

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

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<b>Registration date</b> 22/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/06/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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  
Christof.Doerfer@uksh.de

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Christof Dörfer

**Contact details**

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## Additional identifiers

**Protocol serial number**

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

## **Study type(s)**

Prevention

## **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  $\geq 1$ mm, 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(s)**

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.

## **Key secondary outcome(s)**

There are no secondary outcome measures.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

Arnold-Heller-Strasse 16

Kiel

Germany

24105

## Sponsor information

**Organisation**

Procter & Gamble (United States)

**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 and G, 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

**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?
<a href="#">Basic results</a>			16/06/2025	No	No