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Healing of palatal grafts with and without epithelium

Submission date	Recruitment status	[X] Prospectively registered
13/04/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/04/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/04/2024	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and Study Aims
Gingival (gum) grafting surgery, also known as periodontal plastic surgery, is a common and effective procedure often used to treat receding gums or thin gums and other conditions around a tooth, a dental implant, or a space where a tooth is missing. The gum graft is typically taken from the roof of the mouth (palate). One thing that is thought to affect the healing of the graft after it is placed is de-epithelialization, which is to remove the epithelial cell layer from the graft before placement. The purpose of this study is to evaluate how the healing of gingival grafts is affected depending on whether or not the grafts are de-epithelialized before placement.

Who can participate?
Healthy volunteers aged 21-38 years old

What does the study involve?
This study involves detaching a small piece of gingival tissue from each side of the roof of the mouth and then placing it back into the mouth as a graft. The piece of tissue from one side will be de-epithelialized before it is placed back, and the other one will not. Various aspects of wound healing, for example, swelling and redness in the wound area, will be assessed at the postoperative visits.

What are the possible benefits and risks of participating?
There are no benefits to participation. Possible risks include minor discomfort from receiving local anesthesia and the potential post-operative discomfort and/or pain at the wound area; bleeding from the wound site; mild localized swelling; rarely, infection after the procedure; very rarely, may experience transient numbness or altered sensation at the roof of the mouth; rarely, side effects of the pain pills; rarely, allergic reactions to the study materials and drugs.

Where is the study run from?
The Ohio State University College of Dentistry

When is the study starting and how long is it expected to run for?
January 2024 to June 2025

Who is funding the study?
Intramural funding at The Ohio State University College of Dentistry

Who is the main contact?
Dimitris Tatakis, tatakis.1@osu.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2024H0052

Study information

Scientific Title
The effects of de-epithelialization on palatal gingival graft healing

Study objectives
Removal of epithelium affects the healing of palatal gingival grafts

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/04/2024, Ohio State Biomedical Sciences IRB (130C Mount Hall 1050 Carmack Road, Columbus, Ohio, 43210-1002, United States of America; +1 614-292-1582; irbinfo@osu.edu), ref: 2024H0052

Study design
Longitudinal randomized split-mouth study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healing of gingival grafts

Interventions
The study investigates the healing of palatal grafts that have epithelium or are de-epithelialized.

Participants will be randomised via the side of the palate using the sealed envelope process. Following the harvesting of two free gingival grafts of standardized size from opposite sides of the palate and the subsequent placement of the grafts onto ipsilateral standardized palatal recipient sites (each recipient site being the donor site of the ipsilaterally-placed graft), clinical and patient-centered outcomes will be assessed on postoperative Days 2, 3, 7, and 14. One of the grafts will be harvested and left intact before being placed onto the recipient bed and the other graft will be placed onto its designated recipient bed after being de-epithelialized.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Changes in grafted tissue and wound dimensions measured using photographic image analysis at 2, 3, 7, and 14 days

Key secondary outcome(s))
1. Soft tissue swelling measured using intraoral digital scanning on postoperative days 2, 3, 7, and 14
2. Wound area temperature measured using an infrared temperature camera on postoperative days 2, 3, 7, and 14
3. Wound healing scores measured using hyperspectral imaging (HSI) scoring on postoperative days 2, 3, 7, and 14
4. Color match, wound exudate biomarkers measured using clinical images (photographs) at postoperative days 2, 3, 7, and 14
5. Patient-reported outcomes measured using custom and Oral Health Impact Profile-14 (OHIP-14) questionnaires at baseline and on postoperative days 2, 3, 7, and 14

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Aged between 21-38 years old
2. No systemic diseases; no coagulation disorders; no medications affecting wound healing or periodontal tissues in the previous 6 months; no pregnancy or lactation; no allergy or other contraindication to study medications
3. No tobacco or marijuana use; exhaled air carbon monoxide <8 ppm

4. Absence of untreated caries lesions, extensive caries history, untreated periodontitis, history of cleft palate, inadequate endodontic therapy or tooth mobility >1 on maxillary teeth; full-mouth plaque score [FMPS] and full-mouth bleeding score [FMBS] ≤ 20% at study entry
5. No previous periodontal surgery on the palatal masticatory mucosa (donor area)
6. Adequate apico-coronal space (palatal vault height and upper arch shape) and mouth opening for required wound size and instrument use
7. Ability to tolerate maxillary impression making and use of palatal template, i.e., lack of strong gag reflex
8. No contraindication to receiving any study medications (anesthetics and analgesics), or gingival surgery

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
38 years

Sex
All

Key exclusion criteria
1. Tobacco or marijuana user, or have used any tobacco products in the last 2 years
2. Unable or unwilling to refrain from drinking alcohol during the two weeks of the study
3. Unable or unwilling to refrain from consuming caffeine (in any form) for 3 hours before any of the study visits
4. Unable or unwilling to refrain from exercising for 3 hours before any of the study visits
5. Diagnosed with an uncontrolled systemic disease, such as high blood pressure (hypertension), seizures (epilepsy), high blood sugar (diabetes)
6. Disease or medication that affects blood clotting
7. History of systemic disease affecting healing, such as diabetes
8. Obese
9. Taking medications that can affect the gum tissues
10. Taking medications that can affect wound healing
11. Pregnant, or lactating, or using contraceptive medications
12. Allergic to any of the materials (impression materials, acrylic plastic) or medications (topical or local dental anesthetic; analgesic medication; cyanoacrylate) used in the study
13. Untreated periodontitis (gum) disease
14. Upper (maxillary) teeth that are loose (mobile), or have untreated cavities (caries), or poor or questionable root canal treatment
15. Inadequate oral hygiene or inflamed or swollen gums
16. History of surgery on the roof of the mouth
17. Conditions or diseases affecting the roof of your mouth

18. Use of any removable oral appliances for the upper jaw
19. Gag easily
20. The shape (steepness) of the roof of the mouth could prevent study procedures
21. Contraindication to receiving study medications or procedures
22. Unable or unwilling to adhere to the study visit schedule
23. Unable or unwilling to provide written informed consent

Date of first enrolment
25/04/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United States of America

Study participating centre
The Ohio State University College of Dentistry
305 W. 12th Avenue
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Sponsor information

Organisation
The Ohio State University

ROR
https://ror.org/00rs6vg23

Funder(s)

Funder type
University/education

Funder Name
Ohio State University

Alternative Name(s)

The Ohio State University, Ohio State, Ohio Agricultural and Mechanical College, OSU, tOSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dimitris Tatakis (tatakis.1@osu.edu)

IPD sharing plan summary
Available on request