration¹², and c) re-establishment of biologic width apically, which may cause initial crestal bone loss¹¹⁻¹³. Therefore, the *one abutment at one time* protocol¹¹, with a provisional crown cemented is preferable in order to ensure peri-implant stability as well as an optimal seal around osseointegrated implants¹⁰. That might explain gingival health and stability during healing follow-ups, and specially after definitive ceramic crown cementation in our study. Although no implant system or connection has been able to provide a perfect sealing, the use of conical connections clearly reduce bacterial leakage³⁰. Besides, the use of a customized titanium abutment has shown to be an effective and safe approach for soft tissue handling. In our study, in accordance with other authors³¹, this adequate emergence profile, following gingival architecture, resulted in papilla maintenance.

Formerly, it was thought that implant diameter should fill and be placed precisely in the middle of the socket, providing support to the bone walls. Because of that, 5 mm diameter implants were advocated. This approach has been revised¹¹. In our study, 70% of implants used had a diameter of 4.3 mm and were placed closer to the palatal

wall, which left a gap between implant's shoulder and the inner wall of the socket³². This gap was filled with anorganic bovine bone.

The mean MBL radiographic measurement at baseline included the reconstructive graft, which was partly lost during the following months. This might have been due to the non-use of a collagen membrane allied to a flapless protocol, which prevents soft tissue primary closure^{33,34}. Covani et al have advocated the use of a collagen membrane along with the bone graft, which showed minimal soft tissue remodelling in a 5-year prospective single-cohort study³⁴; however, they have performed a conventional loading protocol.

Therefore, statistically significant difference was found between mean MBL at baseline (i.e. 3.6 ± 1.2 at the mesial aspect, and 3.1 ± 1.2 at the distal aspect), and at the final follow-up (i.e. 1.0 ± 1.2 at the mesial aspect, and 1.2 ± 1.2 at the distal aspect) ($p<0.05$). Besides that, mean MBL at 06 months, at 12 months, and at final follow-up remained statistically similar. In the mesial aspect, MBL remained $1.0 \text{ mm} \pm 1.2 \text{ mm}$ coronal to the implant shoulder, ranging from 0 to 4.1 mm. While in the distal aspect, MBL remained $1.2 \text{ mm} \pm 1.2 \text{ mm}$ coronal to the implant shoulder, ranging from 0 to 3.9 mm. In agreement with other findings^{33,35}, there was a hard tissue remodelling, but the bone remained over the implant shoulder. Radiographically, bone could be seen growing on top of the implant shoulder, and in close contact with the abutment surface. This observation is in accordance with a histologic and histomorphometrical study³⁶. This bone behaviour is probably due to both the lack of micro-motion between the implant and the abutment, a characteristic of the Morse Cone tapered connection implants, and also to the subcrestal positioning of the implants and platform-switching^{19,37,38}. In our study, implants were placed 2.5 mm subcrestally, 2.9 mm in the mesial aspect, and 2.1 mm in the distal aspect.

There was no statistical significant difference between MBLN in the mesial and distal aspects between baseline and final follow-up, and between the four radiographs independently (i.e. at baseline, at 6 months, at 12 months, and at final follow-up). In the mesial aspect, MBLN at baseline was $2.9 \text{ mm} \pm 1.3 \text{ mm}$; and at the final follow-up, the MBLN was $3.2 \text{ mm} \pm 1.0 \text{ mm}$. This growth have indicated that restorative procedures influenced the maintenance of MBLN the presence of papilla over time, which is in agreement with other studies^{38,39}.

Gingival stability is an unquestionable factor for satisfactory esthetic results in single-tooth implants. Thus, the maintenance of the bone peak plays a leading role on the presence of papilla over time⁴⁰. Our study it is not in accordance with Degidi and colleagues. They have found a mean marginal bone loss at adjacent tooth of 0.53 mm. Additionally, in 18.18% of the radiographs, bone peak was apical to the implant shoulder; contradicting our results. However, they used no bone substitutes⁴⁰. However is in accordance with Tarnow and colleagues⁴¹, which have recommended the use of reconstructive graft and immediate provisionalization, in order to reduce bone remodelling and facial/palatal dimensional change.

CONCLUSION

Within the limitations of this study, it has demonstrated that the trimodal approach might offer an advantage in terms of marginal bone levels, specially in MBLN, in a mean follow-up time of 26 months. Additionally, reduced overall treatment time, one surgical intervention, and immediate esthetics can be obtained, with 100% survival and success rates, using a minimally invasive approach. Further long-term, well-conducted, randomized-controlled studies are needed to confirm the validity of the trimodal approach.

Our findings in bone peak maintenance contradicts other study⁴⁰, which have reported resorption of marginal bone levels at the neighbouring tooth even apically to the implant shoulder; thus, prospective studies comparing the maintenance of the MBLN with peri-implant stability and bone remodelling radiographically, are needed.

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3.DISCUSSÃO

O presente estudo mostrou que restaurações imediatas de implantes instalados em alvéolos pós-extração pode proporcionar resultados satisfatórios. Nós focamos nosso estudo em carga e função imediatas em implantes unitários na região ântero-superior, com o uso de pilares protéticos customizados e definitivos em titânio, sem o uso do tradicional retalho mucoperiostal. Vinte pacientes que foram submetidos à Abordagem Trimodal (AT) entre os anos de 2010 e 2014 foram selecionados para análise radiográfica e avaliação clínica. As coroas protéticas definitivas foram cimentadas em uma média de 6 meses pós-cirurgia. Após um período médio de acompanhamento de 26 meses (variando entre 12 e 48 meses), a taxa de sobrevivência dos implantes e das coroas foi de 100%, com uma taxa de sucesso de tratamento de 100%.

A alta taxa de sucesso dos implantes osseointegrados ao longo dos anos questionou os protocolos convencionais de instalação e carga. Lang e colaboradores (2012), em uma recente revisão sistemática da literatura em implantes instalados através de carga imediata e sem o uso de provisório, relataram altas taxas de sobrevivência em estudos com 2 anos de acompanhamento (98.4%, variação de 97.3 a 99%), corroborando com diversos estudos (CHEN et al. 2004, EVANS et al. 2008, CABELLO et al. 2013, KAN et al. 2011). Chen et al. (2004), em análises clínica e histológica, concluíram que taxas de sobrevivência são similares para carga imediata e carga tardia, mas recomendaram a instalação de implantes a partir de 4 a 8 semanas após a extração dentária, a fim de permitir a cicatrização de tecido mole e remoção dos processos inflamatórios e/ou infecciosos, quando presentes (BUSER et al. 2011). Em um ensaio clínico randomizado, não houve diferença estatisticamente significativa em taxas de sobrevivência, assim como nos parâmetros clínicos e radiográficos, entre carga imediata em alvéolos exibindo lesão periapical e alvéolos saudáveis cuidadosamente curetados (TRÜNINGER et al. 2011). Em termos de perda óssea marginal, em uma revisão sistemática da literatura sobre carga e função imediatas, os autores concluíram que função imediata oferece maiores vantagens relacionada à preservação óssea (ATIEH et al. 2009).

Utilizando função imediata na região anterior da maxila é preferível para reestabelecer a estética e a fim de evitar o uso de próteses temporárias removíveis durante o processo de Osseointegração (LAVIV et al. 2010, HARTLEV et al. 2013).

Remoção dos *abutments*, como parte das etapas protéticas, e o seu consequente rompimento do vedamento epitelial, pode causar: a) sinais inflamatórios pronunciados, como sangramento e ulceração (ALVES et al. 2010), b) migração epitelial (GRANDI et al. 2014) e c) reestabelecimento do espaço biológico do periodonto no sentido apical, que pode ser uma das causas para perda óssea cristal inicial (DEGIDI et al. 2011, DEGIDI et al. 2014, GRANDI et al. 2014). Portanto, o protocolo *one abutment at one time* (DEGIDI et al. 2011), com uma coroa provisória cimentada é preferível, a fim de garantir estabilidade periimplantar, assim como um melhor selamento ao redor do implante (ALVES et al. 2014). Isso talvez explique a saúde e a estabilidade peri-implantar durante as consultas de acompanhamento em nosso estudo, especialmente após cimentação das coroas definitivas, concordando com os achados de Canullo et al. (2014). Apesar de não haver sistema de conexão capaz de propiciar um perfeito selamento, o uso de conexões cônicas claramente reduz a infiltração bacteriana (CANULLO et al. 2014). Além disso, o uso de pilares personalizados em titânio se mostrou uma abordagem segura e eficaz em termos de manuseio de tecido mole. Em nosso trabalho, em acordo com outros autores (BORGES et al. 2013), esse perfil de emergência adequado dos *abutments* personalizados, resultou em manutenção de papila.

Anteriormente, se pensava que o diâmetro do implante deveria preencher toda a área do alvéolo, assim como deveria ser posicionado no centro do mesmo, proporcionando suporte as paredes ósseas circundantes. Por conta disso, implantes de plataforma larga (5 mm) eram defendidos. Essa abordagem foi revista e modificada (DEGIDI et al. 2014). Em nosso trabalho, 70% dos implantes utilizados foram de 4,3 mm de diâmetro e foram instalados próximos à parede palatina dos alvéolos, deixando um *gap* entre o ombro do implante e a parede interna do alvéolo (BUSER et al. 2004). Esse *gap* foi preenchido com matriz bovina inorgânica.

A média da medida do nível ósseo marginal (Marginal bone level - MBL) no *baseline* contabilizou esse enxerto xenógeno, que foi parcialmente perdido durante as consultas de acompanhamento. Isso pode ter sido causado pela ausência de membrana de colágeno, juntamente com o uso de uma técnica sem retalho

mucoperiostal, impedindo uma cicatrização da ferida por primeira intenção (BARONE et al. 2014, COVANI et al. 2014). Covani e colaboradores (2014) advogam o uso de uma membrana de colágeno, juntamente com enxerto ósseo, e mostram mínimo remodelamento ósseo em um estudo prospectivo com 5 anos de acompanhamento. Porém, eles conduziram este trabalho com um protocolo convencional de carga, sem o uso de provisório imediato.

Portanto, diferença estatisticamente significativa foi encontrada entre a média de MBL no *baseline* ($3,6 \text{ mm} \pm 1,2 \text{ mm}$ na face mesial e $3,1 \text{ mm} \pm 1,2 \text{ mm}$ na face distal) e o acompanhamento radiográfico final ($1,0 \text{ mm} \pm 1,2 \text{ mm}$ na face mesial e $1,2 \text{ mm} \pm 1,2 \text{ mm}$ na face distal) ($p<0,05$). Além disso, a média de MBL em 6 meses, 12 meses e no acompanhamento radiográfico final permaneceu semelhante. Na face mesial, a MBL permaneceu em $1,0 \text{ mm} \pm 1,2 \text{ mm}$ coronalmente ao ombro do implante, variando de 0 a 4,1 mm. Enquanto que na face distal, a MBL permaneceu em $1,2 \text{ mm} \pm 1,2 \text{ mm}$ coronalmente ao ombro do implante, variando de 0 a 3,9 mm. Indo de encontro com os achados de outros trabalhos (BARONE et al. 2014, SUAID et al 2014), houve remodelamento ósseo, mas o osso se manteve coronalmente ao ombro do implante. Radiograficamente, pode ser visto osso passando pelo ombro do implante e em um íntimo contato com a superfície do pilar personalizado. Esse achado vai de acordo com avaliações histológicas e histomorfométricas (DE CASTRO et al. 2014). Esse comportamento ósseo é provavelmente devido à mínima micro movimentação entre o implante e o pilar protético, uma característica das conexões Morse. Também consequência do posicionamento apical dos implantes e do uso do conceito de mudança de plataforma (ALMEIDA et al. 2011, ELIAN et al 2011, STRIETZEL et al. 2014). No nosso trabalho, os implantes foram posicionados em média 2,9 mm infra ósseo; sendo 2,5 mm apical à crista óssea mesial e 2,1 mm apical à crista óssea distal.

Não houve diferença estatisticamente significativa entre a crista óssea marginal nos dentes adjacentes (Marginal bone level at neighbouring tooth - MBLN) nas faces mesial e distal, quando comparamos *baseline* e o acompanhamento final, e comparando as 4 quatro radiografias de acompanhamento de forma individual (6 meses, 12 meses e acompanhamento final). Na face mesial, MBLN no *baseline* foi de $2,9 \text{ mm} \pm 1,3 \text{ mm}$ e no controle final foi de $3,2 \text{ mm} \pm 1,0 \text{ mm}$. Esse crescimento ósseo indica que os procedimentos de reconstrução óssea influenciaram a manutenção do

nível ósseo a nível dos dentes adjacentes e também a presença de papila durante as consultas de controle, concordando com outros trabalhos (ELIAN et al 2011, SCHROPP et al. 2015).

Estabilidade gengival é um fator inquestionável para resultados estéticos satisfatórios em implantes unitários na região anterior de maxila. Portanto, a manutenção da crista óssea a nível dos dentes adjacentes cumpre papel principal na presença ou ausência de papila. Nossa estudo não está de acordo com Degidi e colaboradores. Eles encontraram uma perda da crista óssea marginal a nível dos dentes adjacentes de 0,53 mm em 7 anos de acompanhamento. Adicionalmente, em 18,18% das radiografias, o nível da MBLN foi medido apicalmente ao ombro dos implantes. Eles não utilizaram substitutos ósseos (DEGIDI et al 2012). Porém vai de acordo com Tarnow et al. (2014), que recomendam o uso de bio-material e provisório imediato para manutenção de tecido duro (TARNOW et al. 2014).

Dentro das limitações desse estudo, foi demonstrado que a abordagem trimodal pode oferecer vantagens em termos de níveis de crista óssea marginal, especialmente na crista óssea a nível dos dentes adjacentes, em um período de acompanhamento médio de 26 meses. Adicionalmente, reduzido tempo de tratamento, uma etapa cirúrgica e estética imediata podem ser obtidas, com taxas de sobrevida e de sucesso de 100%. Ensaios clínicos randomizados e de longo tempo de acompanhamento são necessários para confirmar a validade da abordagem trimodal.

Nossos resultados contradizem outros resultados (DEGIDI et al 2014) que demonstraram reabsorção da crista óssea marginal a nível dos dentes adjacentes, inclusive apicalmente ao ombro do implante. Portanto, estudos prospectivos comparando a manutenção de MBLN com estabilidade periimplantar e remodelamento ósseo do ponto de vista radiográfico são necessários.

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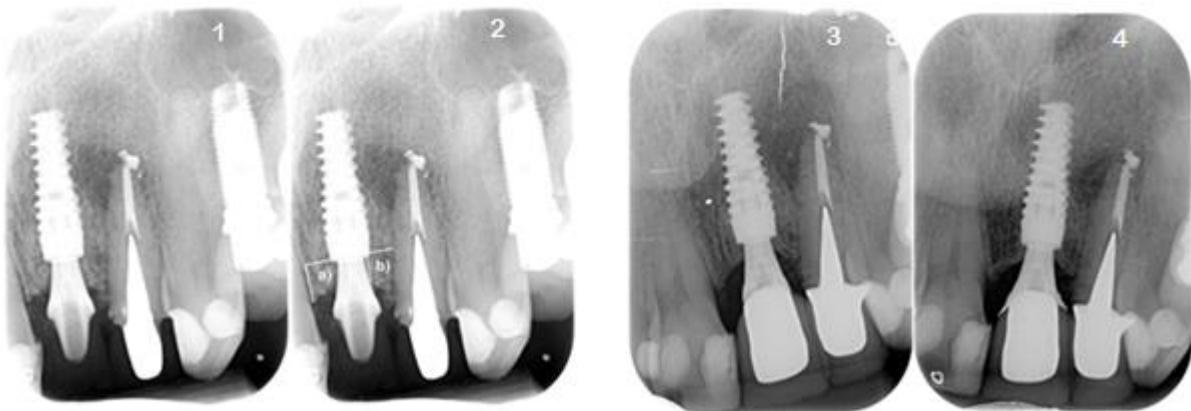
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ANEXOS

ANEXO A – Figura presente no artigo, apresentando as radiografias (*baseline*, controle de 06 meses e controle final) e medições de MBLN e MBL.



ANEXO B – Caso ilustrativo presente no artigo dos procedimentos cirúrgico e protético da abordagem trimodal.



Fig. 2. Initial clinical aspect. Upper left central incisor with indication of extraction due to root fracture.

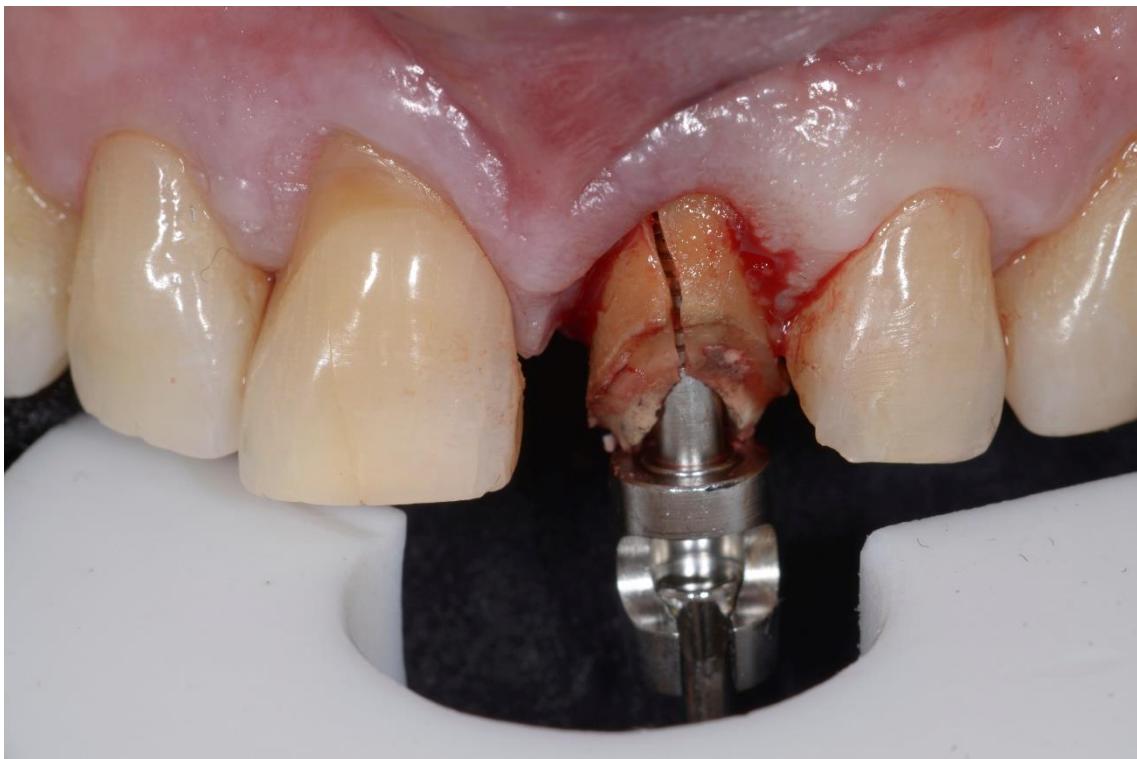


Fig. 3. Atraumatic extraction with the help of a especific extactor (Benex Root Extraction System, Hager and Meisinger GMbH, Neuss, Germany), with a flapless approach.

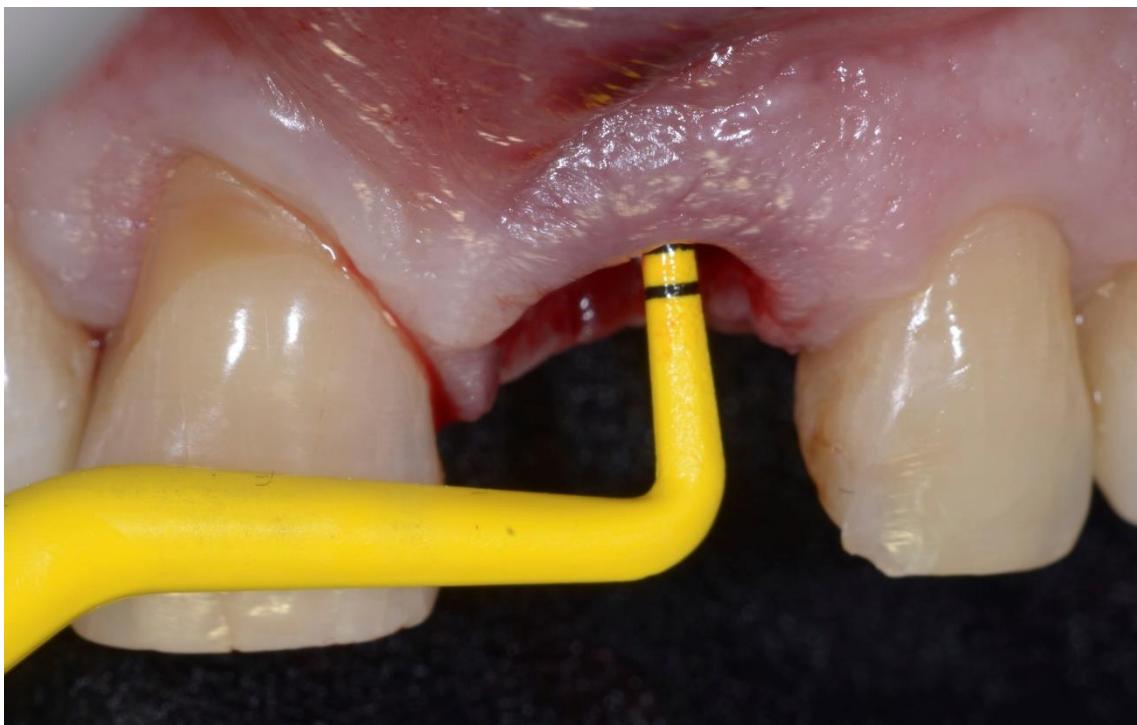


Fig. 4. Careful debridement and probing of the alveolar socket. Notice significant buccal bone wall resorption up to 9mm.

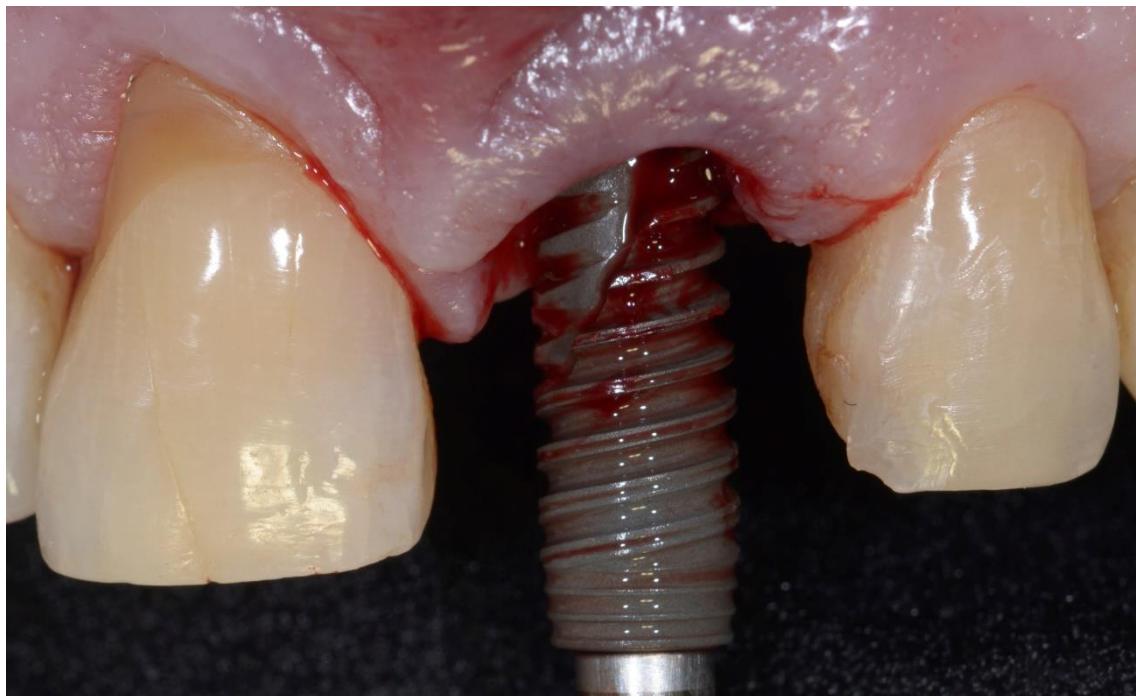


Fig 5. Morse Cone tapered implant placement (CM Drive, Neodent, Curitiba, Brazil). Buccal aspect.

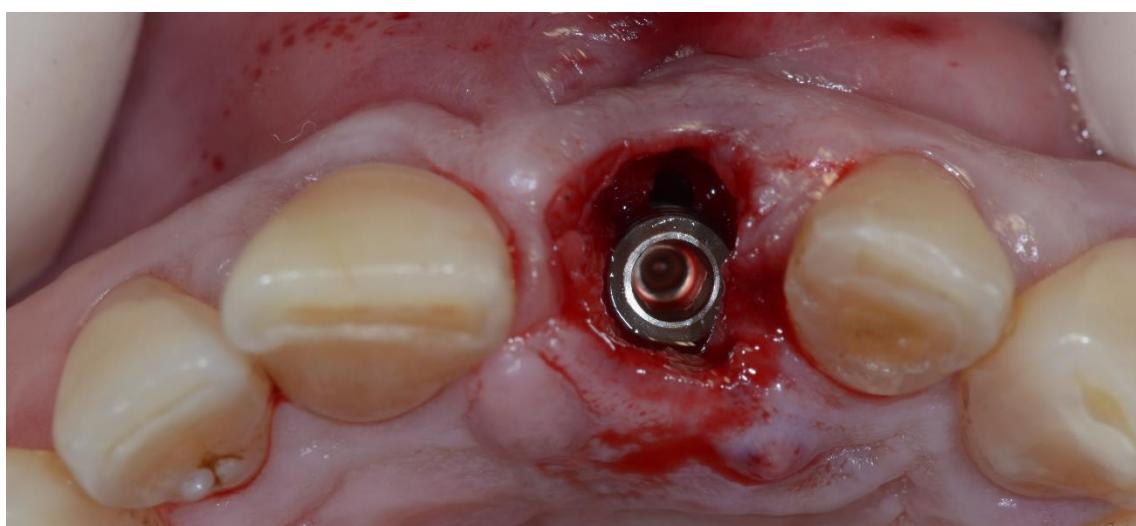


Fig. 6. Impant position. Occlusal aspect. Notice the gap between implant shoulder and the inner wall of the buccal bone wall.



Fig. 7. Implant platform impression with the help of a rubber dam before gap filling with anorganic bovine bone.



Fig. 8. Gap filling with xenograft bone substitute. Buccal aspect. A narrow healing abutment is tightened into the implant platform until definitive abutment is screwed.



Fig. 9. Customized titanium abutment in the master cast before passing through the sterilization process.



Fig. 10. Customized definitive titanium abutment tightened at 20 N/cm. Buccal aspect. Notice the graft material, and its intimate contact with oral environment. These anorganic bovine bone particles will unavoidably be lost, during the first 6 months.



Fig. 11. Provisional crown cemented onto the custom abutment within 24 hours post implant placement, avoiding centric and eccentric occlusal contacts. Buccal aspect. Observe the gap between the gingival margin and cervical aspect of the temporary tooth.



Fig. 12. Buccal aspect of the provisional crown 7 days post-surgery. Notice the soft tissue stability, and how the gingival margin adapted to the surface of the provisional crown.

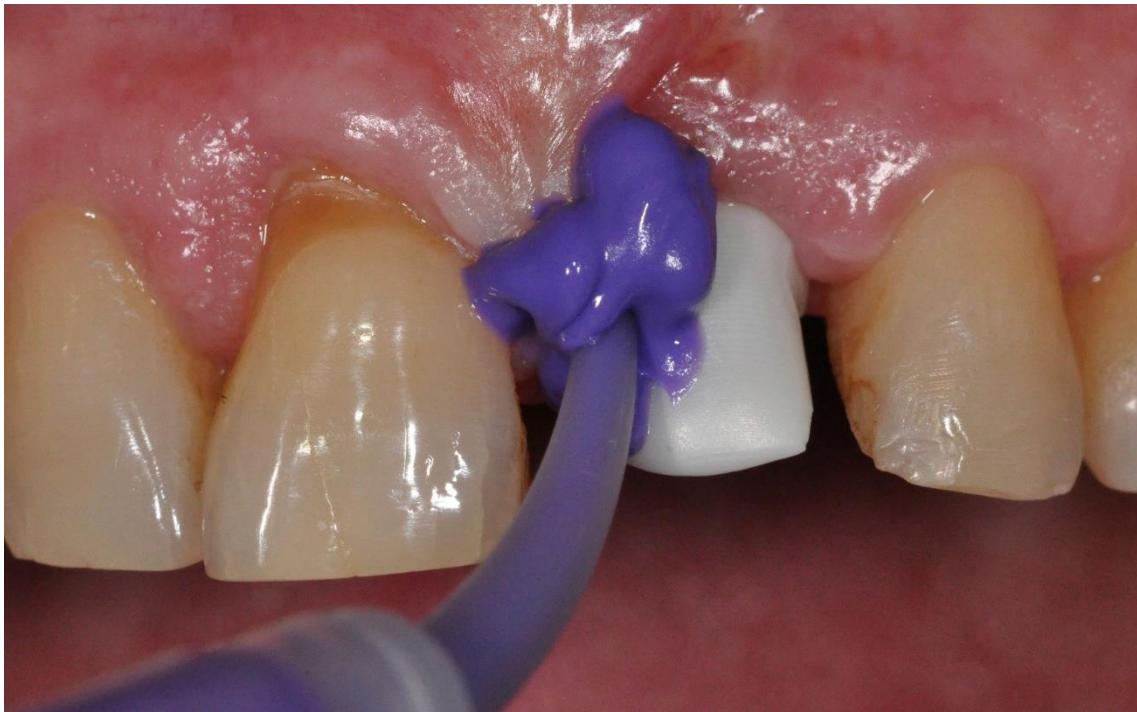


Fig. 13. Coping pick-up silicone impression (Regular Body Normal Set, Elite HD+, Zhermack, Rovigo, Italy), after 05 months of healing. CAD/CAM machined zirconium oxide reinforced coping.



Fig. 14. Definitive crown delivery. At the 06 months follow-up.

ANEXO C – Tabela I presente no artigo, apresentando a descrição amostral.

Table I. Social and demographic characteristics of implant patients and description of implant surgical characteristics ($n = 20$)

Independent variables (n=24)

<u>Age (years)</u>	
Mean (\pm SD)	55.2 (13.2)

Gender (%)

Women	60.0
Men	40.0

ANEXO D – Tabela II presente no artigo, apresentando descrição dos implantes utilizados, regiões da cirurgia e descrição do tempo de acompanhamento.

Table II. Description of surgery and implant component characteristics

<u>Implant size (%)</u>	(n=20)
3.5 x 13.0	15.0
3.5 x 16.0	15.0
4.3 x 10.0	5.0
4.3 x 13.0	45.0
4.3 x 16.0	20.0

Site of implant surgery (%) (n=20)

Upper right central incisor (# 11)	25.0
------------------------------------	------

Upper right lateral incisor (#12)	5.0
Upper right canine (# 13)	5.0
Upper left central incisor (# 21)	45.0
Upper left left incisor (#22)	20.0

<u>Follow-up time (years)</u>	(n=20)
Mean (S.D.)	2.26 (1.03)

<u>Follow-up time (%)</u>	(n = 20)
1.0 year	10.5
1.5 years	31.6
2.0 years	21.1
2.5 years	5.3
3.0 years	10.5
3.5 years	10.5
4.0 years	5.3
4.5 years	5.3

ANEXO E – Tabela III presente no artigo, apresentando as razões para extração.

Table III. Reasons for tooth extraction (%)

Reasons for extraction (n=20)

Root fracture (%)	60.0
Endodontic pathology (%)	
Endo-periodontal lesion	25.0

Root resorption (%)	15.0
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ANEXO F – Tabela IV presente no artigo, apresentando as medidas de crista óssea marginal nas faces mesial e distal nos diferentes tempos de acompanhamento.

Table IV. Comparison of mesial and distal bone / implant shoulder distances among different follow-up time periods (n = 65)

Independent variables:	1 month	6 months	12 months	+12 months
Mean (\pm SD)	(baseline)			
	(n = 20)	(n = 17)	(n = 14)	(n = 15)
<u>Mesial bone crest/implant shoulder (mm)</u>	2.9 (1.3)	3.1 (1.2)	3.2 (1.0)	3.2 (0.9) ^t
	(n = 20)	(n = 17)	(n = 14)	(n = 15)
<u>Distal bone crest/implant shoulder (mm)</u>	2.2 (1.0)	2.2 (1.3)	2.2 (1.1)	2.2 (1.0) ^t

	(n = 20)	(n = 16)	(n = 14)	(n = 15)
<u>Mesial bone insertion/implant shoulder (mm)</u>	3.6 (1.2)	1.8 (0.8)	1.0 (1.2)	1.0 (1.2) *; a,bcd

	(n = 20)	(n = 17)	(n = 14)	(n = 15)
<u>Distal bone insertion/implant shoulder (mm)</u>	3.1 (1.2)	1.7 (1.0)	1.0 (1.2)	1.2 (1.2) *; a,bcd

*Analysis of Variance (ANOVA): * p < 0.05, † NS (non-significant)*

Post-hoc Tukey-b test: a = baseline, b = 6 months, c = 12 months, and d = + 12 months

(a,bcd = value at baseline differed significantly than those at 6, 12, and + 12 months at p<0.05)

ANEXO G - Carta de aprovação do CEP/PUCRS (PLATAFORMA BRASIL).

PONTIFÍCIA UNIVERSIDADE
CATÓLICA DO RIO GRANDE
DO SUL - PUC/RSA



[Continuação da Parecer Mínimo](#)

Avaliação dos Riscos e Benefícios:

Não existem risco associados ao projeto, pois trata-se de uma análise de dados já coletados.

Comentários e Considerações sobre a Pesquisa:

Pesquisa inserida no ambiente de investigação da unidade universitária. Dispensável o TCLE, pois o projeto acima é uma revisão de dados.

Considerações sobre os Termos de apresentação obrigatória:

O procedimento atende aos requisitos exigidos para o tipo de projeto de pesquisa.

Recomendações:

Não há recomendações.

Conclusões ou Pendências e Lista de Inadequações:

Não há pendências ou inadequações no projeto de pesquisa.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

PORTO ALEGRE, 26 de Setembro de 2014

Assinado por:

Rodolfo Herberto Schneider
(Coordenador)

Endereço: Av. Ipiranga, 6681, prédio 40, sala 505
Bairro: Partenon CEP: 90.010-000
UF: RS Município: PORTO ALEGRE
Telefone: (51)3229-3245 Fax: (51)3229-3245 E-mail: cep@pucrs.br

PONTIFÍCIA UNIVERSIDADE
CATÓLICA DO RIO GRANDE
DO SUL - PUC/RN



Continuação da Parecer: 888313

Avaliação dos Riscos e Benefícios:

Não existem risco associados ao projeto, pois trata-se de uma análise de dados já coletados.

Comentários e Considerações sobre a Pesquisa:

Pesquisa inserida no ambiente de investigação da unidade universitária. Dispensável o TCLE, pois o projeto acima é uma revisão de dados.

Considerações sobre os Termos de apresentação obrigatória:

O procedimento atende aos requisitos exigidos para o tipo de projeto de pesquisa.

Recomendações:

Não há recomendações.

Conclusões ou Pendências e Lista de Inadequações:

Não há pendências ou inadequações no projeto de pesquisa.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

PORTE ALEGRE, 26 de Setembro de 2014

Aassinado por:

Rodolfo Herberto Schneider
(Coordenador)

Endereço: Av. Jpiranga, 6681, prédio 40, sala 505	CEP: 90.619-000
Bairro: Partenon	
UF: RS	Município: PORTO ALEGRE
Telefone: (51)3320-3345	Fax: (51)3320-3345
	E-mail: cep@pucrs.br

ANEXO H - Carta de aprovação da comissão científica e de ética da Faculdade de Odontologia da PUCRS.



*Comissão Científica e de Ética
Faculdade da Odontologia da PUCRS*

Porto Alegre 14 de julho de 2014

O Projeto de: Dissertação

Protocolado sob nº: 0035/14

Intitulado: Avaliação da manutenção de crista óssea marginal em implantes instalados a partir da abordagem trimodal: Follow-Up de 1-3 anos.

Pesquisador Responsável: Prof. Dr. Márcio Lima Grossi

Pesquisadores Associados: Fábio Sá Carneiro Scapanik

Nível: Dissertação / Mestrado

Foi *aprovado* pela Comissão Científica e de Ética da Faculdade de Odontologia da PUCRS em *Quatorze de julho de dois mil e quatorze*

Profa. Dra. Luciane Macedo Menézes

Coordenadora da Comissão Científica e de Ética da
Faculdade de Odontologia da PUCRS

ANEXO I – Autorização de uso de arquivo de dados.



**COMISSÃO CIENTÍFICA E DE ÉTICA
FACULDADE DE ODONTOLOGIA DA PUCRS (CCEFO)**

AUTORIZAÇÃO DE USO DE ARQUIVOS PRIVADOS

Data: 19/09/2014

Eu, José Cícero Dinato, estou ciente da utilização dos dados coletados em meu arquivo privado de (radiografias, modelos de gesso, etc), para os fins previstos no protocolo de pesquisa de Fábio Bé Cameiro Szepanik, mestrandando do curso de Odontologia/Prótese Dentária pela FO/PUCRS, autor (a) do projeto de pesquisa intitulado "Avaliação da manutenção de crista óssea marginal em implantes instalados a partir da abordagem trímodal: follow-up de 1-3 anos" e orientado pelo(s) Prof.(a) Márcio Lima Grossi.

Assinatura do professor profissional responsável pelo arquivo

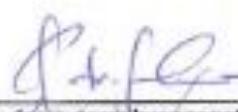
ANEXO J – Termo de compromisso de emprego de dados.

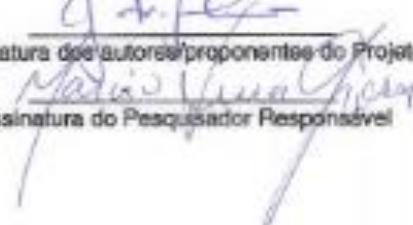


**COMISSÃO CIENTÍFICA E DE ÉTICA
FACULDADE DE ODONTOLOGIA DA PUCRS (CCEFO)**

TERMO DE COMPROMISSO DE EMPREGO DE DADOS

Como autores do projeto intitulado "Avaliação da Manutenção da Crista Óssea Marginal em Implantes Instalados a Partir da Abordagem Trimodal: Follow-up de 1-3 Anos" declaramos que cumpriremos os requisitos da resolução 196/96 e suas complementares. Comprometemo-nos a utilizar os dados coletados nos exames clínicos e laboratoriais exclusivamente para os fins previstos no protocolo de pesquisa submetido, garantindo sigilo quanto à identificação dos mesmos.


Assinatura dos autores/proponentes do Projeto


Assinatura do Pesquisador Responsável

Márcia Grossi
CRON/RS 002

LISTA DE ABREVIATURAS

BA	Bimodal approach
CAD/CAM	Computed aided designed/Computed aided manufactured
CBCT	Cone beam computerized tomography
CEP	Comitê de Ética em Pesquisa
MBL	Marginal bone level
MBLN	Marginal bone level at neighbouring tooth
PUCRS	Pontifícia Universidade Católica do Rio Grande do Sul
TA	Trimodal approach