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# A clinical study to evaluate how effective a dental strip containing an oxalate formulation is at reducing dentine hypersensitivity

**Submission date**
29/07/2016

**Recruitment status**
No longer recruiting

**Registration date**
02/08/2016

**Overall study status**
Completed

**Last Edited**
19/08/2020

**Condition category**
Oral Health

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

## Plain English summary of protocol

Background and study aims
Dentine hypersensitivity is a relatively common condition in which sufferers experience a short sharp pain that commonly is felt in response to hot and cold temperatures and sweet foods or drinks. Although the pain is brief, dentine hypersensitivity can affect quality of life in some sufferers, who may avoid coming into contact with cold air in winter, or avoid foods/drinks that are particularly hot, cold or sweet. Dentine hypersensitivity occurs when dentine (the tissue that forms the bulk of a tooth) is exposed to the mouth, usually following erosion of the tooth enamel (the protective coating of the tooth) or gum recession (when the gums pull back from the tooth surface, exposing the root surfaces of the teeth). Dentine is filled with lots of small holes (tubules), and when these holes are uncovered in the mouth dentine is usually sensitive. Treatments for dentine hypersensitivity, therefore, aim to block these tubules, as this has been shown to reduce the symptoms of dentine hypersensitivity. This two-part study aims to test a new formulation containing potassium oxalate, designed to treat dentine hypersensitivity.

Who can participate?
People aged 18 and over with dentine hypersensitivity

What does the study involve?
In part 1 of the study participants are randomly allocated to receive either the potassium oxalate containing product, or a toothpaste already shown to be effective at reducing the pain of dentine hypersensitivity. The sensitivity of the participants' teeth is measured in three ways before, during and at the end of 4 weeks of treatment with the products, and the results are used to determine how well the products work, and which product is better at reducing dentine hypersensitivity. A small number of those who take part in Part 1 of the study are asked to take part in Part 2. In Part 2, participants are asked to wear an oral appliance (like a removable brace) which holds two samples of dentine. The dentine samples are prepared and examined by scanning electron microscopy and only samples in which the holes (tubules) can be seen to be open are used in the study. Before being placed in the oral appliance one dentine sample is treated with potassium oxalate while the other sample is left untreated. Participants are asked to wear the appliance with the samples continually for 2 weeks, removing it only when they

brush their teeth. At the end of the study the samples are removed from the appliance and viewed under scanning electron microscopy again to determine if, and to what degree the potassium oxalate has blocked the tubules.

What are the possible benefits and risks of participating?
There is no direct, immediate benefit to participants from taking part in this study, but they will have helped the dental profession gain a better understanding of products aimed at reducing tooth sensitivity. It is not anticipated that participants will experience any side effects from the products to be used in this study, but there is always a possibility that a rare or previously unknown side effect may occur in somebody using a different product, trained dental staff are available in the Clinical Trials Unit. If potential participants know they have allergies to some dental product ingredients they will be asked to speak to a study dentist before participating in the study, and all participants will be provided with a list of study product ingredients prior to being enrolled in the study.

Where is the study run from?
Bristol Dental Hospital and School (UK)

When is the study starting and how long is it expected to run for?
July to October 2016

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

Who is the main contact?
Prof. Nicola West
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Nicola West

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# Additional identifiers

### Protocol serial number
2015075

# Study information

### Scientific Title
A clinical study to evaluate the efficacy of an oxalate strip on dentinal hypersensitivity

### Study objectives
An oxalate strip used together with a fluoride toothpaste will relieve the pain of dentine hypersensitivity more than an occluding toothpaste marketed for the treatment of dentine hypersensitivity, and the oxalate strip will reduce the flow rate of dentine fluid through dentine tubules.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
South West - Exeter National Research Ethics Committee, 18/04/2016, REC Ref: 16/SW/0050

### Study design
This is a two-part study, both parts are interventional and will be carried out in one centre.
Part 1: Single-centre clinical randomised controlled examiner-blind parallel study
Part 2: Single-centre randomised placebo-controlled double-blind split-mouth study in volunteers recruited from Part 1

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Dentine hypersensitivity

### Interventions
Part 1 (clinical study)
Adult participants who report dentine hypersensitivity will be recruited to the study. At screening, participants who have given informed consent will be assessed clinically for dentine hypersensitivity, and basic information about their gingival biotype, dental erosion, gingival recession, and gingival health will be recorded. Participants with up to 4 sensitive teeth will be enrolled into the study.

Participants that are enrolled will be given an acclimatisation fluoride toothpaste to use at home instead of their regular toothpaste from screening until the baseline study visit.

At the baseline study visit all participants will be asked to complete a questionnaire about their perceived dentine hypersensitivity. Participants will receive Visual Analogue Score (VAS) training

and their dentine hypersensitivity re-assessed using examiner scored Schiff and patient-reported VAS following cool air and tactile challenges. One or two teeth with Schiff score of 2 or 3, and tactile (Yeaple) score of 20g or greater will be chosen for ongoing study assessments.

Participants who continue to exhibit sensitivity to the level required will be randomised to receive one of two treatments: Oxalate strip + fluoride toothpaste (test), or an arginine occluding toothpaste (which also contains fluoride) (positive control). Participants randomised to the (test) oxalate strip will be shown how to apply it, and will apply it themselves under supervision of the study staff at the baseline visit, and then brush with their fluoride toothpaste. Participants randomised to the occluding toothpaste (positive control) will be asked to brush with this toothpaste under supervision at the baseline visit.

Following the baseline visit, participants will be asked to brush at home with their allocated toothpastes twice a day throughout the treatment period (total of 4 weeks). At the end of week 1, at home, participants randomised to the (test) oxalate strip will be asked to apply a strip to their selected and previously treated 1 or 2 sensitive teeth in the same way as they applied the strip under supervision at the baseline study visit. Participants randomised to the arginine occluding (positive control) toothpaste will be asked to rub this toothpaste on their teeth using the instructions supplied.

After the second week of study treatment at home participants will be asked to return to the study site, where they will be asked to complete a questionnaire about their perceived dentine hypersensitivity, the sensitivity of the teeth selected for the study will be determined by examiner schiff and patient-reported VAS following cool air and tactile stimulation. An oral exam will also be undertaken. Participants randomised to the oxalate strip (test) will be asked to apply this to their previously treated sensitive teeth at the study site, and participants randomised to the arginine occluding (positive control) toothpaste will be asked to apply this to their senstivite teeth at the study site. Following this visit, participants will be asked to continue using their study products at home as instructed until their next (final) visit.

At the final visit after a total of 4 weeks of treatment with study products participants will return to the study site where they will be asked to complete a questionnaire about their perceived dentine hypersensitivity. The sensitivity of the teeth selected for the study will be determined by examiner schiff and patient-reported VAS following cool air and tactile stimulation. An oral exam will also be undertaken.

Part 2
Participants who enrol in part 1 of this study will be invited to also take part in part 2 of the study. Those who agree to take part and give informed consent will attend a screening visit in which their medical history taken for part 1 of the study will be reviewed and an impression of their upper teeth and palate will be taken in order for an intra-oral appliance to be constructed. Participants who meet the study criteria will be given a standard fluoride toothpaste and toothbrush to use at home twice a day until the study baseline visit. At the baseline visit each participant will receive their intra-oral appliance fitted with two dentine samples, one of which that has been pre-treated with potassium oxalate, and the other of which that has received no treatment. Participants will also be asked to provide a 5ml sample of saliva. Participants will be asked to wear the appliance containing the dentine samples continually for a period of 2 weeks, only removing it when they clean their own teeth twice a day with the standard fluoride toothpaste and toothbrush provided. The appliance can also be cleaned at this time with water only.

At the final study visit after wearing the appliance for 14 days continuously, participants will return their appliance containing the dentine samples, and be given a full oral soft tissue exam to conclude their study participation.

### Intervention Type
Mixed

### Primary outcome(s)
Part 1:
Dentine hypersensitivity as measured by examiner reported Schiff and patient-reported VAS in response to cool air and tactile stimuli. Measured at baseline, after 2 weeks, after 4 weeks

Part 2:
Tubule occlusion score as determined by assessment of scanning electron microscope images. Measured at baseline and after 2 weeks

### Key secondary outcome(s))
Part 1:
Participants' perceived dentine hypersensitivity as determined by questionnaire. Measured at baseline, after 2 weeks, after 4 weeks

### Completion date
31/10/2016

## Eligibility

### Key inclusion criteria
Both part 1 and part 2:
1. At least 18 years of age
2. In good general health
3. Able to follow study procedures
4. Have at least one tooth with a Schiff sensitivity score of 2 in response to a cool air challenge

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment

### Key exclusion criteria
1. Severe periodontal disease
2. Active treatment for periodontitis
3. Any medical condition requiring pre-medication prior to dental procedures
4. Any disease or condition that might interfere with the participant completing the study safely
5. Fixed orthodontic appliances
6. A history of kidney stones
7. Self-reported pregnancy or nursing
8. Daily doses of medication that interfere with pain perception such as anti-inflammatory drugs, anti-depressants, sedatives, antihistamines
9. Use of desensitising toothpastes within the 3 months prior to the screening visit
10. Allergy to ingredients in commercial dental products, such as potassium oxalate, potassium sorbate
11. Analgesia within the 8 hours prior to screening

### Date of first enrolment
07/07/2016

### Date of final enrolment
30/09/2016

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Bristol Dental Hospital and School**
Clinical Trials Unit
Lower Maudlin Street
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United Kingdom
BS1 2LY

## Sponsor information

### Organisation
The Proctor and Gamble Company (USA)

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

# Funder(s)

**Funder type**
Industry

**Funder Name**
The Proctor and Gamble Company (USA)

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2019 | 03/06/2019 | Yes | No |
| Results article | results | 01/09/2020 | 19/08/2020 | Yes | No |
| Abstract results | | 26/07/2018 | | No | No |
| HRA research summary | | | 28/06/2023 | No | No |