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Comparison using the patient's own soft tissue vs an animal material to improve the soft tissue around dental implants

Submission date
26/09/2025

Registration date
01/10/2025

Last Edited
01/10/2025

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Soft tissue deficiencies around dental implants have an impact on aesthetic outcomes and long-term implant health maintenance. Using the patient's own soft tissue to create a graft (known as autologous grafting) is a useful technique, but it can lead to further complications. Using animal-derived materials is an option that could make treatment easier, reduce surgery time, and make patients more comfortable. This study aims to provide information that can be used to compare the results of using an animal-derived material and traditional autologous grafting to treat horizontal volume deficiencies dental around implants.

Who can participate?
Healthy patients over 18 years old with volume deficiencies around implants

What does the study involve?
Participants will be randomly placed in one of two groups: Group 1 (test group) will receive an animal-derived material and Group 2 (control group) will receive an autologous graft. The study team will measure and compare several outcomes between the two groups. These include changes in volume, the width of the firm gum tissue, aesthetic outcomes, pain afterwards, whether they need extra pain medication, their oral-related quality of life and bleeding following the treatment.

What are the possible benefits and risks of participating?
Participants might have a treatment easier to predict and less uncomfortable. Participants don't need to undergo any additional procedures, except for a non-invasive dental arch scan. By taking part in this study there is no extra risk compared to the autologous graft procedure.

Where is the study run from?
Egas Moniz University Clinic (Portugal)

When is the study starting and how long is it expected to run for?
November 2024 to July 2027

Who is funding the study?
Oral Reconstruction Foundation (Switzerland)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ORF-2024-74

Study information

Scientific Title
Comparison of volumetric changes in the peri-implant mucosa in horizontal defects using connective tissue graft vs acellular dermal matrix: a randomized clinical trial

Acronym
NDERMATRIX

Study objectives
Primary objective:
To evaluate and compare the volumetric augmentation achieved through two distinct peri-implant soft tissue enhancement techniques: porcine dermal matrix versus connective tissue graft.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 04/08/2025, Ethics Committee of Egas Moniz (Campus Universitário, Quinta da Granja Monte de Caparica, Almada, 2829 - 511, Portugal; +351 (0)212 946 700; comissaoetica@egasmoniz.edu.pt), ref: 1600

Study design
Interventional blinded randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Quality of life, Treatment, Efficacy

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
Peri-implant mucosa horizontal defects

Interventions
Participants will be randomly allocated to either:
Test group (n= 16): Porcine dermal matrix (NovoMatrix™) intervention
Control group (n= 16): Autogenous connective tissue graft

A calibrated examiner (JL), who will remain blinded to treatment allocation and uninvolved in therapeutic interventions, will perform all clinical measurements to minimize assessment bias. Prior to study initiation, examiner calibration will be conducted to ensure measurement reliability.

In the first appointment a clinical examination and a intra-oral scanning (3shape, Copenhagen, Denmark) will be performed for baseline peri-implant mucosal volume documentation. A full mouth plaque index and peri-implant probing will be performed at six standardized positions: mesio-vestibular (mv), mid-vestibular (v), disto-vestibular (dv), mesio-palatine/lingual (mp/ml), mid-palatine/lingual (p/l), disto-palatine/lingual (dp/dl). Measurements obtained using a calibrated periodontal probe (CP-15), measured in millimetres from the mucosal margin to the bottom of the probable pocket. The height of keratinized tissue will be measured using a graduated periodontal probe and Lugol's solution. Tissue phenotype assessment via periodontal probe transparency method, placed in the peri-implant sulcus. Standardized radiographic examination using a film holder for baseline bone level documentation

All the surgical procedures will be performed by the same operator (MB), to ensure standardization. Following a rinse with 0,2% chlorohexidine for 30 seconds and local anesthesia administration (2% articaine with 1:100,000 epinephrine) an intrasulcular incision around the implant and adjacent teeth will be performed. A partial thickness tunnel will be prepared using a spoon microblade, overpassing the mucogingival junction. During the tunnel preparation, care will be taken to ensure complete graft coverage. After preparing the tunnel, an opaque envelope will be opened, which will determine whether an autologous graft or a dermal matrix will be used. In the control group, a connective tissue graft is harvested from the palatal mucosa with the single incision technique (Lorenzana & Allen, 2000). The connective tissue graft is placed inside the flap and fixed with 6/0 poliamide suture. The flap will be sutured tension-free with primary closure, using the same suture material. In the test group, the dermal matrix, NovoMatrixTM will be hydrated for five minutes in sterile saline solution. The matrix will be placed in the recipient bed and the remaining surgical procedure (fixation and closure protocol) will be identical to the one described in control group. To ensure standardization of graft dimensions, the acellular dermal matrices (15 x 15 mm) will be trimmed to precise measurements of 10 mm in width and 8 mm in height. These standardized dimensions were determined based on the requirement for the graft to extend 3 mm both mesially and distally beyond the circumference of a regular platform implant (4 mm). Autogenous connective tissue grafts will be harvested to match these predetermined dimensions, with the height specification accounting for potential anatomical constraints of the donor site. The length of the surgery will be recorded.

After the surgery, patients from both groups will be instructed to rinse twice daily with 0.2% chlorhexidine for 60 seconds for 10 days, maintain a soft diet, regular oral hygiene measures avoiding surgical site and anti-inflammatory medication (Ibuprofen 600 mg) will be prescribed. Sutures removal will be scheduled at 14 days post-operative and patients will be instructed to use a soft post-surgical toothbrush. Furthermore, a range of patient-reported outcomes (PROMs) will be evaluated, including postoperative pain using a Visual Analogue Scale (VAS), the need of rescue medication (to be evaluated twice daily for the first five days, followed by once daily until 14 days postoperatively), oral health-related quality of life using the OHIP-14 questionnaire, and postoperative bleeding on the seventh day.

Standardized evaluations will be conducted at baseline, 3 months, 6 months, and 1 year post-intervention, comprising: plaque index, peri-implant probing depths, height of keratinized tissue, tissue phenotype assessment, marginal bone level measurements and the Pink Esthetic Score

(PES). For volumetric assessment, digital scan acquisitioned filles will be superimposed and compared in the different stages of healing. Volume differences will be calculated using a specific software program (Medit 2D).

Patient-centered outcomes will be evaluated through a standardized questionnaire assessing three primary domains. First, participants will complete a comprehensive treatment satisfaction assessment regarding aesthetics. Subsequently, they will be queried regarding their willingness to undergo the same procedure again if necessary. Finally, participants will indicate their likelihood of recommending the intervention to others requiring similar treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Volumetric augmentation measured using a digital scan at baseline, 3 months, 6 months, and 1 year post-intervention

Secondary outcome measures
1. Keratinized tissue width measured using a graduated periodontal probe and Lugol's solution at baseline, 3 months, 6 months, and 1 year post-intervention
2. Aesthetic outcomes measured using the Pink Esthetic Score (PES) at baseline, 3 months, 6 months, and 1 year post-intervention
3. Patient Reported Outcome Measures (PROMs) including:
3.1. Postoperative pain measured using a Visual Analogue Scale (VAS) at 6 hours post-intervention, twice daily for the first 5 days, followed by once daily until 14 days postoperatively
3.2. The need of rescue medication, measured using a questionnaire twice daily for the first 5 days, followed by once daily until 14 days postoperatively
3.3. Oral health-related quality of life using the Oral Health Impact Profile-14 (OHIP-14) questionnaire at day 7 post-intervention
3.4. Postoperative bleeding measured using a questionnaire at day 7 post-intervention

Overall study start date
04/11/2024

Completion date
30/07/2027

Eligibility

Key inclusion criteria
1. >18 years old
2. Presence of a single osseointegrated implant with horizontal volumetric deficiency
3. Full-mouth plaque score (FMPS) <25%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Presence of vertical defects
2. Palate thickness <2.5 mm
3. Systemic conditions affecting soft tissue healing (e.g., diabetes with HbA1c >7%)
4. Current chemotherapy or radiotherapy treatment
5. Immunocompromised status
6. Pregnancy or lactation
7. Smoking >10 cigarettes/day
8. Previous bone augmentation in the treatment area
9. Active periodontal disease or local inflammation and/or infection
10. Known hypersensitivity to porcine-derived materials

Date of first enrolment
26/09/2025

Date of final enrolment
29/05/2026

Locations

Countries of recruitment
Portugal

Study participating centre
Egas Moniz University Clinic
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Organisation
Oral Reconstruction Foundation

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Sponsor type
Charity

Website
https://orfoundation.org/

ROR
https://ror.org/0178qr782

Funder(s)

Funder type
Charity

Funder Name
Oral Reconstruction Foundation

Alternative Name(s)
OR Foundation, Oral Reconstruction (OR) Foundation, ORF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/07/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository

IPD sharing plan summary

Stored in publicly available repository