

# Perforated punctal plug as an alternative to the three snip punctoplasty for the treatment of acquired lacrimal punctum stenosis

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<b>Registration date</b> 12/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/09/2018	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Acquired punctal stenosis is a condition whereby the hole that drains the tears, the punctum, gets blocked leading to watery eyes. This can have a significant impact on someone's quality of life, like difficulties in performing everyday activities and temporary impairment of vision. There are a number of treatment options available to open up the punctum and drain the tears. The conventional treatment for this condition is a three-snip punctoplasty, which involves having a small operation to surgically enlarge the punctum. This is the procedure that is routinely offered to patients at our hospital. More recently, a "plug" has been developed that stretches the punctum. It is placed in the punctum and stays there for two months and is then removed. The plug is safe and is licensed for this use. Most people are not aware of it when it is in place. The advantage of the plug is that it does not involve cutting open the punctum, i.e. it avoids having an operation, so it is a smaller procedure and is less invasive. It is also reversible and does not preclude having the operation at a later stage. The aim of this research study is to compare the two treatment options to assess whether the perforated punctal plugs and three-snip procedures are similarly effective. We will assess the outcome of each in terms of impact on quality of life as well amount of watering after procedures.

### Who can participate?

Adults aged 18 and older who have acquired punctal stenosis of the lower eyelid.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive the plug treatment. The plugs are removed after two months. Those in the second group receive the 3-snip procedure. All participants attend a follow up appointment at six months and receive a telephone call after 12 months to assess the severity of participant's watery eyes.

### What are the possible benefits and risks of participating?

There are no direct benefits with participating. Those in the punctal plug group require a extra follow-up visit to the clinic to remove the plug. Participants receive a follow up telephone one year after the procedure to see if there is any illness or discomfort during the study.

Where is the study run from?  
Western Eye Hospital (UK)

When is the study starting and how long is it expected to run for?  
June 2014 to January 2020

Who is funding the study?  
The British Oculoplastic Surgery Society (BOPSS) (UK)

Who is the main contact?  
Dr Jeremy Hoffman  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
35158

## Study information

**Scientific Title**  
Perforated Punctal Plug as an alternative to the three snip punctoplasty for the treatment of acquired lacrimal punctum stenosis: the POPPY study

**Study objectives**  
The aim of this study is to determine if perforated punctal plugs are an acceptable alternative to 3-snip punctoplasty in the treatment of acquired punctal stenosis.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

London - Central Research Ethics Committee, 20/07/2017, ref: 17/LO/1003

## **Study design**

Randomised; Interventional; Design type: Treatment, Diagnosis, Device, Imaging, Surgery

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Specialty: Ophthalmology, Primary sub-specialty: Other; UKCRC code/ Disease: Eye/ Other disorders of eye and adnexa

## **Interventions**

Randomisation is computer generated sequential binary randomisation in blocks of 10.

### **Punctal plugs treatment arm:**

Perforated punctal plugs, coated with a thin layer of polyvinylpyrrolidone (PVP) silicone (FCI Ophthalmics), are available as 0.7mm and 0.9mm devices. Since the puncta they are used in are by definition stenosed, the 0.7mm size is suitable in most cases. These are inserted under topical anaesthesia (0.5% proxymetacaine) or local anaesthesia as described for 3-snip punctoplasty above. As in the 3-snip procedure, the first step is punctal dilatation; with the lower eyelid on lateral stretch, the punctum and proximal canaliculus is dilated with a Nettleship dilator. The PPP is inserted soon after dilatation. The inserter is held between the thumb and index finger, and the plug is orientated in the correct plane. The plug is introduced gently in a vertical and progressive manner. The plug is released from the inserter by depressing the inserter handle. Attention is given to the final position of the plug to achieve an optimal fit against the lid margin.

### **3-snip procedure:**

The 3-snip procedure, is performed as follows. Local anaesthetic (such as xylocaine 1% with 1:200,000 adrenaline) is injected inferior to the punctum (transcutaneously and/or transconjunctivally). With the lower eyelid on lateral stretch, the punctum and proximal canaliculus is dilated with a Nettleship dilator. A blade or fine scissors are used to make a vertical cut through the posterior aspect of the proximal canaliculus. The proximal horizontal portion of the canaliculus (less than one third of the length) is then opened using the blade / scissors. Finally, a small posterior lamellar triangle of conjunctiva and canaliculus is removed.

Treatment is a once-only surgical procedure. The plugs are removed at two-months. Each arm is reviewed in person at six months and then by telephone follow-up at 12 months.

## **Intervention Type**

Other

## **Primary outcome(s)**

Estimated number of times eye has watered in the past week, as assessed by questions 2 and 3 in the Imperial Watery Eye Quality of Life Questionnaire at baseline, 6 months and 12 months

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

1. Effect of watering on quality of life, assessed on an 11-point numerical rating scale as part of the watery eye quality of life questionnaire (Appendix 6), at 12 months post procedure; in the case of PPPs this will be 12 months post plug removal.
2. Slit lamp examination of punctum. A punctum size of Grade 3-5, as defined on the visual grading system by Kashkoui et al, (Appendix 4) will be considered successful
3. Slit lamp examination of tear meniscus. A tear meniscus greater than 0.3mm will be considered raised, a secondary measure of anatomical failure.
4. OCT of lacrimal punctum. There are not sufficient normative databases in the literature to use as a reference but we will compare figures pre- and post-operatively to assess the effect of the treatments and to assess the utility of OCT as a tool for analysing puncta

### **Completion date**

31/01/2020

## **Eligibility**

### **Key inclusion criteria**

1. Age  $\geq$  18 years (men and women)
2. Epiphora as a result of acquired punctal stenosis of lower lids
3. Full patency on lacrimal syringing
4. Willing to undergo a procedural intervention
5. Willing and able to give written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. History of congenital punctal stenosis
2. History of punctal stenosis associated with chemotherapy
3. Completely stenosed or occluded punctum
4. Abnormality on lacrimal syringing
5. Moderate or severe lower eyelid laxity or eyelid malposition
6. Use of eye drops, other than lubricants, within the past 3 months or planned in the study eye

during the course of the trial

7. Eyelid or ocular surgery within the past 3 months or planned surgery in the study eye, during the course of the trial

8. Planned chemotherapy during the course of the trial

9. Planned nasal or sinus surgery during the course of the trial

10. Any other condition or situation that, in the opinion of the investigator, may prevent the participant complying with the study or follow-up procedures

**Date of first enrolment**

04/09/2017

**Date of final enrolment**

31/01/2019

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Western Eye Hospital**

153-173 Marylebone Road

London

United Kingdom

NW1 5QH

## **Sponsor information**

**Organisation**

Imperial College Healthcare NHS Trust

**ROR**

<https://ror.org/056ffv270>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No