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Patient perception and clinical effectiveness of an allogeneic cortical sheet versus an autologous laminated bone graft for the treatment of horizontal bone defects

Submission date 20/01/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/01/2021	**Overall study status** Completed	
Last Edited 04/12/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background study and aims
The loss of one or more teeth causes changes in the alveolar process (the thickened ridge of bone that contains the tooth sockets) that can sometimes compromise or hinder the placement of an implant in the appropriate position. An autologous bone graft (using bone from the same patient) is considered to be the gold standard for the reconstruction of bone defects. However, autologous grafts have disadvantages such as having to go to a second surgical area to obtain the bone graft. As a result in recent decades there have more studies of non-autologous grafts. The non-autologous bone grafts with the greatest scientific support are those of xenogenic origin (from another species), but they lack osteogenic (bone-forming) capacity. Bone grafts of allogeneic origin (transplanted from one person to another) could be a valid alternative to autologous grafts. However, these types of grafts do not have an osteogenic capacity and therefore bone formation will require a longer healing time and will result in a lesser amount of newly formed bone. Therefore, the aim of this study is to analyze the effectiveness of bone allografts in the three-dimensional reconstruction of atrophic maxillae (upper jaws) before implant placement.

Who can participate:
Adults at least 18 years of age with a bone defect requiring bone augmentation for implant placement

What does the study involve?
Participants are randomly allocated to receive a bone allograft sheet (LifeNet Health OraGRAFT Cortical Plate®) or an autologous bone graft sheet. The horizontal bone gain is measured during the first surgery.

What are the possible benefits and risks of participating?
The risks and benefits of participating in the study are the same as if the patient receives the surgical intervention but is not participating in the study.

Where is the study run from?
Periocentrum Bilbao and Periocentrum Madrid-Reina Mercedes (Spain)

When is the study starting and how long is it expected to run for?
June 2017 to September 2023

Who is funding the study?
ThinkingPerio Research and Arrow Research Development SL (Spain)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
2017017 (PS)

Study information

Scientific Title
Patient perception and clinical effectiveness of an allogeneic cortical sheet versus an autologous laminated bone graft for the treatment of horizontal bone defects: a randomized multicenter clinical trial

Study objectives
Allograft Bone Sheet (OraGRAFT Cortical Plate®) provides results similar to an autologous sheet graft in terms of horizontal bone gain but with higher overall patient satisfaction with treatment due to lower morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/06/2017, Ethical Committee of the Basque Country (CEIm de Euskadi [Comité de Ética de la Investigación Clínica con medicamentos] Farmaziako Zuzendaritza / Dirección de Farmacia. Osasun saila / Departamento de Salud. Eusko Jaurlaritza / Gobierno Vasco C/ Donostia-San Sebastián, 1 – 01010 Vitoria-Gasteiz; +34 (0)945 01 64 59; ceic.eeaa@euskadi.eus), ref: PS2017017

Primary study design
Interventional

Study design
Multicenter randomized controlled clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atrophic alveolar ridge that does not allow implant placement

Interventions
Randomization:
The randomization will be done in blocks according to a randomization list generated by a computer using the SPSS program. Treatment allocation will be hidden in sealed, opaque envelopes until the time of surgery. In this study, neither the patient nor the operator nor the examiner can be blinded. The statistician will be blinded.

On day 0 the first surgical procedure will be performed, which will include the following phases:
1. Pre-surgical measurement of the width of the buccal mucosa with a probe millimeter CP15 and impression of the area to be treated
2. Pre-surgical and post-surgical periapical x-ray of the area to be intervened
3. The stopwatch is activated to measure the intervention time
4. Local anesthesia and elevation of a full-thickness flap to expose the area bone that will

receive the bone graft
5. Measurement of the width of the alveolar process using a millimeter gauge 2 mm apically to the alveolar ridge in each of the positions to receive an implant
6. The flap is released by cutting the deep periosteum and a superficial release of the flap muscle attachments
7. Randomization of the type of graft to receive: bone allograft sheet (LifeNet Health OraGRAFT Cortical Plate®) versus autologous bone graft sheet. In case of receiving an autologous bone graft, the posterior retromandibular area (oblique line) will be anesthetized and a graft will be taken that has the length and width of the treated area between 1 and 2 mm in diameter thickness (Barbieri et al. 2017)

Intervention Type
Procedure/Surgery

Primary outcome(s)
The horizontal bone gain measured clinically 2 mm from the ridge using a calliper during the first surgical intervention

Key secondary outcome(s)
1. The general satisfaction of the patient with the treatment as well as the pre-surgical expectations, measured by the VAS scale calibrated from 1 to 100 points immediately after surgery and at 2, 4, 12, 26, and 52 weeks
2. Horizontal bone gain measured radiographically by CBCT before implant placement (second surgery)
3. Horizontal bone gain measured with a volumetric study using digital impressions (3Shape®) and stone models at baseline, before the second surgery, before the third surgery, and at 1 year, 3 years and 5 years follow-up
4. The peri-implant indices around the implants (bleeding on probing, plaque index, recession of the peri-implant mucosa, probing depth and clinical attachment level and radiographic bone level) measured with a manual periodontal probe during the period of observation up to 52 weeks
5. Time spent in peri-implant bone augmentation treatment measured using a watch during the first surgical procedure
6. Depth of the vestibule in the treatment area measured using digital impressions (3Shape®) at 12, 26 and 52 weeks after the intervention
7. Follow-up of patients and peri-implant health using a manual periodontal probe to measure clinical parameters and periapical x-ray to measure radiographic changes at 3 and 5 years

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Informed consent after detailed information
2. Adults at least 18 years of age
3. Candidates to receive a bone augmentation for implant placement
4. Presence of a bone defect (≥2 teeth) with at least 2 mm of mucosa
5. Keratinized remnant whose bone width is insufficient (<4 mm) measured on a CBCT-type

scanner
6. The patient must be periodontally treated at least 1 month before the surgical intervention and in addition to all those oral factors that may affect the treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. General contraindications for dental/surgical treatment
2. Inflammatory or autoimmune disease of the oral cavity
3. Smokers of more than 10 cigarettes a day
4. Allergy to collagen and analgesics/anti-inflammatory NSAIDs
5. History of cancer in different parts of the body that has required radiotherapy or chemotherapy in the last 5 years
6. Radiation therapy to the head or neck in the last 5 years
7. Current medication with immunosuppressants, bisphosphonates or high doses of corticosteroids
8. Pregnant or nursing women
9. Women of childbearing age who are not using an effective contraceptive method
10. Participating in other biomedical research studies in the 24 weeks prior to the start of the study

Date of first enrolment
01/09/2017

Date of final enrolment
23/10/2022

Locations

Countries of recruitment
Spain

Study participating centre

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Sponsor information

Organisation
ThinkingPerio Research - Periocentrum Bilbao

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
ThinkingPerio Research and Arrow Research Development SL

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1		04/02/2021	No	No