

# Nationwide survey of prosthetic eye users

<b>Submission date</b> 22/03/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/09/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Patients who wear an ocular prosthesis (also known as an artificial eye) often suffer with dry eye symptoms. Up to 90% will also complain of socket discharge, many on a daily basis. No literature exists on their quality of life post eye loss or adapting to monocular vision. There is little data in the field of artificial eye care. A nationwide study could provide the data on current artificial eye patients, ranging from reason for eye loss through to experience on wearing their ocular prosthesis and finally any change in quality of life following eye loss. The aim of this study is to compare patient comfort and satisfaction existing ocular prosthesis users and collate data on prosthetic eye users.

### Who can participate?

Adults aged 18 and older who wear a prosthetic eye attending any Eye Service.

### What does the study involve?

Participants are asked to fill out an anonymous questionnaire while waiting for an outpatient appointment. The questionnaire will ask about their experience of their ocular prosthesis and related care. There is no follow up required.

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

There are no benefits or risks with participating.

### Where is the study run from?

This study is being run by the Queen Victoria Hospital (UK) and takes place in any Eye service or National Health Service Maxillofacial Prosthetic Departments (UK).

### When is the study starting and how long is it expected to run for?

April 2017 to August 2019

### Who is funding the study?

1. Queen Victoria Hospital (UK)
2. Institute of Maxillofacial Prosthetists and Technologists (UK)

### Who is the main contact?

Dr Emma Worrell

# Contact information

## Type(s)

Scientific

## Contact name

Dr Emma Worrell

## Contact details

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# Additional identifiers

## Integrated Research Application System (IRAS)

218611

## Protocol serial number

IRAS No 218611

# Study information

## Scientific Title

A nationwide survey of prosthetic eye users: A collaborative study with all NHS ocular prosthetic service providers

## Study objectives

The aim of this study is to compare patient comfort and satisfaction existing ocular prosthesis users and collate data on prosthetic eye users.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

East of Scotland Research Ethics Service, 21/02/2017, ref: NRES 17/ES/0010

## Study design

Observational cross sectional study

## Primary study design

Observational

**Study type(s)**

Quality of life

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

Artificial eye users

**Interventions**

Participants are given anonymous questionnaires to fill out while they are waiting for their outpatient appointments. The questionnaires are available to patients in all eye services (Ocular /Corneoplastic/Ophthalmology) or National Health Service Maxillofacial Prosthetic Departments. The questionnaires will ask about their ocular prosthesis and related care. The study runs until May 2019 and there is no follow up required. Questionnaires are collected by the research team and entered on study databases.

**Intervention Type**

Device

**Primary outcome(s)**

1. Incidence of anophthalmia is analysed using participant questionnaires
2. Length of prosthetic eye use is analysed using a participant questionnaires
3. Length of ocular wear is analysed using participant questionnaires
4. Age of prosthesis is analysed using participant questionnaires
5. Cleaning regime is analysed using participant questionnaires
6. Lubricant use is analysed using participant questionnaires
7. Inflammation is analysed using participant questionnaires
8. Comfort is analysed using participant questionnaires
9. Discharge is analysed using participant questionnaires
10. Quality of life is analysed using participant questionnaires

**Key secondary outcome(s)**

There are no secondary outcome measures.

**Completion date**

01/08/2019

**Eligibility****Key inclusion criteria**

1. Patients wearing a prosthetic eye or cosmetic shell, attending any Eye Service (Ocular /Corneoplastic/Ophthalmology) or National Health Service Maxillofacial Prosthetic Departments.
2. Over 18 years of age

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

1185

**Key exclusion criteria**

1. Patients under the age of 18 years of age
2. Patients not wearing a prosthetic eye (e.g. purely an eye conformer)
3. Patients who are unable to give their own consent, under Mental Capacity Act (MCA) 2005

**Date of first enrolment**

07/07/2017

**Date of final enrolment**

31/05/2019

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Queen Victoria Hospital**

Holtye Road

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**Sponsor information****Organisation**

Queen Victoria Hospital

**ROR**

<https://ror.org/01ywpj09>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Queen Victoria Hospital

## Funder Name

Institute of Maxillofacial Prosthetists and Technologists

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The current 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="#">Results article</a>	comfort and satisfaction results	26/10/2020	23/09/2021	Yes	No
<a href="#">Results article</a>	demographics, comfort and satisfaction results	05/09/2020	23/09/2021	Yes	No
<a href="#">Results article</a>	maintenance, management and quality of life results	04/01/2021	23/09/2021	Yes	No
<a href="#">Results article</a>	visual function and quality of life results	01/03/2021	23/09/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No