

# The potential of own dentin as material to regenerate bone after tooth extraction

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<b>Registration date</b> 14/08/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/08/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Following tooth extraction where there is damage to the bone, it is necessary to reconstruct the damaged area. There are different methods for this including use of synthetic material or material gathered from the extracted tooth (Autogenous Undemineralized Dentin (UDD)). This study aimed to compare the clinical efficacy and pain experience of autogenous UDD versus Bio-Oss® granules in guided bone regeneration (GBR).

### Who can participate?

Patients seeking tooth extraction for implant placement

### What does the study involve?

Participants will be randomly allocated to receive either autogenous UDD or Bio-Oss® granules to aid reconstruction after tooth extraction. Patients will be followed up for 2 years.

### What are the possible benefits and risks of participating?

Possible benefits are the rehabilitation with dental implants with both safe procedures. The risks are the standard complications during implant rehabilitation and oral surgery.

### Where is the study run from?

Clínica Dentária de Carnaxide (Portugal)

### When is the study starting and how long is it expected to run for?

January 2018 to July 2020

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

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## Contact information

**Type(s)**

Public

**Contact name**

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**Additional identifiers****Protocol serial number**

CES-FMDUL-9/3/2018

**Study information****Scientific Title**

Autogenous undemineralized dentin versus bio-oss in guided bone regeneration for delayed implantation in postextraction sites

**Acronym**

AUD-PROJECT

**Study objectives**

There will be a difference in histological and clinical characteristics between 100% UDD grafts (test group) and 100% Bio-Oss® grafts (control group), in postextraction sites for delayed dental implant placement.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 09/03/2018, Faculty of Dentistry at the University of Lisbon Ethical Committee (Cidade Universitária, R. Profa. Teresa Ambrósio, 1600-277 Lisboa; +351 21 792 2600), ref: CES-FMDUL-9/3/2018

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Dental postextraction sites for implant placement

## Interventions

In both groups, minimally invasive atraumatic tooth extraction was performed. Surgery was performed under local anesthesia using 4% articaine HCl with epinephrine (1:100,000). Teeth were removed after a full thickness flap was performed with a 15C blade to access the vestibular bone dehiscence. Atraumatic extraction was secured using periostomes (PT1 and PT5, Hu-Friedy, Chicago, Illinois, USA) and avoiding forceps use, though when forceps were necessary precautions were taken to avoid damaging marginal bone. In molar teeth, roots were separated by high-speed drills. After extraction, the alveolus was meticulously handled with a Lucas mini cutter (#611748, Hu-Friedy, Chicago, Illinois, USA). Then, the assigned graft material was placed inside the alveolus according to its manufacture protocol, and primary closure of the surgical sites was done with a free gingival graft harvested from the palate and sutured with non-absorbable synthetic monofilament suture made of polyamide polymers (Dafilon® 5/0m B /Braun Surgical, Spain).

### Preparation of the autogenous UDD graft

We followed the manufacturer protocol for UDD (Smart dentin Grinder™, KometaBio, USA). In a separate room, remaining soft tissues were carefully removed and adequately dried. Each tooth was placed inside the milling chamber and was crushed into two compartments: 1) particles of diameter between 250 and 1200 µm; and 2) particles of diameter below 250 µm, which were wasted. Then, the particulate was immersed in a cleanser solution (0.5 M NaOH and 30% (v/v) alcohol) for 7 minutes, replaced by a saline solution of Phosphate Buffered Saline (PBS) for 3 minutes. Finally, the saline solution was carefully removed with sterile gauze, and the final graft material was stored in temperature room for clinical use.

### Postoperative care

Both groups of patients were instructed to rinse the mouth twice a day with 0.10% chlorhexidine gluconate solution (Eludril Classic, Pierre Fabre Oral Care) and to take oral antibiotics, amoxicillin plus clavulanate potassium (875mg/125mg) every 12 hours for 8 days, or 500 mg of azithromycin in cases of allergy to penicillin, once a day for 3 days), nonsteroidal anti-inflammatory drugs (ibuprofen 600mg) every 12 hours for 4 days. An analgesic was prescribed to be taken immediately after surgery (300 mg clonixin, 1 pill), or when necessary during the follow-up, and this was registered in a diary for further analysis.

After a healing period of six months, graft site was reopened and, at the planned location for implant placement, trephine core harvesting was performed using a trephine bur (outer diameter 2.35 mm, inner diameter 2.30 mm, length 7.00 mm; #1749-023, Schwert, Germany). We collected a core from each site, and all biopsies (from the 66 sites) were processed and analysed. Immediately after the harvest procedure, each core was preserved in a 10% formalin solution and sent for histologic analysis. During implant insertion, no addition of graft material was made.

## Intervention Type

Procedure/Surgery

## Primary outcome(s)

The stability of implants was recorded as the average between buccolingual and mesiodistal measures (ISQ) using the Osstell IDx Mentor Resonance Frequency Analyser (Osstell AB, Goteborg, Sweden), at baseline and 3-months after placement

### **Key secondary outcome(s)**

1. Condition of periapical areas measured using radiographs carried out before tooth extraction, after GBR, and 6 months after GBR, during implant placement, at baseline, 6 months, 12 months and 24 months after prosthesis loading. Also, all patients underwent cone beam computed tomography (CBCT) scan six months after tooth extraction.

At baseline, 6 months, 12 months and 24 months:

2. Histomorphometric analysis measured using light microscopy:

2.1. Percentage of newly formed bone volume compared to total volume

2.2. Percentage of residual bone substitute material volume compared to total volume

2.3. Percentage of soft tissue component volume compared to total volume (as the subtraction of the percentage of newly formed bone and residual bone from the total area). These set of analyses was carried out by one examiner (G.B.) blinded to the allocated group

3. Patient-related outcomes:

3.1. Patient's pain and discomfort perceptions were rated using the visual analogue scale (VAS) score (0–10), using 'No Discomfort' and 'Worst Discomfort' as anchors

3.2. Frequency of analgesic consumption was registered by the patient during the follow-up period in daily diary

### **Completion date**

01/07/2020

## **Eligibility**

### **Key inclusion criteria**

1. 18 years old or older

2. Requiring alveolar preservation through guided bone regeneration after tooth extraction towards the placement of dental implant and type 2 extraction sockets, where the mucosal tissues are present but there is a midfacial osseous dehiscence defect classification and subclassification Type 2B with a dehiscence defect involving the middle one-third of the labial plate, approximately 7 to 9 mm from the free gingival margin

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

## **Total final enrolment**

56

## **Key exclusion criteria**

1. Heavy smokers (more than 10 cigarettes per day or an electronic cigarette dose of >6mg/ml of nicotine)
2. Presence of active infection or severe inflammation in the intervention zone
3. Relevant medical history that contraindicates implant surgery
4. Immunosuppression (eg. HIV, solid-organ transplants)
5. Head and neck-irradiated patients in the past 5 years
6. Regular intake of bisphosphonates, anticoagulants or anti-inflammatories
7. Chronic drug abuse or alcoholic habits
8. Patients with poor oral hygiene (full-mouth plaque score and full-mouth bleeding score >15%) and lack of motivation
9. Uncontrolled diabetes (reported levels of glycated haemoglobin exceeding 7%)
10. Uncontrolled and /or untreated periodontal disease
11. Previous history of bone graft in the intervention zone
12. An acute endodontic lesion in the tooth to be extracted or in adjacent teeth

## **Date of first enrolment**

01/04/2018

## **Date of final enrolment**

01/08/2018

## **Locations**

### **Countries of recruitment**

Portugal

### **Study participating centre**

**Clínica Dentária de Carnaxide**

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Lisbon

Portugal

2790-129

## **Sponsor information**

### **Organisation**

Clinica Dentária de Carnaxide

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to no consent given by participants for sharing.

**IPD sharing plan summary**

Not expected to be made available