

A surgical gum-grafting procedure used to cover exposed tooth roots and treat receding gums

Submission date 11/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/10/2026	Condition category Oral Health	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Gingival recession occurs when the gums move away from their normal position, exposing the roots of the teeth. This can cause tooth sensitivity, aesthetic concerns, and difficulties with oral hygiene. A common treatment involves surgically repositioning the gums and using connective tissue taken from the patient's palate. However, this requires an additional surgical wound. Human acellular dermal matrix, a specially processed tissue graft, may provide an alternative without the need for additional tissue harvesting.

This study aims to compare the effectiveness of these two grafting materials when combined with gum repositioning surgery. The main objective is to determine whether the human acellular dermal matrix provides comparable root coverage to the patient's own connective tissue graft after 12 months.

Who can participate?

Adults aged 18–60 years with gum recession on both sides of the same dental arch may participate. Participants must be generally healthy, non-smokers, and have good oral hygiene without active periodontal disease.

What does the study involve?

Each participant receives two different surgical treatments during the same appointment. One side is treated using a coronally advanced flap combined with human acellular dermal matrix, while the opposite side receives the same surgical procedure combined with a connective tissue graft taken from the patient's palate. The treatment assigned to each side is determined randomly.

Participants undergo clinical examinations, digital dental scans, and cone-beam CT imaging before surgery and at 6 and 12 months after treatment. These assessments measure root coverage, gum thickness, and changes in gum tissue volume.

What are the possible benefits and risks of participating?

Both treatments aim to cover exposed tooth roots and improve gum conditions. The dermal

matrix may reduce the need for tissue harvesting from the palate. Possible risks include postoperative pain, swelling, bleeding, and discomfort associated with oral surgery. Cone-beam CT examinations also involve exposure to ionizing radiation.

Where is the study run from?

Department of Periodontology, Peking University School and Hospital of Stomatology, Beijing, China.

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

February 2023 to May 2026

Who is funding the study?

1. Capital's Funds for Health Improvement and Research, China.
2. Natural Science Foundation of Beijing Municipality, China.

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Capital's Funds for Health Improvement and Research grant

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L2602114

Study information

Scientific Title

Treatments for Cairo recession type 1 gingival recessions with coronally advanced flap and human acellular dermal matrix: a 1-year split-mouth randomized clinical trial with digital assessment

Study objectives

The primary objective of this randomized split-mouth clinical trial is to evaluate whether coronally advanced flap (CAF) combined with human acellular dermal matrix (HADM) is non-inferior to CAF combined with autogenous connective tissue graft (CTG) in terms of gingival recession reduction at 12 months in patients with Cairo recession type 1 (RT1) gingival recessions, using a non-inferiority margin of 0.50 mm.

The secondary objectives are to compare clinical and digital outcomes between the two treatments at 6 and 12 months, including root coverage, keratinized tissue width, gingival thickness, three-dimensional root surface area coverage, and soft-tissue volume changes.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/05/2020, Biomedical Ethics Committee of Peking University School and Hospital of Stomatology (No. 22, Zhongguancun South Avenue, Beijing, 100081, China; +86 10 82195759; keyanchuethics@163.com), ref: PKUSSIRB-202054029

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Gingival recession

Interventions

This study used a randomized split-mouth design. A computer-generated random sequence was used to determine which side in each participant received a coronally advanced flap combined with human acellular dermal matrix (CAF + HADM) and which side received a coronally advanced flap combined with an autogenous connective tissue graft (CAF + CTG). Sealed envelopes were used to implement the treatment allocation.

Intervention group (CAF + HADM):

Gingival recession defects were treated using a CAF combined with HADM (Kexing Biological Engineering Co., Ltd., Nanchang, China).

Control group (CAF + CTG):

Gingival recession defects were treated using CAF combined with an CTG, prepared using an extraoral de-epithelialization technique.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Recession reduction (RR) measured using a Williams periodontal probe to calculate the change in midfacial gingival recession depth (mm) at baseline, 6 months postoperatively, and 12 months postoperatively

Key secondary outcome(s)

Completion date

19/05/2026

Eligibility

Key inclusion criteria

1. Patients aged 18–60 years
2. Bilateral Cairo recession type 1 (RT1) gingival recession defects involving anterior teeth or premolars within the same dental arch
3. Systemically healthy individuals
4. Non-smokers
5. No active periodontitis
6. Good oral hygiene, defined as a full-mouth plaque score <20% and bleeding on probing at <20% of examined sites

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

All

Total final enrolment

17

Key exclusion criteria

1. Uncontrolled periodontitis
2. Systemic diseases or tumors associated with periodontal status

3. Use of medications that may affect wound healing or bleeding
4. An unidentifiable cemento-enamel junction (CEJ) at the proposed study sites
5. Abnormal frenal or muscle attachments at the study sites

Date of first enrolment

03/02/2023

Date of final enrolment

19/05/2025

Locations

Countries of recruitment

China

Sponsor information

Organisation

Peking University School and Hospital of Stomatology

ROR

<https://ror.org/00s2xkh70>

Funder(s)

Funder type**Funder Name**

Capital's Funds for Health Improvement and Research

Funder Name

Natural Science Foundation of Beijing Municipality

Alternative Name(s)

Beijing Municipal Natural Science Foundation, Beijing Natural Science Foundation, Natural Science Foundation of Beijing,

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			12/10/2026	No	Yes