Plan Overview

A Data Management Plan created using DMPonline

Title: Visual Performance and Optical Quality with the Rayner EMV Intraocular Lens

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Project abstract:

Cataract surgery involves the implantation of an Intraocular lens (IOL). A new type of IOL called an extended depth of focus (EDoFs) IOL has entered the market that increase a patients range of vision. The Rayner EMV IOL utilises spherical aberration to increase the range of focus. This new technology promises to resolve the issue of the blur circle that has plagued other such designs from their inception.

The research team at the University of Plymouth has a primary interest in the assessment of intraocular lenses both in-vivo and in-vitro. They have developed a unique approach to the evaluation of IOLs that blends both bench testing and the clinical assessment of IOL patients together. In summary this approach involves measuring a number of ocular characteristics (corneal spherical aberration, pupil size, IOL tilt, and IOL decentration) of patients who have been implanted with the IOL. Using these parameters, along with the actual power of the IOL implanted, model eyes can be created on the optical bench that are representative of each patients eye.

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Visual Performance and Optical Quality with the Rayner EMV Intraocular Lens

Data Collection

What data will you collect or create?

The project involves two visits following the implantation of the Rayner EMV intraocular lens: Visit 1 occuring 3-6 post implantation and visit 2 12-18 months post implantation.
The following data will be collected at each visit

1. General screening questionnaire will be completed where data on: age, gender, occupation, ethnicity, ocular history, medical and general health history will be collected
2. At each visit the following non-invasive visual function tests will be conducted:

- Monocular and binocular Unaided (UCVA) and Best Corrected Visual Acuity (BCVA) will be measured at 6 meters in LogMAR units.
- Subjective and objective refraction will be used to determine if there is any residual refractive error.
- Defocus curve profiles (visual acuity over imposed defocus) will be measured for each patient over a defocus range of +1.50D to -5.00D in 0.50D steps.
- Uncorrected and best distance corrected near acuity will be measured at 40cm using the near EDTRS chart
- Uncorrected and best distance corrected intermediate acuity will be measured at 80cm using the near EDTRS chart
- Contrast sensitivity with the Peli-Robson contrast sensitivity chart
- The subject will be given a subjective questionnaire that involves illustrations of dysphotropia in order to assess the type of dysphotopsia present at each visit
- Pupil size will be captured under photopic and mesopic conditions

1. In order to assess the ocular biometry and record features of the IOL, at each visit pentacam imaging will be conducted prior to and following instillation of Tropicamide 1% to dilate the pupil

- Abberometry will be conducted following the instillation of Tropicamide.
- At each visit the following subjective assessment tests will be given to the patient to complete:

The Visual satisfaction questionnaire will be used to determine the patient’s overall satisfaction with their vision
Near Assessment Visual Questionnaire (NAVQ) will be used to assess the patients satisfaction with their near and intermediate vision

How will the data be collected or created?

1. Non-invasive visual function tests

In-vivo visual function will be conducted using logMAR visual acuity charts following a full subjective and objective refraction. Contrast sensitivity will be collected using the Peli-Robson Contrast sensitivity chart and pupil size will be collected using a pupilometer.

1. Ocular biometry

A short term topical mydriatic tropicamide HCl (either 0.5% or 1%) will be used to dilate the pupils of both eyes. The eye drops are disposable single use applicators (Minims®, Bausch & Lomb, Kingston-Upon-Thames, UK). One drop of tropicamide will be instilled in both eyes. The duration of mydriasis with this eye drop is approximately 4 to 6 hours. Tropicamide is used routinely in general optometric practice and will have been instilled prior to cataract surgery
Pentacam imaging will be conducted prior to and following instillation of Tropicamide 1% to dilate the pupil
Abberometry will be conducted following the instillation of Tropicamide.

At each visit two validated questionnaires designed to asses the patients subjective perception of their vision.

Subjects will be asked to visit BMI Southend Hospital for the two visits. This hospital is the location where the implantation of the IOL took place.

Documentation and Metadata

What documentation and metadata will accompany the data?

All data will be anonymised and stored electronically using OneDrive and only accessed using password protected personal computers, in a document file that is also password protected. The output of data from ocular biometry devices will be exported as a combination of excel, CSV and image files. All data will be anonymised and stored electronically using OneDrive and only accessed using password protected personal computers, in a document file that is also password protected.

Paper Case Report files (CRFs) will be stored in a locked cabinet within the BMI Southend Hospital the principle investigators office.

Upon conclusion of the study, the paper CRFs will be scanned and the originals will be shredded. The electronic data from this project will then be stored on sharepoint for 10 years at the University of Plymouth according to their Information governance policies (https://www.plymouth.ac.uk/students-and-family/governance/information- governance/policies).

Ethics and Legal Compliance

How will you manage any ethical issues?

Ethics approval:

Data collection for the project will only start after successfully obtaining the ethical approval of the University of Plymouth Faculty of Health Ethics and integrity research committee.

Informed consent:

All patient participants will be given the study participant information sheet and informed consent about whether they would lie to participate in the project. Full written informed consent will be provided by signing, dating and initialing the consent form (paper or electronic), which will be witnessed by one of the research team. Any related paperwork will be stored in a locked cabinet at the BMI Southend Hospital

Anonymisation:

Participants in the project will be known by a unique study identification code to preserve anonymity.

Legal compliance:

Patients and researchers will be informed that in the unlikely event that any disclosure of safeguarding issues about themselves, a relatives, researchers or patients involved in the project, a referral to appropriate services/ organisation will be made.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

IP and copyright will be owned by the University of Plymouth.

Storage and Backup

How will the data be stored and backed up during the research?

Microsoft One Drive , which is governed and securely maintained by the University of Plymouth, will be used to preserve and analyse data. All related paper documents will be stored in a secure and lockable cabinet at the BMI hospital, upon conclusion of the project they will be scanned and stored within a University of Plymouth sharepoint folder owned by the principle investigator

How will you manage access and security?

Access to the databases will be password protected and limited to staff involved in the study and only for the purpose of quality control, audit or data analysis. The principle investigator will decide which users require read-only and editing access. Remote access will be via the University of Plymouth portal and follow the remote access guidelines set by the University. All members of the study are clinically qualified and registered Optometrists, Ophthalmologists or researchers who are bound by a code of conduct and data protection.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

This is research data involving human participants. As such it will be retained at the University of Plymouth for 10 years.

What is the long-term preservation plan for the dataset?

Raw data files and data collection sheets will be stored on OneDrive and paper case report files (CRFs) will be stored at the BMI Southend Hospital until completion of study. The CRFs will be scanned and then retained by the University of Plymouth for 10 years. The original paper copies will be destroyed.

Data Sharing

How will you share the data?

Researchers are encouraged to make their data publicly available as supporting material for published research findings through platforms such as the Open Science Framework

(OSF) platform. If data is shared with the wider scientific community then anonymised data will be made publicly accessible. Neither name nor information disclosing participant identity will be released or published without explicit consent to the disclosure. It is hoped that we will be able to publish at least some of the results by the end of 2024. Individual results will not be identified in the publications.

Participants will be recruited and assessed at the BMI Southend Hospital. Only anonymous data will be shared with the University of Plymouth.

Are any restrictions on data sharing required?

No restrictions

Responsibilities and Resources

Who will be responsible for data management?

The principle investigator (Phillip Buckhurst) will have overall responsibility for implementing the data management plan, data capture, quality, storage and initial archive. The faculty IT manager of the University of Plymouth will be responsible for ensuring the electronic file permissions have be correctly assigned, maintaining the OneDrive, recovery of data and for advising on other aspects of data storage and security. Staff involved in the project will be responsible for following data management procedures. The data management plan will be monitored in meetings with the project team.

What resources will you require to deliver your plan?

No additional resources are required