ISRCTN25552154 https://doi.org/10.1186/ISRCTN25552154

Comparing two methods to preserve the bone after tooth extraction

Submission date
09/11/2025

Recruitment status
No longer recruiting

Registration date
11/11/2025

Overall study status
Completed

Last Edited
02/06/2026

Condition category
Oral Health

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

Plain English summary of protocol
Background and study aims
When a tooth is extracted, the surrounding bone naturally shrinks and changes shape during healing. This process can make it more difficult to place dental implants later. The aim of this study is to compare two different techniques used to preserve the bone after tooth extraction. One technique uses a thin sheet of bone material called a cortical lamina to protect and support the bone wall. The other technique fills the socket with a bone substitute (xenograft) and covers it with a collagen membrane. The study will evaluate which approach better maintains the shape and volume of the bone for future implant placement.

Who can participate?
Adults aged 21 years or older who require extraction of a tooth with poor prognosis (such as due to fracture, infection, or periodontal disease) may take part. Participants must be in good general health and willing to attend all follow-up visits.

What does the study involve?
Participants will be randomly assigned to one of two groups. After tooth extraction, one group will receive the cortical lamina technique, while the other will receive the xenograft and membrane technique. Healing will be monitored over a six-month period using X-rays and digital models. Afterwards, dental implants will be placed, and small bone samples will be collected to study how the tissue has healed under a microscope.

What are the possible benefits and risks of participating?
The procedures used in this study are already applied in dental practice and are considered safe. Participants may benefit from better preservation of bone at the extraction site, which could help with future implant treatment. Minor risks include temporary swelling, discomfort, or minor infection after surgery, which will be managed with standard postoperative care.

Where is the study run from?
The study is coordinated by ARDEC Academy (Rimini, Italy) in collaboration with the University of Medical Sciences of Havana (Cuba), where the clinical procedures will take place.

When is the study starting and how long is it expected to run for?
The study is expected to start in 2025 and continue for approximately 18 months, including the six-month healing period and data analysis.

Who is funding the study?
The study is funded by ARDEC Academy with support from Tecnoss®, the manufacturer of the biomaterials used.

Who is the main contact?
Dr. Daniele Botticelli
ARDEC Academy
Via Empoli 33 47838/Riccione, Rimini, Italy
Email: daniele.botticelli@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Daniele Botticelli

ORCID ID
https://orcid.org/0000-0003-2804-1632

Contact details
viale Giovanni Pascoli 67
Rimini
Italy
47923
+39 333 9070450
daniele.botticelli@ardec.it

Additional identifiers

Protocol serial number
AVAL 2025/01

Study information

Scientific Title
Alveolar ridge preservation using cortical lamina versus xenograft and collagen membrane: a randomized clinical study

Acronym
ARP

Study objectives
The objective of the present study is to assess the efficacy of alveolar ridge dimension preservation through the placement of a cortical lamina between the elevated flap and the

buccal bone plate after tooth extraction compared to the use of a xenograft and collagen membrane

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/10/2025, Faculty of Dentistry, University of Medical Science, La Habana, Cuba (Calle 146 # 3102, Playa La Habana, La Habana, 3102, Cuba; +53 53852670; joaquinurbizo@infomed.sld.cu), ref: AVAL 2025/01

Primary study design
Interventional

Study design
Parallel randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Teeth with poor prognosis scheduled for extraction

Interventions
This is a randomized, parallel-arm clinical study designed to evaluate the efficacy of two alveolar ridge preservation (ARP) techniques following tooth extraction. Forty participants requiring extraction of teeth with poor prognosis (premolars, canines, or maxillary incisors) will be recruited and randomly assigned (1:1) to one of two intervention arms.

Test group: After tooth extraction and elevation of a full-thickness flap without releasing incisions, a cortical lamina (Lamina Soft, Tecnoss®, Italy) will be inserted between the buccal bone plate and the flap. The lamina, derived from heterologous cortical bone and processed to maintain hydroxyapatite integrity and flexibility, acts as a barrier isolating the periosteum from the bone surface. The flap will be repositioned and sutured to allow non-submerged healing.

Control group: After tooth extraction, the alveolus will be filled with a xenograft composed of cortico-cancellous granules enriched with collagen (GTO®, Tecnoss®, Italy) and covered with a resorbable collagen membrane (Evolution®, Tecnoss®, Italy). The wound will be closed for submerged healing.

All patients will receive standard postoperative care, including chlorhexidine mouth rinses (0.12%, three times daily for two weeks) and analgesics as needed. Sutures will be removed after approximately two weeks.

After a healing period of six months, dental implants will be placed in all sites. Bone biopsies will be collected using trephine burs during implant site preparation for histological evaluation.

Radiographic (CBCT) and clinical impressions will be taken before extraction and after six months to measure volumetric and linear dimensional changes in the alveolar ridge. Randomization will be computer-generated, and allocation concealment will be maintained until surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Linear and volumetric changes of the alveolar ridge measured using cone-beam computed tomography (CBCT) and 3D analysis of digital impressions at baseline (pre-extraction) and 6 months after alveolar ridge preservation

Key secondary outcome(s)
1. Percentage of newly formed bone measured using histomorphometric analysis of resin-embedded biopsy sections obtained with trephine burs at 6 months after alveolar ridge preservation (during implant site preparation)
2. Percentage of residual graft material measured using histomorphometric analysis of resin-embedded biopsy sections at 6 months after alveolar ridge preservation
3. Presence of inflammatory cells and vascularization assessed through light microscopy of stained histological sections at 6 months after alveolar ridge preservation
4. Soft tissue healing quality evaluated through clinical examination and photographic documentation at 2 weeks (suture removal) and 6 months

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults aged 21 years or older
2. Presence of at least one tooth with poor prognosis (e.g., due to advanced periodontal disease, vertical root fracture, endodontic failure, or non-restorable caries) requiring extraction
3. Extraction sites limited to premolars, canines, or maxillary incisors
4. Adequate oral hygiene and willingness to maintain it throughout the study period
5. Sufficient bone volume and soft tissue condition to allow flap elevation and alveolar ridge preservation procedures
6. Good general systemic health, with no contraindications for routine oral surgery
7. Non-pregnant and non-lactating women
8. Ability and willingness to understand the study procedures, sign informed consent, and comply with all study visits and follow-up appointments

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
21 Years

Upper age limit

90 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Presence of any uncontrolled systemic disease (e.g., diabetes mellitus, cardiovascular disorders, coagulation defects, immune suppression)
2. History of radiotherapy or chemotherapy to the head or neck region
3. Current or recent use (within the past 6 months) of medications known to affect bone metabolism, such as bisphosphonates, denosumab, or long-term corticosteroids
4. Smokers of more than 10 cigarettes per day or users of other tobacco products
5. History of previous bone regeneration procedures or implant placement at the intended surgical site
6. Presence of acute infection, abscess, fistula, or cystic lesion at the tooth to be extracted
7. Severe periodontal disease extending beyond the target tooth and compromising adjacent bone
8. Allergy or hypersensitivity to any of the study materials (xenograft, collagen membrane, or lamina)
9. Pregnant or breastfeeding women
10. Patients who are unable or unwilling to attend scheduled follow-ups or provide informed consent

Date of first enrolment
20/10/2025

Date of final enrolment
30/12/2025

Locations

Countries of recruitment
Cuba

Study participating centre
Faculty of Dentistry, University of Medical Science
Calle 146 # 3102, Playa
La Habana
Cuba
3102

Sponsor information

Organisation
ARDEC Academy

Funder(s)

Funder type
Research organisation

Funder Name
ARDEC Academy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current single-centre clinical study will be available upon reasonable request from the corresponding author.

Contact:
Dr. Daniele Botticelli – ARDEC Academy, Riccione/Rimini, Italy
Email: daniele.botticelli@gmail.com

Type of data shared:
Anonymised individual participant data (IPD), including CBCT measurements, digital impression analyses, and histomorphometric results obtained from biopsy samples.

Availability:
Data will be made available after publication of the main study results and will remain accessible for at least five years thereafter.

Access criteria:
Requests will be evaluated by the principal investigator to ensure that data use is consistent with participant consent and ethical approval. Access will be granted to qualified researchers for legitimate scientific purposes related to bone regeneration and implantology.

Ethical and privacy considerations:
All shared datasets will be fully anonymised, with no identifiable personal data. Data management complies with the Declaration of Helsinki, the EU General Data Protection Regulation (GDPR), and the ethical standards of the University of Medical Sciences of Havana.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in English and Spanish		11/11/2025	No	Yes

Protocol file	11/11/2025	No	No