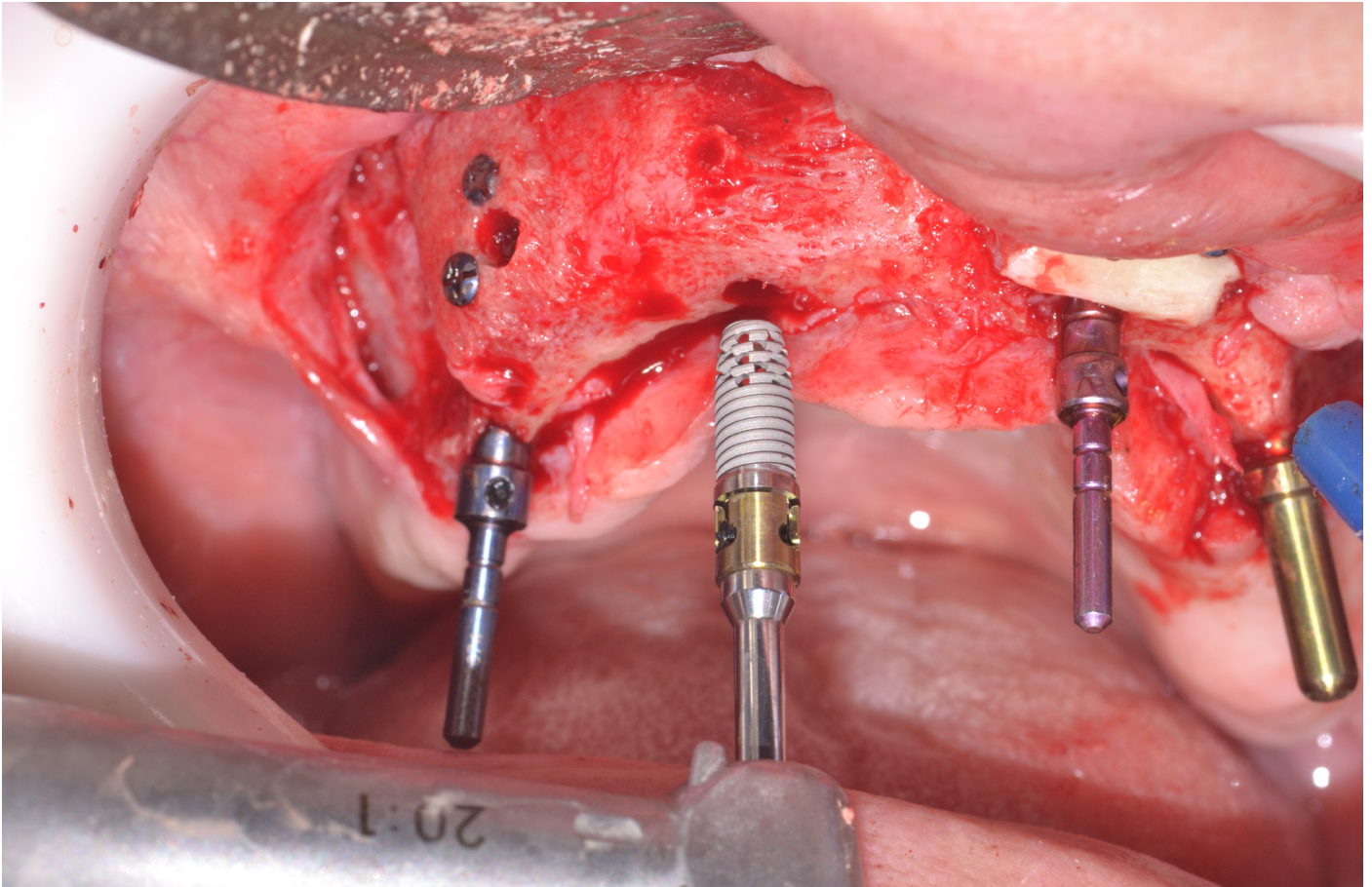


# clinical cases report.



e.book Pedro HA Carvalho | Valfrido A Pereira Filho e co-autores

”

A Bionnovation Biomedical é uma empresa brasileira que oferece soluções avançadas para a reposição de elementos dentais e reconstrução de tecidos. Atualmente, a linha de produtos é composta por implantes dentários e biomateriais capazes de proporcionar resultados clínicos e estéticos altamente satisfatórios.

**Os biomateriais são produtos auxiliares nos processos de regeneração tecidual que apresentam soluções clínicas de excelente resultado, com elevado índice de sucesso e mínimo desconforto para o paciente.**

A linha de biomateriais Bionnovation é composta por materiais alternativos para preenchimento nos procedimentos de enxertia óssea, membranas absorvíveis, barreiras não-absorvíveis, malhas de titânio, parafusos de enxertos e parafusos tendas.

**Bionnovation**  
b i o m e d i c a l

## **Avaliação clínica, tomográfica e histológica da reconstrução alveolar horizontal por meio de enxerto autógeno e heterógeno em bloco: estudo clínico prospectivo de boca-dividida.**

### **RESUMO**

O objetivo deste trabalho será realizar um ensaio clínico randomizado em modelo de boca dividida para comparar a reconstrução da região anterior de maxila por meio de dois tipos de enxerto em bloco: osso bovino desproteinizado (Bonefill Porous Block -Bionnovation, Brasil) e osso autógeno do ramo mandibular. Para tanto, serão selecionados 14 pacientes desdentados totais com atrofia horizontal da região anterior da maxila. Cada lado da região anterior de maxila será reconstruído com um tipo de enxerto em bloco, conforme randomização. Para tanto, serão realizadas quatro avaliações: clínica, tomográfica, histológica e da estabilidade dos implantes. Clinicamente, serão realizadas mensurações com espessímetro cirúrgico no período trans-operatório inicial, antes e imediatamente após a fixação dos enxertos e no pós-operatório de 9 meses, no momento da instalação dos implantes. A análise volumétrica será realizada por meio de tomografias computadorizadas obtidas em três períodos: pré-operatório, pós-operatório imediato e no pós-operatório de 9 meses. Os volumes serão então sobrepostos para avaliar o ganho inicial e taxa de reabsorção/remodelação dos dois tipos de enxerto. A avaliação histológica será realizada por meio de biópsia do tecido ósseo enxertado no momento da instalação dos implantes, para análise por microCT, histomorfometria e PCR, a fim de verificar a qualidade óssea obtida em cada grupo. Ainda, os implantes instalados serão analisados em relação ao torque de inserção, e o coeficiente de estabilidade (ISQ).

Os enxertos serão fixados com dois parafusos de titânio de 1,4 x 12 mm e serão recobertos por membranas de Politetrafluoretileno (PTFE) para futura instalação de implantes hexágono externo BioDIRECT.

### **Produtos utilizados:**

- Bonefill Bloco 5 x 20 x 20 mm Cód **16498** Lote **058323** = 34 unidades
- Parafuso de Fixação 1,4 x 12 mm Cód **7152** Lote **058785** = 68 unidades
- Surgitime PTFE 30 x 20 x 0,25 mm Cód **16044** Lote **57292** = 68 unidades

**Notas Fiscais 0000135302 | 0000136217 | 0000141387**



UNESP - FACULDADE DE  
ODONTOLOGIA - CAMPUS  
ARARAQUARA



## PARECER CONSUBSTANCIADO DO CEP

### DADOS DO PROJETO DE PESQUISA

**Título da Pesquisa:** Enxertos xenógenos

**Pesquisador:** Valfrido Antonio Pereira Filho

**Área Temática:**

**Versão:** 2

**CAAE:** 67443017.0.0000.5416

**Instituição Proponente:** Faculdade de Odontologia de Araraquara - UNESP

**Patrocinador Principal:** Financiamento Próprio

### DADOS DO PARECER

**Número do Parecer:** 2.070.842

#### Apresentação do Projeto:

O estudo tem a duração prevista para 3 anos, e buscará comparar o sucesso de enxerto xenógeno de origem bovina (disponível comercialmente) com o enxerto autógeno de ramo mandibular, na reabilitação de maxilas com atrofia de rebordo alveolar para ganho ósseo e posterior implante dentário.

Serão selecionados 14 pacientes desdentados totais com atrofia horizontal da região anterior da maxila. Cada lado da região anterior de maxila será reconstruído com um tipo de enxerto em bloco, conforme randomização.

Serão realizadas comparações clínicas pré cirúrgicas, trans cirúrgicas imediatas e trans cirúrgicas e clínicas tardias. Bem como comparações laboratoriais em biópsias obtidas das regiões enxertadas submetidas a histomorfometria, micro tomografia, análise de reação em cadeia de polimerase (PCR), além de comparação volumétrica tomográfica dos enxertos através de TCs obtidas no pré operatório, pós imediato e pós operatório de 9 meses. Por fim será realizada a instalação de quatro implantes dentários na região enxertada seguindo a técnica de protocolo all-in-four, e realizada mensurações de estabilidade do implante com auxílio de mensurador específico.

#### Objetivo da Pesquisa:

Comparar a qualidade da osseointegração de enxertos ósseos em bloco de origem animal com o

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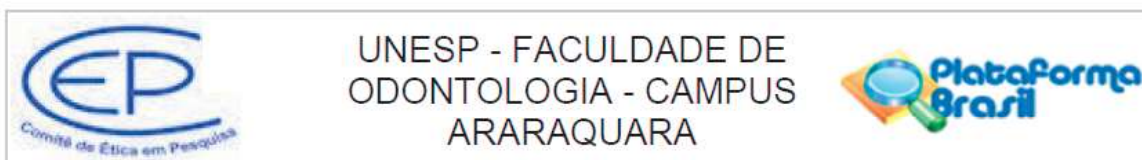
**CEP:** 14.801-903

**UF:** SP

**Município:** ARARAQUARA

**Telefone:** (16)3301-6459

**E-mail:** cep@foar.unesp.br



Continuação do Parecer: 2.070.842

padrão ouro (osso autógeno).

#### **Avaliação dos Riscos e Benefícios:**

Riscos: Os riscos do presente trabalho incluem algumas complicações pós-operatórias que podem ocorrer na área doadora do enxerto ósseo como dor, inchaço, desconforto, parestesia (dormência) e sangramentos; ou na área de instalação dos enxertos e implantes como: inflamação, dor, inchaço, desconforto, sangramento, comunicação buco sinusal ou contaminação do seio maxilar. Existe ainda o risco de perda de um ou mais implantes dentários ou enxertos.

Benefícios: Os pacientes receberão sem custo o tratamento dentário com implantes osseointegráveis e próteses do tipo protocolo superiores, além de todas as consultas prévias a cirurgia bem como suas consultas de retorno.

#### **Comentários e Considerações sobre a Pesquisa:**

A metodologia no projeto está bem descrita em 4 etapas: 1) Avaliação pré-operatória: Anamnese, exame clínico, avaliação de exame tomográfico pré-operatório e planejamento cirúrgico; 2) Procedimento cirúrgico de enxerto ósseo: Realização de enxerto ósseo conforme seleção por randomização, obtenção de exame tomográfico pós-operatório imediato; 3) Procedimento cirúrgico para instalação de implantes dentários: avaliação do exame tomográfico para planejamento, remoção de biópsia óssea para avaliação histomorfométrica, e instalação de implantes; 4) Análise: avaliação volumétrica das tomografias e avaliação por microCT, histomorfometria e PCR das biópsias.

#### **Considerações sobre os Termos de apresentação obrigatória:**

Estão presentes os termos de autorização de uso de clínica, de ciência orçamentária, de ressarcimento de gastos e de cumprimento das normas do CEP.

#### **Conclusões ou Pendências e Lista de Inadequações:**

Não existem pendências.

#### **Considerações Finais a critério do CEP:**

Protocolo APROVADO em reunião de 18 de Maio de 2017.

O pesquisador deverá encaminhar relatórios parciais a cada 01 (um) ano até o prazo final da pesquisa, quando deverá encaminhar o relatório final.

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

Tipo Documento	Arquivo	Postagem	Autor	Situação
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**Endereço:** HUMAITA 1680

**Bairro:** CENTRO

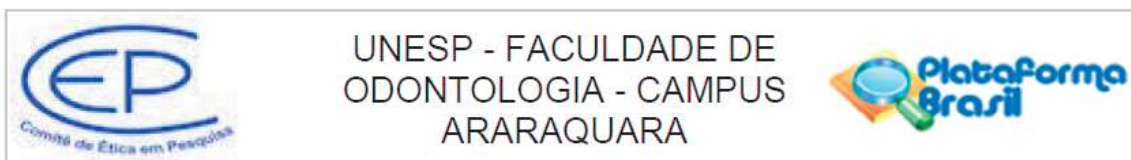
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**UF:** SP

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**E-mail:** cep@foar.unesp.br



Continuação do Parecer: 2.070.842

Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_867509.pdf	16/05/2017 09:18:36		Aceito
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Orçamento	Termo_de_Ciencia_Orcamentaria.pdf	11/04/2017 19:36:35	PEDRO HENRIQUE DE AZAMBUJA CARVALHO	Aceito
Declaração de Instituição e Infraestrutura	Termo_de_autorizacao_clinica_laboratorial.pdf	11/04/2017 19:36:18	PEDRO HENRIQUE DE AZAMBUJA CARVALHO	Aceito
Projeto Detalhado / Brochura Investigador	Avaliacao_Clinica_e_Histologica_de_Xenoinxertos_em_bloco.pdf	15/03/2017 11:18:30	PEDRO HENRIQUE DE AZAMBUJA CARVALHO	Aceito
Folha de Rosto	folha_de_rosto_assinada.pdf	06/03/2017 10:10:39	PEDRO HENRIQUE DE AZAMBUJA CARVALHO	Aceito
Declaração de Pesquisadores	termo_de_ressarcimento_de_gastosassinado.pdf	06/03/2017 10:10:20	PEDRO HENRIQUE DE AZAMBUJA CARVALHO	Aceito
Declaração de Pesquisadores	Termo_de_cumprimento_das_normas_do_CEP_assinado.pdf	06/03/2017 10:09:48	PEDRO HENRIQUE DE AZAMBUJA CARVALHO	Aceito

**Situação do Parecer:**

Aprovado

**Necessita Apreciação da CONEP:**

Não

ARARAQUARA, 18 de Maio de 2017

Assinado por:  
Lígia Antunes Pereira Pinelli  
(Coordenador)

**Endereço:** HUMAITA 1680

**Bairro:** CENTRO

**UF:** SP

**Telefone:** (16)3301-6459

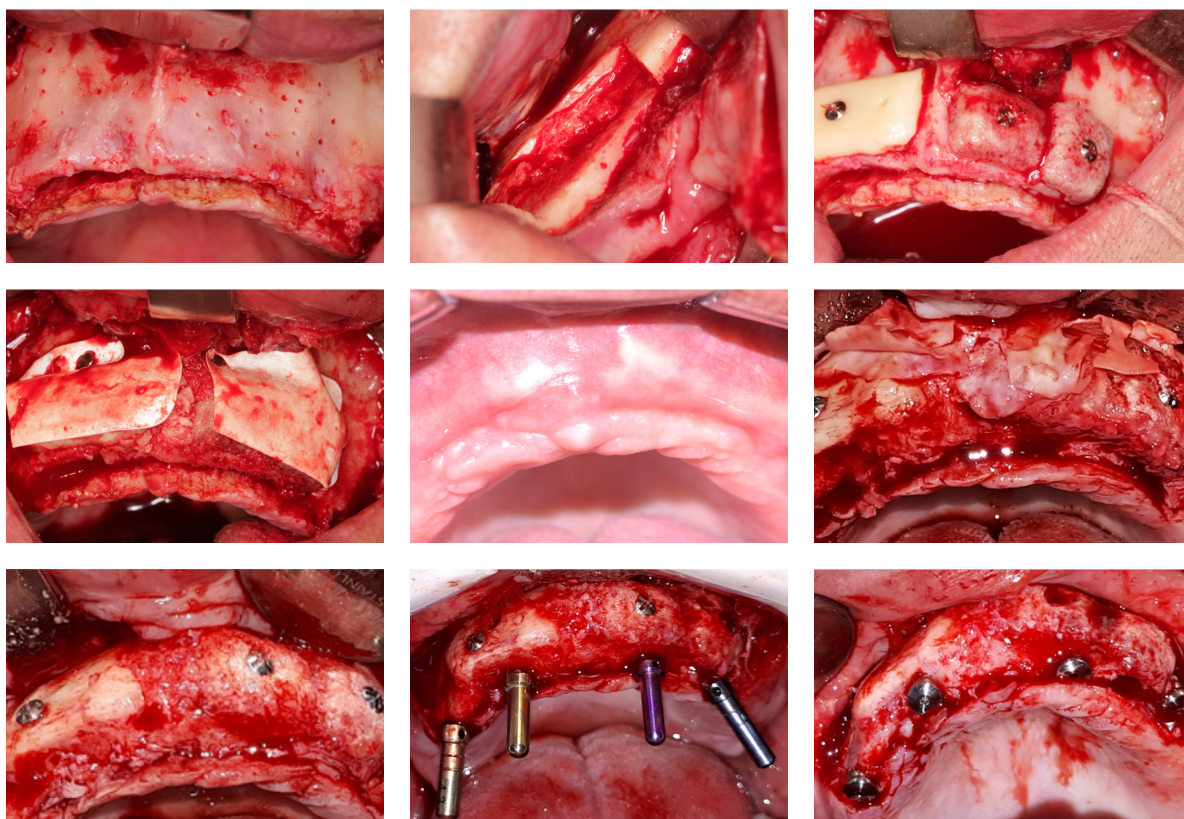
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Follow-up: 9 meses

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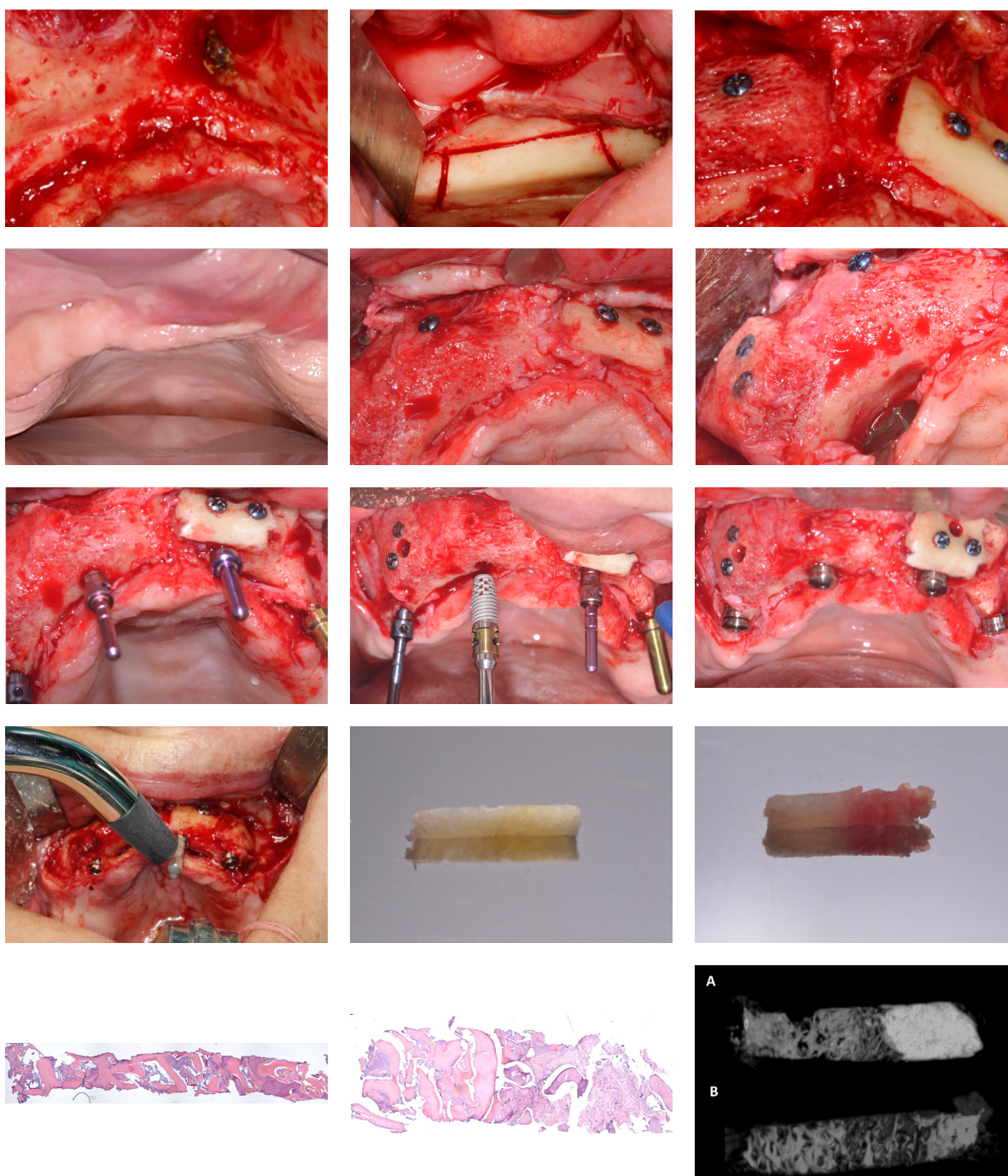
### Study design

Patient selection with total edentulism and maxillary resorption with at least 10mm of ridge height and 2mm of thickness. Split mouth graft placement. Reopenig of grafts after 9 months, biopsy and implant placement. Core biopsies of autogenous and bovine bone blocks for microCT and Histology.

**Follow-up:** 9 meses

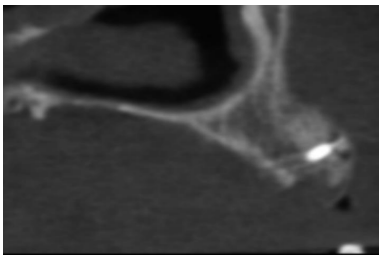
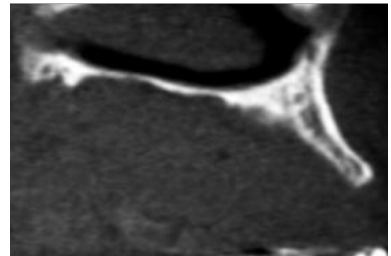
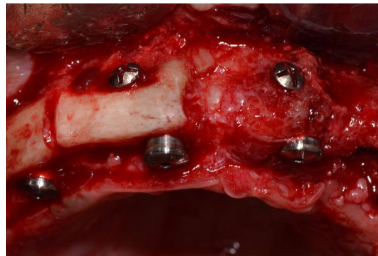
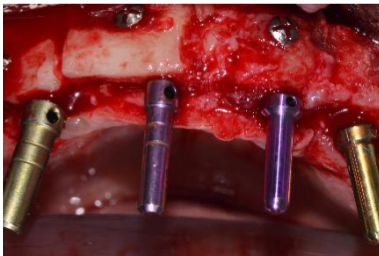
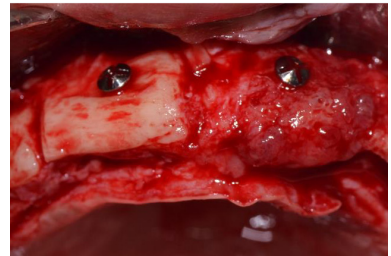
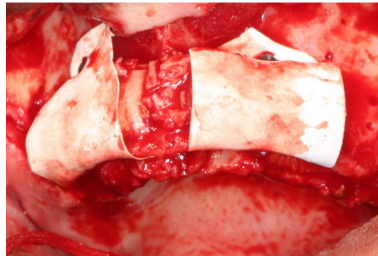
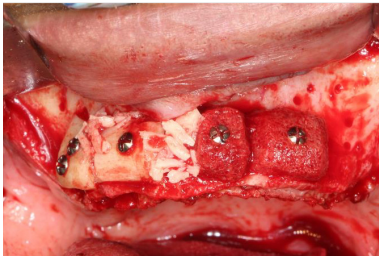
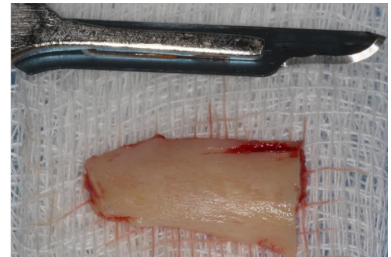
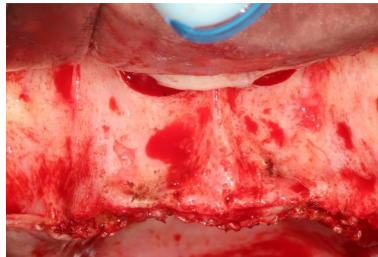
Carvalho, P. H., Valfrido Antonio Pereira-Filho, Trento, G. D. S., Okamoto, R., & Gonçalves, M. (2019). Xenogenous bone blocks for maxillary reconstruction—Histologic and microtomographic split mouth clinical trial. *Morressier*. <https://doi.org/10.26226/morressier.5d3880c03ceb062ea26e5230>

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Follow-up: 9 meses



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# P-SU-069

## IMPLANT THERAPY OUTCOMES; SURGICAL ASPECTS

# Xenogenous bone blocks for maxillary reconstruction- histologic and microtomographic split-mouth clinical trial

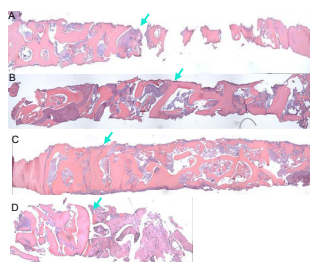
Carvalho PHA<sup>1</sup>, Trento G<sup>1</sup>, Okamoto R<sup>2</sup>, Gonçalves M<sup>1</sup>, Pereira-Filho VA<sup>1</sup>

<sup>1</sup> São Paulo State University, Dental School at Araraquara, Department of Diagnosis and Surgery  
<sup>2</sup> São Paulo State University, Dental School at Araçatuba, Department of Basic Sciences

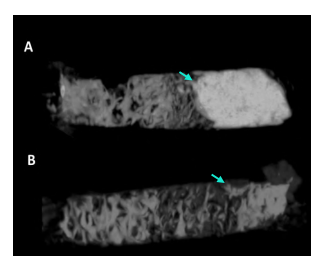
### Abstract

**Background:** Atrophic ridges are a challenge in the oral rehabilitation with osseointegrated implants. Autogenous bone graft is the gold standard in ridge augmentation. However, the resorption rates and donor site morbidity limit its use. The deproteinized bovine bone (DPBB) are a viable alternative. DPBB can be particulate or compacted in a block, like the autogenous bone block. There are few clinical studies evaluating the DPBB graft incorporation to the receptor site and its remodeling properties. **Aim/hypothesis:** This study hypothesis is deproteinized bovine bone blocks (DPBB) sintered in low temperatures, present similar characteristics of mineralization and bone neoformation than autogenous graft from mandibular ramus. **Material and methods:** Six patients with edentulous atrophic maxillary ridges were randomized selected in a list of patients whose sought for oral rehabilitation with implants. The inclusion criteria were absence of systemic health issues, age between 20 and 70 years old, with hormonal stability, and consent. Irradiated patients, patients with systemic diseases and post menopause women were excluded. The patients were submitted to reconstruction surgery under general anesthesia. Each side of anterior maxilla received one type of graft, according to randomization process, xenogenous block (test) or Mandibular ramus block graft (control). After 9 months of healing, at implant placement, a biopsy was performed with a 2mm trephine bur, in horizontal direction. Specimens were first processed in 10% formaldehyde for 48h, washed for 24h and stored in 70% alcohol, after they were processed in a digital microCT scan, and then submitted to paraffin inclusion and histomorphometry analysis. **Results:** The analyzed parameters were tissue volume, bone volume, bone volume percent, tissue surface, bone surface, bone density and porosity, soft tissue and mineralized tissue. The trabecular number, thickness and separation were also evaluated. All the evaluated parameters respect the normal distribution (Shapiro-Wilk;  $p = 0.060 - 0.975$ ) and homoscedastic (Levene;  $p = 0.250 - 0.972$ ). There was statistical difference between groups only for the trabecular thickness. Autogenous bone graft presented larger trabeculae (0.45mm) than DPBB (0.29mm) ( $p < 0.05$ ). **Conclusions and Clinical Implications:** Results suggest that the DPBB block tested presented similar micro structural and bone formation characteristics to the autologous bone graft from mandibular ramus, furthermore, Deproteinized Bovine Block grafts could be a suitable clinical alternative to autologous bone when this is contraindicated, for example in compromised health patients or in cases with no sufficient autologous bone donation site.

### Results



**Figure 3.** Histomicrographs of entire biopsies removed from (A and C) Autogenous graft from mandibular ramus and (B and D) Bovine deproteinized bone block (green arrows indicate the interface between host bone and graft). Hematoxylin-eosin stain (100µm)



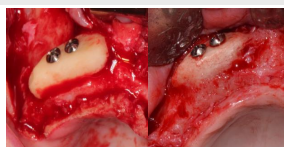
**Figure 4.** Microtomographs of entire biopsies removed from (A) Autogenous graft from mandibular ramus and (B) Bovine deproteinized bone block (green arrows indicate the interface between host bone and graft).

**Table 1.** Distribution of evaluated parameters on microtomographic analysis. Mean (SD) for Autogenous bone and Deproteinized bovine bone block grafts (DPBB)

	Autogenous (6)	DPBB (6)
<b>Sample vol.</b>	23,01 (8,29)	32,94 (6,57)
<b>Bone vol.</b>	8,66 (4,44)	9,15 (3,36)
<b>Bone vol. (%)</b>	37,84 (10,93)	28,43 (9,84)
<b>Bone surface vol.</b>	11,45 (2,06)	13,28 (2,43)
<b>Bone surface</b>	96,15 (40,74)	116,9 (39,54)
<b>Tissue surface</b>	51,94 (15,47)	67,17 (10,33)
<b>Trabecular number</b>	0,87 (0,33)	0,95 (0,29)
<b>Trabecular separation</b>	0,39 (0,12)	0,49 (0,17)
<b>Trabecular thickness</b>	0,46 (0,15)*	0,29 (0,04)*
<b>Bone density</b>	4,20 (1,04)	3,59 (0,98)
<b>Porosity</b>	62,16 (10,93)	71,56 (9,84)

### Background and Aim

Early teeth loss;  
 Atrophic ridges;  
 Implant rehabilitation;  
 Autogenous bone as gold standard;  
 Alternatives to autogenous bone grafting

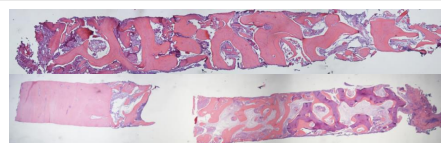


**Figure 1.** Volume comparison between initial (A) and after 9 months (B) for autogenous bone graft.

#### AIM

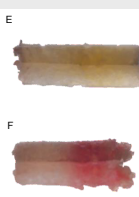
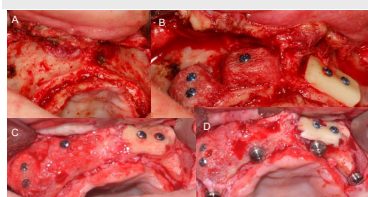
To evaluate the mineralization and new bone formation of a bovine deproteinized bone block in comparison to autogenous graft from mandibular ramus.

### Conclusion



DPBB block tested presented similar micro structural and bone formation characteristics to the autologous bone graft from mandibular ramus.

### Methods and Materials



**Figure 2.** Study design. (A) Patient selection with total edentulism and maxillary resorption with at least 10mm of ridge height and 2mm of thickness. (B) Split mouth graft placement. (C) Reopening of grafts after 9 months, biopsy and (D) implant placement. (E and F) core biopsies of autogenous and bovine bone blocks for microCT and Histology.

### References

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 Schwarz F, Ferrari D, Balic E, Buser D, Becker J, Sager M. Lateral ridge augmentation using equine- and bovine-derived cancellous bone blocks: A feasibility study in dogs. Clin Oral Implants Res. 2010;21(9):904–12.  
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 Enayef B, Porta C, del Amo F, Mordini L, Gargallo-Albiol J, Hernández-Alfaro F. The Fate of Lateral Ridge Augmentation: A Systematic Review and Meta-Analysis. Int J Oral Maxillofac Implants. 2018;33(3):622–35.  
 Spin-Neto R, Stavropoulos A, Coletti FL, Faeda RS, Pereira LAVD, Marcantonio E. Graft incorporation and implant osseointegration following the use of autogenous and fresh-frozen allogeneic block bone grafts for lateral ridge augmentation. Clin Oral Implants Res. 2014;25(2):226–33.



Presented at

Lisbon 2019

# P-SU-112

IMPLANT THERAPY  
OUTCOMES; SURGICAL  
ASPECTS

## Xenogenous bone blocks for maxillary reconstruction: clinic and tomographic split-mouth trial

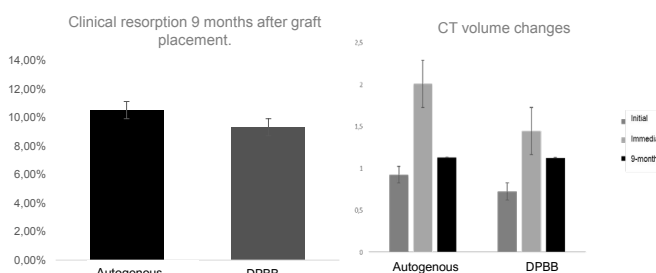
Pereira-Filho VA<sup>1</sup>, Carvalho PHA<sup>1</sup>, Gonçalves M<sup>1</sup>, Moura LB<sup>2</sup>, Okamoto R<sup>3</sup>.

<sup>1</sup> São Paulo State University, Dental School at Araraquara, Department of Diagnosis and Surgery  
<sup>3</sup> Pelotas Catholic University, School of Dentistry, Department of Oral Surgery  
<sup>2</sup> São Paulo State University, Dental School at Araçatuba, Department of Basic Sciences

### Abstract

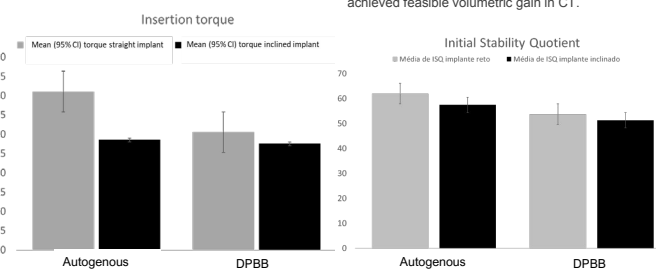
**Background:** Autogenous bone graft still the gold standard in ridge augmentation. However, the resorption rates and donor site morbidity limit its use. Many bone substitutes, as the deproteinized bovine bone (DPBB), are an alternative for ridge reconstruction. DPBB can be particulate or compacted in a block, with autogenous block like structure. There are few clinical studies evaluating the block of DPBB graft clinical behavior, resorption, incorporation and implant stability in xenogenous block area. **Aim/hypothesis:** This study hypothesizes deproteinized bovine bone blocks (DPBB) sintered in low temperatures, present similar clinical behavior, similar implant initial stability and less resorption rates than autogenous graft from mandibular ramus. **Material and methods:** Ten patients with edentulous atrophic maxillary ridges were randomized selected in a list of patients for oral rehabilitation with implants. The inclusion criteria were: absence of systemic health issues, age between 20 and 70 years old. Irradiated patients, patients with general diseases and post menopause women were excluded. The patients were submitted to reconstruction surgery under general anesthesia. Each side of anterior maxilla received one type of graft, according to randomization, xenogenous block (test) or Mandibular ramus block graft (control). The alveolar ridges were scanned by CBCT at three times: pre-graft surgery (T0), immediate post-operative (T1) and pre-implants (T2). At the moment of graft surgery the alveolar ridges were measured with surgical caliper in three standardized position. Nine months later an all-on-four protocol was installed, and the clinical measurements were repeated, and it was measured implant torque and implant stability quotient (ISQ). **Results:** All the 20 grafted areas were able to implant placement, at post operative period of grafting, 5 patients presented one or more complications, 2 related with xenogenous bone and 3 in the autogenous group. The main complications were wound dehiscence and graft exposure, with a mean time of 74,2 days after surgery, ranging from 20 to 120 days. Membrane exposures were kept with chlorhexidine 0,12% gel and follow-up, in 3 cases the membrane needs removal due soft tissue impairment. Three patients presented complications of donor site, like seroma, infection, swelling and hemorrhage, treated with local procedures. The volumetric changes had not statistic difference between the test and the control graft, implant volume was 81.5 (SD 10.27) in autogenous group and 89.75 (SD 8.34) in the bovine block, mean resorption percentages were 10.53 (7.08) and 9.33 (10.41) respectively. Installation torque (control: 41; test: 30.5) and ISQ (control: 62; test: 53.37) presented no statistical difference. **Conclusions and Clinical Implications:** The tested xenogenous block presented similar clinical behavior of mandibular ramus autogenous block, for maxillary horizontal reconstruction. The complication rates, resorption and implant torque and stability presented no statistical difference in this clinical trial.

### Results



**Figure 3.** Comparison between percentage of clinical resorption (result from difference between T1 and T2 measures), for autogenous and Deproteinized bovine block graft (DPBB).

**Figure 4.** 95% CI for the Bone volume in mm<sup>3</sup> prior grafting, immediate after grafting and 9 months earlier. There was no difference for autogenous bone and DPBB in all evaluated periods, and both groups have achieved feasible volumetric gain in CT.

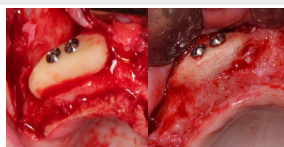


**Figure 5.** 95% CI for the insertion torque (N), for straight and inclined implants. Inclined implants presented lower insertion torque in both autogenous and DPBB.

**Figure 6.** 95% CI for the Initial Stability Quotient (ISQ), for straight and inclined implants. No difference was observed for both autogenous and DPBB.

### Background and Aim

Early teeth loss;  
Atrophic ridges;  
Implant rehabilitation;  
Autogenous bone as gold standard;  
Alternatives to autogenous bone grafting



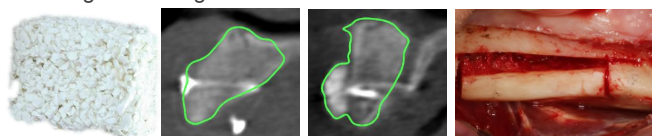
**Figure 1.** Volume comparison between initial (A) and after 9 months (B) for autogenous bone graft.

#### AIM

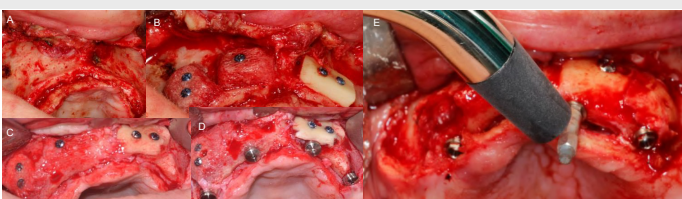
To evaluate the graft incorporation, the volume changes and the implant stability of a bovine deproteinized bone block in comparison to autogenous graft from mandibular ramus.

### Conclusion

There were no differences for resorption, complication rates and clinical behavior between DPBB block tested and the autologous bone graft from mandibular ramus.



### Methods and Materials



**Figure 2.** Study design. (A) Patient selection with total edentulism and maxillary resorption with at least 10mm of ridge height and 2mm of thickness. (B) Split mouth graft placement. (C) Reopening of grafts after 9 months, biopsy and (D) implant placement. (E) Initial stability measurement with Ostell G.

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Presented at

