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The effect of different gum graft materials in preventing bone resorption after tooth extraction: a clinical trial

Submission date	Recruitment status	[ ] Prospectively registered
21/06/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/07/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/02/2025	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
After dental (tooth) extraction, bone resorption/remodelling is expected as a result of the healing process. However, this could have a negative impact on the dental implants used to replace missing teeth when this remodelling is too extensive or the residual bone is too thin. Ridge preservation techniques are interventions aimed at minimising this amount of bone resorption and therefore increasing the probability of successful implant placement without the need for any artificial bone graft. The aim of this study is to compare two treatments to achieve more efficient bone preservation after dental extraction.

Who can participate?
Healthy adult patients aged 18 to 90 years who require dental extraction where implant therapy is a feasible option

What does the study involve?
Participants are randomly allocated to one of two groups. In the control group, a xenograft (Bio-oss) in combination with an autogenous gingival (gum) graft will be used as a soft tissue seal. In the intervention group, a xenograft (Bio-oss) is used with another xenograft material (Muograft) as a soft tissue seal.

What are the possible benefits and risks of participating?
The main benefit of ridge preservation procedures is to increase the amount of available bone for dental implant placement at a later stage whereas the risks of these procedures are minimal or similar to any other oral surgery.

Where is the study run from?
Murcia University Teaching Hospital (Morales Meseguer) (Spain)

When is the study starting and how long is it expected to run for?
January 2022 to January 2024

Who is funding the study?
Universidad de Murcia (Spain)

Who is the main contact?
Dr Guillermo Pardo Zamora, gparza@um.es

Contact information

Type(s)
Principal investigator

Contact name
Dr Guillermo Pardo Zamora

ORCID ID
https://orcid.org/0000-0002-6080-0216

Contact details
Universidad Murcia. Hospital Morales Meseguer
Facultad de Medicina.
Departamento Odontologia.
Avenida de los Velez
s/n
Murcia
Spain
30008
+34 (0)606064848
gparza@um.es

Type(s)
Scientific

Contact name
Dr Ruben Garcia-Sanchez

ORCID ID
https://orcid.org/0000-0003-2051-0668

Contact details
Guys and St Thomas' Hospital
Dental Restorative Division
Periodontology Department
Great Maze Pond
London
United Kingdom
SE1 9RT
+44 (0)7864929396
ruben.garciasanchez@gstt.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
RUxFMqXf-UhdsIxv5-1DNV1zfn-BBJQx6TC

Study information

Scientific Title
The effect of free gingival graft and connective tissue substitutes on the preservation of the ridge after tooth extraction: a clinical trial

Study objectives
The aim of this study was to test the main null hypothesis that there were no differences in alveolar preservation using xenograft material and Mucograft as a soft tissue seal vs the use of the same xenograft material and autogenous soft tissue graft as a seal vs the alternative hypothesis of a difference at 6 months.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/01/2022, University of Murcia Ethics Committee (Universidad De Murcia Campus de la Merced. Calle Santo Cristo, Murcia, 30001, Spain; +34 (0)868 88 36 14; comision.etica.investigacion@um.es), ref: RUxFMqXf-UhdsIxv5-1DNV1zfn-BBJQx6TC

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Alveolar ridge preservation after dental extraction

Interventions
Patients were randomly assigned to the test or control group by balanced block randomization using a computer-generated table. Treatment assignment was concealed to the treating surgeon by opaque envelopes that were opened only after the completion of tooth extraction.

In the control group, a xenograft (Bio-oss) in combination with an autogenous gingival graft will be used as a soft tissue seal. In the intervention group, a xenograft (Bio-oss) is used with another xenograft material (Muograft) as a soft tissue seal.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Soft tissue volumetric changes measured in plaster study models obtained at baseline, 3 and 6 months. Additionally, further measurements will be taken with a periodontal probe at baseline and 6 months to evaluate the location of certain anatomic landmarks using a custom-made prefabricated stent for each patient.

Key secondary outcome(s))
1. Hard tissue volumetric changes assessed with intraoperative measures at the bone level at the time of dental extraction and at 6 months before placement of dental implants at those locations. A periodontal probe and calipers will be used to evaluate the location of certain anatomic landmarks using a custom-made prefabricated stent for each patient.
2. Probing pocket depth measured with a periodontal probe at baseline and 6 months
3. Gingival phenotype measured with a periodontal probe at baseline and 6 months
4. Plaque and gingival bleeding indexes measured with a periodontal probe at baseline and 6 months

Completion date
01/01/2024

Eligibility

Key inclusion criteria
Healthy adult patients for which dental extraction was required and implant therapy was a feasible option to be offered/discussed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Patients with medical history in which any dental intervention would be contraindicated such as uncontrolled diabetes, head and neck radiation for cancer treatment or current treatment with intravenous bisphosphonates

2. Presence of clinically symptomatic periapical radiolucencies, acute abscesses or chronic sinus tracts at the site of extraction
3. Heavy smokers (+10 cigarettes/day)
4. Pregnancy
5. Presence of active periodontal disease
6. Inability or unwillingness to return for follow-up visits

Date of first enrolment
10/01/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Morales Meseguer
Avenida Marques de los Velez
s/n
Murcia
Spain
30008

Sponsor information

Organisation
Hospital General Universitario Morales Meseguer

ROR
https://ror.org/00cfm3y81

Funder(s)

Funder type
University/education

Funder Name
Universidad de Murcia

Alternative Name(s)
University of Murcia

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are currently unknown and will be made available at a later stage.

IPD sharing plan summary
Data sharing statement to be made available at a later date