Validation of the SightSave contrast sensitivity application against standard logMAR contrast sensitivity charts

Validation of SightSave contrast sensitivity analyser (VASCA Study)

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Project summary

Purpose: To compare the visual acuity across a range of contrast levels using the SightSave app (SightSave Ltd, UK) and standard contrast sensitivity charts. **Patients and methods:** Ethical approval will be sought. A prospective comparison study of 50 eyes of patients on the waiting list for cataract surgery, will be tested before and after surgery. Subjects unable to read the chart letters will be excluded. Consent will be obtained prior to testing and a depression score administered. LogMAR Visual Acuity (VA) will be recorded at 4m using standard contrast sensitivity visual acuity charts at 1.25%, 5%, 10%, 25% and 100% contrast (Sussex Vision Ltd, UK) and using the SightSave app. The time taken to take each test will be recorded and a questionnaire using a 5-point scale assessing the ease of using each test will be recorded. LogMAR acuity at each level of contrast will be compared between the 2 tests using a Bland-Altman plot. **Expected results:** That there is close concordance between the 2 tests in terms of LogMAR VA at each level of contrast, the SightSave app is likely to be faster to complete and possible for most subjects to self-administer. **Discussion:** A positive result would validate the use of the SightSave test for determining contrast sensitivity tests, potentially for home use, demonstrating advantages in terms of self-administration and ease of use over formal chart testing.

Rationale & background information: In the UK permanent sight loss is being directly caused by delays in ophthalmic treatment in the NHS.i This has a life changing impact on patients and leads to spiralling costs relating to care. Eye health costs the UK £28 billion pounds per year (Deliotte, RNIB).

Our planned innovation is the SightSave app, a clinically valid digital eye test that measures contrast sensitivity vision on common digital devices such as smartphones. It is a fast and simple test that can be done from home. Our results are extremely promising showing high accuracy, and we wish to compare our test to a 'gold standard'.

Contrast sensitivity is the ability to distinguish objects that are increasingly faint against their background, across a range of size. It is different to the visual acuity test, which just measures the ability to recognise reducing letter sizes, at a single high contrast. It is a particularly good measure of the quality of vision, especially in situations of low light (e.g. driving at night). If you have good visual acuity but poor contrast sensitivity, your overall vision will be poor.

Contrast vision deteriorates before visual acuity in a range of diseases making contrast sensitivity a better test for detection and tracking (cataracts, glaucoma, age related macular degeneration and diabetic retinopathy). Contrast sensitivity is also affected by neural processing and is reduced in neurodegenerative diseases such as Parkinson disease, Alzheimer disease and disseminated sclerosis / retrobulbar neuritis syndromes. Contrast sensitivity tests can be used to track progression of these diseases.

Up to now routine testing of contrast sensitivity has not been effective as it is time consuming and difficult to control the lighting environment. There is a clear clinical need for improved and rapid contrast

sensitivity testing for those with eye and neurological diseases as well as an opportunity to deliver a test that more effectively measures quality of vision in the general population.

Smartphone screens can display fine changes in contrast resulting in a very sensitive test. Leveraging fast touchscreen means the test can be completed quickly. 'The test uses low contrast letter acuity across 12 different sizes resulting in a 'contrast sensitivity function. This increased level of accuracy coupled with more frequent home testing may result in early detection of problems and more effective disease and treatment tracking.

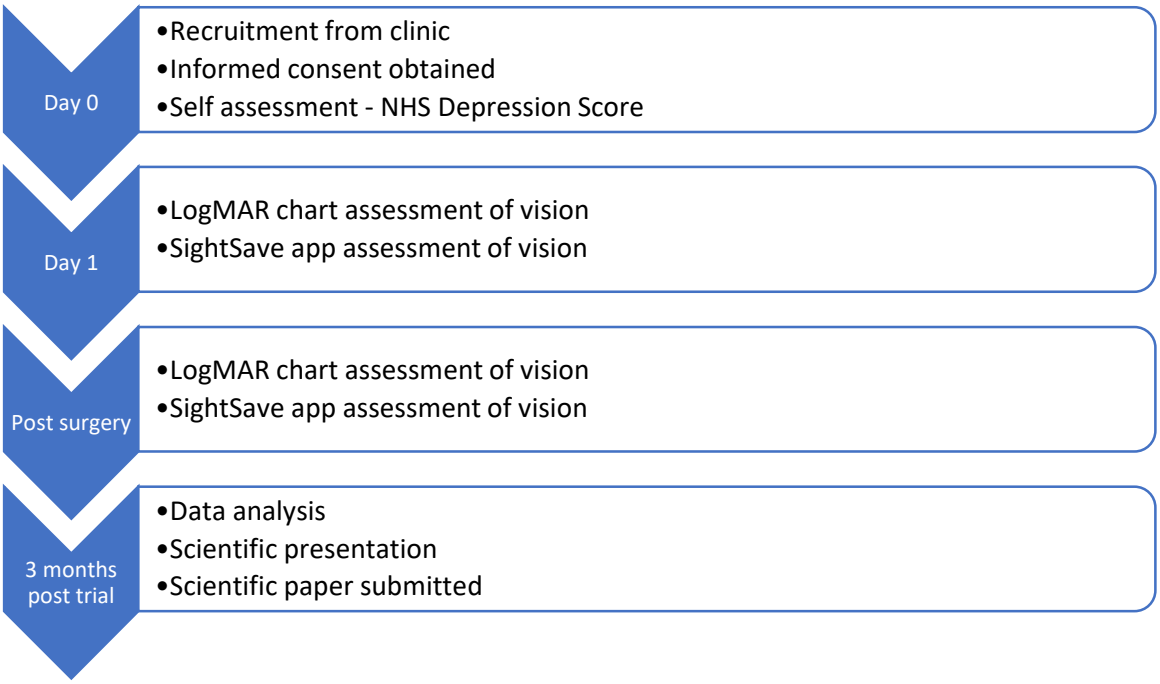
Study goals and objectives: The study goal is to compare compare the visual acuity across a range of contrast levels using the SightSave app (SightSave Ltd, UK) and standard contrast sensitivity charts to see if the SightSave app will test vision to the same accuracy. Secondary objectives include measuring the time each test takes and if it subjects find it easier to use the SightSave app than standard testing.

Study design
Type of study: This is a cohort observational study of two comparable methods of measuring vision.
The research population: Participants will be patients recruited from an eye clinic.
Inclusion criteria: Individuals who have been listed for cataract surgery.
Exclusion criteria: Potential participants who are unable to use a LogMAR vision chart or are found to be at risk of suffering depression after completing the NHS self-assessment depression questionnaire.
Withdrawal criteria: Participants can withdraw from the study at any point for any or no reason until start of data analysis. Withdrawing from the study will have no effect on the patient or their clinical care.
Expected duration of the study: The study is planned to start on 1 April 2023 and will run for 6 months data collection 3 months data analysis and publication – total 9 months

Methodology: We will test the hypotheses is that there is no significant difference between vision measured on the standard Bailey Lovey Vision Charts at across the range of contrast levels and the SightSave app. We will test 50 eyes of subjects with visually significant cataracts, listed for surgery who will be screened and if suitable, recruited to the study. Consent will be obtained prior to testing and a depression score administered. Patients unable to use the Bailey Lovey Vision Chart or assessed as suffering from significant depressive symptoms will be excluded from the study.

For each subject, the spectacle-corrected contrast sensitivity will be measured using Bailey Lovey Charts at each level of contrast available (1.25%, 5%, 10%, 25% and 100% contrast). The tests will be recorded by a vision testing assistant and the subject will read down the chart until they cannot read any more letters[ii]. The same assistant will teach the subject how to use the SightSave app according to the manufacturer's instructions and supervise the subject measuring their own vision across the same range of contrast.

All interviews and testing will be performed at the Edgbaston Eye Consultants Eye Hospital, 22 George Road, Birmingham B15 1PJ. There will not be any planned interim analyses/reports. To reduce bias, the same technician will be used to measure the chart vision and the patient will measure their own SightSave app vision after being instructed on how to use the app.



Graphic outline of the study design and procedures.

Safety considerations: There are no inherent safety issues from the tests themselves. Patient safety will be ensured as part of the normal clinic environment, as per our clinic protocols that are regularly reviewed by the CQC regulator.

Follow-up: All study participants will also be cataract patients within the clinic and will be followed-up in the course of their pre and postoperative care. Their best-corrected vision across the range of contrast levels will be tested using both methods prior to their surgery and again 4-6 weeks after surgery. If there are any issues associated with the surgery or the tests, further appointments will be scheduled to address them, as appropriate.

Data management and statistical analysis: The 2 types of vision test results will be compared using Bland-Altman plots. This is a method used for comparing two measurements of the same variable, in this case the contrast sensitivity vision. It is especially useful for validating new measurement techniques that have advantages over the standard ones.

The number of 50 eyes of subjects recruited is designed to attain 100 comparison plots, as each eye is tested twice and has a change in their contrast sensitivity vision from the cataract surgery. This is sufficient for the intended analysis giving a confidence limit to the result that is acceptable (CI+/-0.34s; where s is the standard deviation of the differences between measurements by the two methods).

Your data will be stored permanently in your electronic patient record and the anonymised datasheet will be kept for at least 3 years on a trial computer, in case it needs to be reviewed. The information will not be used for any other purpose than the study.

I would like to take the opportunity to thank you for your consideration of enrolment to the VASCA Study. I personally believe that home monitoring of vision will be of great benefit to patients, their carers and their healthcare professionals.

Quality assurance: All researchers will have current training in Good Clinical Practice and obtaining informed consent. The conduct of the study will conform to the clinical and data security policies of Edgbaston Eye Consultants.

Expected outcomes of the study: It is expected that there is close concordance between the 2 tests in terms of LogMAR VA at each level of contrast, the SightSave app is likely to be faster to complete and possible for most subjects to self-administer. A positive result would validate the use of the SightSave test for determining contrast sensitivity tests, potentially for home use, demonstrating advantages in terms of self-administration and ease of use over formal chart testing.

Dissemination of results and publication policy: The results of the study will be presented at a scientific meeting and then in the peer reviewed scientific press, a copy of this will be available on the study website page on https://www.scotthealth.co.uk/ and a copy of these publications will be sent to you by email. The responsibility for presenting the results of the study is with the Chief Investigator (Robert Scott) the responsibility for sending the results to participants is with the Research Assistant (Hawa Omar).

Duration of the project: We aim to start the project on 1 April 2023 and it is likely to take 9 months to complete i.e. 31 December 2023. Each test subject will have their vision measured before surgery and 4-6 weeks after surgery, when they will have completed their involvement in the trial.

The study is therefore scheduled to take 6 months to complete this is inclusive of preparation, convening meetings/conducting screening interviews. Once the results have been tabulated it will take a further 3 months for interpreting and analysing findings, then preparing the final report for publication as a poster at a scientific meeting, followed by a peer-reviewed scientific publication.

Problems anticipated: We do not have any concerns about successfully completing the trial. Our main concern is with the recruitment rate and therefore completion of the trial in a timely fashion. We will make sure that we are efficient in offering participation in the trial to patients and may contact them to prepare them for potential inclusion prior to their clinic appointment in order to improve the recruitment rate.

Project management: Ms Hawa Omar will work in the role of a research assistant for the trial. Her responsibilities include a) testing the vision of the subjects using the Bailey Lovey Charts; b) supervising the subjects using the SightSave app to assess their own vision; c) ensure that the necessary paperwork for enrolment is available and that there is appropriate time allocated for informed consent to be taken and for the vision tests to be completed as well as the clinical assessment of the cataracts; d) to act as a point of contact for participants; e) to disseminate the results of the study.

Professor Robert Scott will work in the role of Chief Investigator for the trial. He will a) obtain informed consent from the participants; b) record the results of each vision test on an anonymised database; c) manage any queries and issues relating to the participants; d)analyse the data; e) publish the data in the form of a poster at a scientific meeting; f) publish the data in a peer-reviewed journal.

Ethics: Research participants will be recruited from Edgbaston Eye Consultants Clinic, after listing for cataract surgery. They will be given a copy of the protocol and invited to participate in the trial by Professor Robert Scott, the Chief Investigator. Any questions will be answered and signed consent will be obtained to conduct the tests. A suitable appointment time will be arranged to perform the tests after this.

The main ethical issue is that the tests may uncover poor vision that the subject was not aware of. This is mitigated by using it on cataract patients who have already presented with poor vision for cataract surgery. In this way, there is a good explanation for the poor vision and the patient is unlikely to be distressed.

Informed consent form: See below;

You have been invited to participate in a clinical trial of a new device that measures your vision at different levels of contrast. The trial is called the Validation of SightSave contrast sensitivity analyser (VASCA) Study.

What is the research about? We are conducting the study because current visual acuity tests are generally performed only in clinic and are chart based, usually measuring a small part of the vision at high contrast, though a range of lower contrast charts can also be used. Eye disease tends to affect low contrast discrimination before the high contrast vision and patients can suffer failing vision for some time before it is detected. The SightSave app is a test of contrast sensitivity across all levels of contrast that can be self-administered at home. If the SightSave app and visual acuity chart tests are comparable, the SightSave app could allow patients to measure their own vision at home and attend their healthcare professional earlier, when they measure a drop in their vision.

We want to see if the results of vision testing from the SightSave app are comparable to the normal vision chart. We aim to test people, like yourself, who are having cataract surgery and we will measure the change in vision after surgery to see if this is also comparable. We also want to see which test takes longer to complete and ask you which test was easier to do.

Do I have to take part? It is up to you to decide if you want to take part, you do not have to take part if you do not want to. If you do decide to take part I will ask you to sign a consent form which you can sign before we conduct your vision tests.

What will my involvement be? If you consent to participate in the study, we will arrange to measure your vision on both types of chart, this will take around 10-20 minutes. Initially we will ask you to complete a routine self-assessment questionnaire about your mental health, to make sure that you feel well in yourself to complete the trial. This will take no longer than 5 minutes. We also record the time taken for each test and give you the opportunity to rate the ease of completing each test on a 5-point rating scale. If you do not give your consent, you will have your vision measured on a standard chart at high contrast.

How do I withdraw from the study? You can withdraw from the study at any point until 31 December 2023, when I will begin analysis of the data, without having to give a reason. If any questions during the consenting process make you feel uncomfortable, you do not have to answer them. Withdrawing from the study will have no effect on you. If you withdraw from the study we will not retain the information you have given thus far, unless you are happy for us to do so. Withdraw from the study will not affect your care at Edgbaston Eye Consultants.

Will my taking part and my data be kept confidential? Will it be anonymised? The records from this study will be kept as confidential as possible. Only I (Robert Scott) will have access to your clinic notes where the results are kept and Hawa Omar the Research Assistant will have access to your trial vision results. Outside the trial your data will be anonymised – your name will not be used in any reports or publications resulting from the study. All digital files, transcripts and summaries will be given codes and stored separately from any names or other direct identification of participants. Any hard copies of research information will be kept in locked files at all times.

Limits to confidentiality: confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm and unable to act for themselves; in this case, we may have to inform the relevant agencies of this, but we would discuss this with you first.

Who has reviewed this study? This study has undergone ethical review at the Birmingham and Solihull Research Ethics Committee.

Data Protection Privacy Notice: Edgbaston Eye Consultants Data Privacy Policy can be obtained on request by email: admin@edgbastoneye.co.uk . The legal basis used to process your personal data will be for a Public Task. The legal basis used to process special category personal data will be for statistical purposes. To request a copy of the data held about you please contact: admin@edgbastoneye.co.uk

What if I have a question or complaint? If you have any questions regarding this study please contact the researcher, Hawa Omar on hawa@edgbastoneye.co.uk . If you have any concerns or complaints regarding the conduct of this research, please contact Chief Investigator, Robert Scott on rob.scott@edgbastoneye.co.uk .

I would like to take the opportunity to thank you for considering participation in the study. If you are happy to take part in this study, please sign the consent sheet attached/below.

Edgbaston Eye Consultants

CONSENT FORM

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PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY

I have read and understood the study information dated [DD/MM/YY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	YES / NO
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and that I can withdraw from the study at any time up until XXX, without having to give a reason.	YES / NO
I understand that the information I provide will be used for research publication and that the information will be anonymised.	YES / NO
I understand that any personal information that can identify me – such as my name, address, will be kept confidential and not shared with anyone other than the researcher /study team.	YES / NO
I give permission for the (anonymised) information I provide to be deposited in a data archive so that it may be used for future research.	YES / NO

Please retain a copy of this consent form.

Participant name:

Signature: _____ Date _____

Interviewer name:

Signature:_____ Date _____

For information please contact: Hawa Omar hawa@edgbastoneye.co.uk

Research protocol: part 2

Budget

The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.

Other support for the project

This section should provide information about the funding received or anticipated for this project from other funding organizations.

Collaboration with other scientists or research institutions

Links to other projects

Curriculum Vitae of investigators

The CV of the Principal investigator and each co-investigators should be provided. In general each CV should not be more than one page, unless a complete CV is specifically requested for.

Other research activities of the investigators

The Principal investigator should list all current research projects that he/she is involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.

Financing and insurance

Financing and insurance if not addressed in a separate agreement, and where relevant should be described.

[ii] Foot and MacEwen, Surveillance of sight loss due to delay in ophthalmic treatment or review: frequency, cause and outcome Eye. 31(5):771-775 (2017)

[ii] Lovie-Kitchin, J. E. Validity and reliability of visual acuity measurements. Ophthalmic Physiol. Opt. J. Br. Coll. Ophthalmic Opt. Optom. 8, 363–370 (1988).