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

Submission date
13/08/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Completed

Last Edited
14/08/2020

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 periotomes (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 meticulous 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 measure
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

Secondary outcome measures
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 microspcopy:
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 dairy

Overall study start date
01/01/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Sample size calculation was performed based on previous data, indicating that a minimum number of 24 individuals was needed to determine a 0.7 difference in stability value (ISQ), one of the outcome variables of interest, between groups immediately after surgery (85% power, with a 5%, two-sided, significance level). Considering a 10% dropout rate, a final number of 26 participants per group was set as the minimum required sample.

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
Avenida de Portugal nº24 Piso 1 Loja 27
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/08/2020

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