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Study on the efficacy of resorbable collagen membranes in rebuilding alveolar bone

Submission date
22/09/2025

Recruitment status
No longer recruiting

Registration date
24/09/2025

Overall study status
Completed

Last Edited
23/09/2025

Condition category
Musculoskeletal Diseases

[ ] 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
This study will evaluate the effectiveness of a new resorbable collagen membrane used in guided bone regeneration (GBR) procedures. GBR is a surgical technique that helps rebuild bone in the jaws when there is not enough bone to place dental implants. A membrane is placed to protect the healing area and eventually a grafting material, allowing new bone to form. Traditional non-resorbable membranes require a second surgery for removal and carry higher risks of complications. Resorbable collagen membranes, on the other hand, naturally dissolve and may reduce these problems. The main aim of the study is to measure how much horizontal bone gain is achieved after GBR. Secondary aims include assessing the biocompatibility of the collagen membrane, checking bone stability around the implants with radiographs, and recording patient discomfort (pain, swelling, bleeding) after surgery.

Who can participate?
Patients aged 18 years and over who are missing teeth in the upper or lower jaw and do not have enough bone volume for implant placement

What does the study involve?
All patients will receive GBR using the new collagen membrane together with bovine bone particulated substitute material.

What are the possible benefits and risks of participating?
Main risks include flap dehiscence, exposure of the collagen barrier membrane, graft infection, and loss of implant stability. Benefits include ideal augmentation of the missing bone allowing peri-implant hard and soft tissue stability, by using a resorbable collagen membrane that does not require a second-stage intervention to remove it. Furthermore, with this kind of membrane, the risk of dehiscence/exposures is reduced, and the clinical handling is increased. Surgical time may also be reduced.

Where is the study run from?
Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico (Italy)

When is the study starting and how long is it expected to run for?
January 2016 to June 2025

Who is funding the study?
Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico (Italy)

Who is the main contact?
Dr Pier Paolo Poli, pierpaolo.poli@unimi.it

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Type(s)
Public, Scientific

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
In partially edentulous patients with maxillary or mandibular atrophies requiring implant placement, are collagen porcine pericardium membranes effective in horizontal guided bone regeneration procedure?

Acronym
TGEN

Study objectives
This prospective cohort study aimed to evaluate the clinical, radiographic and patient-centered outcomes of horizontal guided bone regeneration using a native, non–cross-linked resorbable porcine pericardium membrane fixed with titanium pins, in conjunction with simultaneous implant placement.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/07/2016, Comitato Etico Territoriale Lombardia 3 (via Francesco Sforza 28, Milan, 20122, Italy; +39 (0)2 55032982; giuliana.fusetti@policlinico.mi.it), ref: 448_2016bis

Study design
Observational prospective single-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
University/medical school/dental school

Study type(s)
Safety, 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
Mandibular and maxillary alveolar bone atrophies requiring bone augmentation

Interventions

Implant placement (T0):
Before the surgical procedure, hydrocolloid impressions are taken and poured with dental stone. A surgical guide implemented with a diagnostic wax-up of the crown to be replaced is manufactured with a ~2-mm-diameter guiding hole to achieve a correct prosthetically-driven implant placement. A cone-beam computed tomography (CBCT) scan is acquired to evaluate the edentulous site and verify the feasibility of an implant placement with simultaneous GBR according to the prosthetic waxing. The day of surgery, under local anaesthesia, a crestal incision followed by oblique releasing incisions are made to allow for a wide flap basis as well as sufficient access to the defective ridge area. The flaps are carefully raised using tissue elevators. The bone ridge is examined and any soft tissues remaining on the crest are meticulously removed with a surgical curette. At this point, implant(s) are placed according to the manufacturer's instructions in a prosthetically ideal position with the aid of the surgical stent. The cortical bone plate is perforated at numerous locations using a round bur in order to allow access of the cells from the bone and bone marrow to the area of regeneration. Subsequently, granules of cancellous deproteinized bovine bone mineral (DBBM) (Bio-Oss, Geistlich AG, Wolhusen, Switzerland), are placed in the defect area. A collagenous resorbable membrane (T-Gen, HYUNDAI BIOLAND Co., Ltd, 162, Gwahaksaneop 3-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, 28125, Republic of Korea) is shaped and trimmed to cover the graft and to extend 2–3 mm onto the intact bony borders of the defect. The membrane is hydrated and the fixation is accomplished using fixation pins (MC Bio S.r.l., Como, Italy). Releasing incisions are made through the periosteum at the base of the flap in order to allow tension-free adaptation of the wound margins. Horizontal mattress sutures as well as single interrupted sutures (CV-5 and CV-7, Gore-Tex ; W.L. Gore & Associates, Flagstaff, AZ, USA) are placed to achieve healing by primary intention.

Re-entry surgery (T1):
Six months following augmentation, re-entry surgery is carried out to uncover the implants and connect the healing abutments. Under local anaesthesia, crestal incisions as well as releasing incisions along the same lines as the ones during augmentation surgery are performed. Mucoperiosteal flaps are raised in order to visualize the augmented bone volume.
Healing abutments are screwed to the implants and the flaps are sutured. Additional peri-implant plastic surgery procedures (connective tissue grafts or free gingival grafts) are performed when needed in order to have at least 2 mm of attached keratinized mucosa. The prosthetic phases start upon healing of the soft tissues, and definitive screw-retained prostheses are finally delivered.

Intervention Type

Procedure/Surgery

Primary outcome measure

Horizontal bone gain assessed clinically by means of two intraoperative measurements: during the GBR surgery (T0) and subsequently at the implant uncovering (T1) after 6 months of healing. The measurements of the entire buccal-lingual/palatal ridge thickness is performed with a Castroviejo surgical caliper 2 mm apically from the top of the crest and rounded to the nearest mm at the centre of the implant site. The remaining teeth adjacent to the defect and the surgical guide are used as reference points, in order to repeat the exact mesio-distal measurement position during the second examinations at T1. Furthermore, at T1 the BBT is measured with a periodontal probe (PCP-UNC 15, Hu-Friedy, Chicago, Illinois, USA) rounded to the nearest 0.5 mm at the centre of the implant site.

Secondary outcome measures
1. The clinical evaluation of the biocompatibility of the CM is performed throughout the healing period from T0 to T1. During the 6-month healing period, the complication rate is assessed to evaluate the biocompatibility of the CM in relation to the post-operative complications, namely flap dehiscences, membrane exposures, presence of infections and fistulae with pus discharge amongst others. At T1, the macroscopic appearance of the reconstructed site is assessed intra-surgically to evaluate graft integration and detect any remnants of the CM or its complete resorption due to the degradation phases.
2. With respect to patient-reported outcome measures (PROMs), the evaluation of the postoperative morbidity is carried out by means of a specific form. Indeed, a questionnaire about the postoperative course from 5 to 6 h postoperatively (before intake of the prescribed analgesics) and until the third postoperative day is filled by the patients. A 100-mm visual analogue scales (VAS) with extreme endpoints is used to record the following:
2.1. The intensity of postoperative pain on the day of surgery, 1, 2 and 3 days after surgery (no and extreme pain)
2.2. The severity of swelling on the day of surgery, 1, 2 and 3 days after surgery (no and severe swelling)
2.3. The severity of bleeding from the wound on the day of surgery, 1, 2 and 3 days after surgery (no and severe bleeding)
Furthermore, on the day of the surgery, the patients scored their satisfaction with their perception of the operation (not and very unpleasant). The questionnaires are collected at the time of the first postoperative recall 7 days after T0. By means of a ruler, the VAS scores are measured and rounded off to the nearest mm.
3. For the evaluation of the mesial and distal marginal bone loss, intraoral digital radiographs are taken using the long-cone paralleling technique with the central beam directed to the alveolar crest. Periapical radiographs are taken at the delivery of the prosthesis and after 1 year of prosthetic loading (T2). The mesial and distal MBL, i.e. the distance between the top of the implant shoulder and the first visible bone-to-implant contact, are measured at the mesial and distal aspect with a 10–15 x magnification using an image analysis program (ImageJ v 1.49, NIH, Bethesda, MA, USA). The length of the implant is used as known measure for the calibration and determination of the exact magnification and distortion of the images. All measurements are performed by two examiners to the nearest 0.1 mm. In case of disagreement, the evaluation is re-done and results discussed until an agreement is found.
4. To evaluate soft tissue health, peri-implant probing pocket depth (PPD), keratinized mucosa width (KMW), and bleeding on probing (BoP) are registered at T2 with a periodontal probe (PCP-UNC 15, Hu-Friedy, Chicago, Illinois, USA). PPD is measured at six sites around each implant; KMW defined as the apico-coronal distance from the mucogingival junction to the gingival margin is measured at the zenith of each prosthetic crown; BoP is recorded as present or absent at each site.

Overall study start date
01/01/2016

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Male and non-pregnant/lactating female patients aged 18 years or older
2. Presence of mono-edentulism or partial edentulism up to two adjacent teeth located in the

upper or in the lower jaw
3. Residual horizontal ridge thickness <6 mm requiring bone augmentation
4. Primary stability of the placed implant
5. Loss/extraction of teeth occurred at least 2 months before the date of the supposed GBR, with healed soft tissues at the implant site
6. American Society of Anaesthesiologists (ASA) physical status classification 1 or 2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Presenting with full mouth plaque and bleeding scores ≥25%
2. Smoking habits (>10 cigarettes/day)
3. Uncontrolled diabetes
4. In therapy with antiresorptive agents

Date of first enrolment
01/05/2017

Date of final enrolment
01/05/2022

Locations

Countries of recruitment
Italy

Study participating centre
Implant Centre for Edentulism and Jawbone Atrophies, Maxillofacial Surgery and Odontostomatology Unit, Fondazione IRCCS Cà Granda Maggiore Policlinico Hospital, Milan, Italy
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Sponsor information

Organisation
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.policlinico.mi.it/

ROR
https://ror.org/016zn0y21

Funder(s)

Funder type
Charity

Funder Name
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Alternative Name(s)
Policlinico of Mila, Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico, "Ca' Granda Ospedale Maggiore Policlinico" Foundation, Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
Italy

Results and Publications

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

Intention to publish date
01/10/2025

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon request form (Dr Pier Paolo Poli, pierpaolo.poli@unimi.it)

IPD sharing plan summary
Available on request