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The effect of two oral gels on contour and durability of gum tissue

Submission date
22/12/2021

Recruitment status
No longer recruiting

Registration date
22/12/2021

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Aging can have a profound impact on the gingiva (gums) and can result in a thinning of the epithelial component of the gingiva leading to changes in the appearance of contour and coloration. Importantly, this normal oral gingival aging process can predispose consumers to gingival recession, with the majority of older individuals experiencing gingival recession. Gingival recession in healthy patients does not generally have health implications for the teeth and gingiva, but it can lead to significant cosmetic appearance consequences.
Topical retinoids represent an important class of molecules for the treatment of aged skin (and gums). In addition, peptides have been shown to have clinical benefits that include reduction in fine lines and wrinkles when used in conjunction with retinoids.
The intent of the current study is to understand whether daily oral gel application can delay the effects of aging in gingiva, specifically measuring contour and tissue height, as well as durability of keratinized surface of the gingiva at sites with age related recessed gingiva (not periodontitis related recessions) over a 2-year period in a population that is generally healthy (no underlying periodontal disease).

Who can participate?
Generally healthy adults with age related recessed gingiva.

What does the study involve?
Participants will be randomly assigned to either one of the two test groups (gels with different active concentrations) or the control group (placebo gel).
Participants are instructed to apply the test gel at home once daily in the evening after brushing their teeth on the gum tissue of up to two selected test teeth for the duration of the study (2 years). Test products will be returned at the end of the study. The study is designed to assess if the participants in the test group experience an improvement in contour and durability of their gum tissue.
Digital scans, assessments of gingival recession (gum tissue contour) and gingival abrasion (gum tissue resilience) are taken at baseline, months 6, 12, 18 and 24 visits.

What are the possible benefits and risks of participating?
Participation will help with the development of products that aim to improve oral health.

The study involves the daily use of an oral gel as part of a normal oral hygiene routine. The key actives in the test gels are Retinol and peptide. All other components are widely used in paste and other oral care products.
Retinol is a necessary ingredient in human body, which could get from dietary, supplementary food as well as other products like cosmetic. The amount of retinol to which participants are exposed to by the daily use of the test products still provides enough safety margin compared with the recommended retinol TUL (Tolerable Upper Intake Levels) level.
The Amino-peptide complex has been assessed in numerous pre-clinical safety evaluations (unpublished data) including acute oral toxicity, bacterial reverse mutation, acute eye irritation, acute dermal irritation and in a local tolerance study after repeated topical application. These studies demonstrate a favorable safety profile for use in this study.

Where is the study run from?
Christian-Albrechts-Universität zu Kiel
Klinik für Zahnerhaltungskunde und Parodontologie
Arnold-Heller-Str. 16, D-24105 Kiel, Germany

When is the study starting and how long is it expected to run for?
June 2021 to May 2024

Who is funding the study?
Procter and Gamble Company (USA)

Who is the main contact?
Prof. Dr. Christof Dörfer
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Clinical Protocol 2021041

Study information

Scientific Title
A 2-year clinical study to investigate the effect of two oral gels on the durability and contour of gingival tissue

Study objectives
The objective of this study is to evaluate the contour and durability of the gum tissue after once a day application of two oral gels with different active concentrations over a duration of 2 years. Gum tissue contour will be assessed based on measurements of gingival recession and the digital impressions; gum durability (abrasion of the stratum corneum) will be evaluated using the Danser index. In addition to that, hard and soft tissue safety will be assessed via oral examination and periodontal measurements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-center randomized controlled examiner-blind three-treatment parallel study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Prevention

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
Age related recessed oral gingiva

Interventions

Participants are stratified at baseline on age, right- or left-handed, number sites with recessions ≥1mm, and type of toothbrush used (manual/electric). Within these strata, participants are randomly assigned to either one of two test groups (gels with different active concentrations) or the control group (placebo gel).
Participants are instructed to apply the test gel at home once daily in the evening after brushing their teeth on the gum tissue of up to two selected test teeth for the duration of the study (2 years).
Digital scans, assessments of gingival recession and gingival abrasion (gum tissue resilience) are taken at baseline, months 6, 12, 18 and 24 visits.

Intervention Type
Other

Primary outcome measure
1. Gum tissue contour as measured by gingival recession at baseline, months 6, 12, 18 and 24 visits.
2. Gum tissue resilience as measured by gingival abrasion at baseline, months 6, 12, 18 and 24 visits.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
18/06/2021

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Give written informed consent;
2. Agree to be contacted for appointment reminders;
3. Be 18 to 65 years of age;
4. Be in good general health;
5. Have up to two test teeth with buccal gum recessions (1-5mm & present keratinized gingiva) which are not related to periodontal disease, periodontal treatment, malocclusion, use of orthodontic appliance or partial denture do not have class V restorations or root caries, not crowns, and are preferably in the maxillary arch;
6. Agree not to participate in any other clinical study for the duration of this study;
7. Agree to continue to use their current type of toothbrush and dentifrice for the study duration;
8. Agree not to add any other oral hygiene products, including whitening products, and not to change the rinse or interdental hygiene device(s) if they are currently using one until the study ends (regular use of CHX rinses are not allowed);
9. Agree to follow study procedures and to return for all scheduled clinical visits;
10. Agree to refrain from elective dentistry, including refraining from a dental prophylaxis any time within the 4 weeks prior to Months 6, 12, 18 and 24 visits and agree to report any dentistry received any time during the course of the study;
11. Agree to refrain from orthodontic treatment during the study duration.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
195

Key exclusion criteria
1. Participating in another oral care clinical study within the last 30 days;
2. Tobacco usage;
3. Having a disease, illness or condition that could be expected to interfere with examination procedures or might influence results or preclude the subject safely completing the study (e.g. AIDS, diabetes);
4. Presence or history of periodontal disease (at least 2 pockets 6mm in two quadrants);
5. Currently taking any drug that can cause gum overgrowth (i.e., Nifedipine, Hydantoin, Ciclosporin);
6. Bad oral hygiene;
7. Taking a vitamin A supplement or using retinoid dermal application such as a cosmetic product;
8. Allergy or sensitivity to dyes, benzyl alcohol, sunflower seed oil, BHA (Butylatedhydroxyanisole), Polysorbate 20;
9. Allergy or sensitivity to Vitamin A/retinol;
10. Any physical limitations that might preclude normal oral hygiene procedures;
11. Self-reported pregnancy or breast feeding;
12. Requiring any type of medication prior to dental procedures;
13. Major hard or soft tissue lesions or trauma or carious lesions requiring restorative treatment or actively in treatment for periodontitis;
14. Gingival recession that was a consequence of periodontal treatment or chronic periodontitis;
15. Having a dental prophylaxis any time within the 4 weeks prior to study initiation;
16. Actively in orthodontic treatment or having completed an orthodontic treatment any time within the 3 months prior to study initiation.

Date of first enrolment
24/01/2022

Date of final enrolment
14/03/2022

Locations

Countries of recruitment
Germany

Study participating centre
Christian-Albrechts-Universität zu Kiel, Klinik für Zahnerhaltungskunde und Parodontologie
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24105

Sponsor information

Organisation
Procter & Gamble (United States)

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Sponsor type
Industry

Website
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ROR
https://ror.org/04dkns738

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble

Alternative Name(s)
Procter & Gamble, PandG, The Procter & Gamble Company, P&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			16/06/2025	No	No