Plan Overview

A Data Management Plan created using DMPonline

Title: Artificial tear rheology and smartphone-measured blink kinematics: new insights into personalized dry eye treatment (mREOBLINK)

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Project abstract:

Artificial tears are the first-line treatment for dry eye disease, but they are chosen largely empirically: their rheological properties are rarely reported and their effect on eyelid behaviour is unknown. mREOBLINK will determine whether the viscosity and viscoelasticity of artificial tears modify blink dynamics and kinematics in healthy and dry eye subjects of both sexes. The project will (1) develop and validate, against expert manual analysis, a web application that automatically measures blink parameters from 240 fps smartphone videos; (2) characterise the rheological and physicochemical properties of about 20 commercial artificial tears at storage and ocular surface temperatures, and select representative high- and low-viscosity formulations; and (3) evaluate their effect on blink kinematics in a randomised, double-masked crossover clinical study, exploring whether baseline blink pattern and sex predict the response. Data are collected and generated to answer these questions and to provide an open rheological catalogue, a validated blink reference dataset and open-source analysis software.

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Artificial tear rheology and smartphone-measured blink kinematics: new insights into personalized dry eye treatment (mREOBLINK)

Data description and collection or re-use of existing data

How will new data be collected or produced and/or how will existing data be re-used?

All data will be newly generated by the project; no existing third-party datasets will be re-used. Data will be produced in two complementary studies:

- **Study 1 (development and validation of the web application).** High-frame-rate videos (240 fps) of the ocular region will be recorded in 30 adult participants (15 healthy, 15 with dry eye disease, balanced by sex), two 60-s recordings each, with the native camera of a single smartphone model. A standardised capture protocol is used: frontal view, chin and forehead rest, tripod at 30 cm, constant diffuse illumination, fixation target at 3 m, and controlled and recorded room temperature and humidity. Two independent expert observers will annotate the upper eyelid margin and pupil centre frame by frame with a web annotation tool, producing the manual reference dataset. The automated application, developed in Python, will extract dynamic and kinematic blink parameters from the videos.
- **Study 2, Phase 1 (rheological and physicochemical characterisation).** About 20 artificial tears marketed in Spain will be characterised in the laboratory:
  - flow curves at 4, 18 and 34 °C, oscillatory sweeps at 34 °C and temperature ramps from 4 to 36 °C (AR1000-N rotational rheometer and ViscoQC 300 viscometer);
  - kinematic viscosity (Micro-Ubbelohde viscometer);
  - bioadhesion on ex vivo bovine cornea, plus compression force to dispense a drop and drop weight (texture analyser);
  - surface tension (du Noüy ring tensiometer);
  - interaction with simulated tear fluid (dynamic light scattering, Zetasizer Nano ZS).
- **Study 2, Phase 2 (randomised, double-masked, crossover clinical study).** Up to 70 participants (30 healthy and 30 with dry eye, balanced by sex, plus replacements) will attend two sessions. Blink videos will be recorded at baseline and 2, 5, 10 and 15 minutes after instilling a high- or low-viscosity formulation, then analysed with the validated application. Clinical data will be collected with:
  - the OSDI-6 questionnaire;
  - non-invasive tear film break-up time, tear meniscus height, meibography, corneal/conjunctival staining and visible iris diameter (OCULUS Keratograph 5M);
  - ocular surface temperature (FLIR C5 thermal camera);
  - sociodemographic and hormonal variables, and screen time.

Data will be pseudonymised at the point of collection. Each participant receives a study code, and the key linking codes to identities is stored separately, with access restricted to the principal investigator. Files follow a common naming convention (study_participant_session_timepoint_recording) and a predefined folder structure. All variables are defined in a single codebook shared by the clinical, physicochemical and image analysis teams.

What data (for example the kinds, formats, and volumes) will be collected or produced?

Data type	Content	Format	Estimated volume
Blink videos	Ocular region at 240 fps, approximately 760 recordings of 60 s (Study 1: 60; Study 2: up to 700)	.mov / .mp4	~300–400 GB
Manual reference annotations	Eyelid margin and pupil centre coordinates per frame	.csv / .json	< 5 GB
Blink parameters	Mean and peak closing/opening velocity, amplitude, closing and total duration, blink rate, interblink interval, complete/incomplete blinks, confidence index	.csv	< 1 GB
Clinical and sociodemographic data	OSDI-6, NIBUT, staining, tear meniscus, meibography, iris diameter, ocular temperature, sex, age, menopausal status, hormonal therapy, screen time, room conditions	.csv / .xlsx; instrument images and videos (.jpg/.png/.mp4)	~10–20 GB
Rheological and physicochemical data	Flow curves, oscillatory sweeps, temperature ramps, kinematic viscosity, bioadhesion, compression force, drop weight, surface tension, DLS particle size	Instrument exports converted to .csv / .xlsx	< 5 GB
Software	Source code of the analysis application and annotation tool, trained model weights	.py, model files	< 10 GB
Documentation	README files, codebook, capture and laboratory protocols, informed consent templates	.txt / .md / .pdf	< 1 GB

Data from proprietary instrument formats will be exported to open, non-proprietary formats (.csv) for analysis, sharing and preservation. Total storage required during the project is estimated at about 0.5 TB.

Documentation and data quality

What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany data?

Each dataset will be accompanied by:

- **A README file** describing the study, collection methods, file structure, naming convention, variables, units, instruments and software versions, licence and how to cite.
- **A codebook** shared by the three teams, defining every variable: name, description, unit, permitted values, coding of categorical variables and treatment of missing data.
- **Protocols:** the standardised blink-video capture protocol; the manual annotation guidelines for the reference observers; the laboratory protocols for each rheological and physicochemical measurement (temperatures, shear range, contact times, simulated tear fluid composition and 40:7 dilution); and the clinical examination protocol, with dry eye classification according to TFOS DEWS III criteria.
- **Contextual metadata for each recording:** session date and time, time point relative to instillation, room temperature and humidity, device model and recording settings (240 fps), and coded formulation (kept masked until the end of the study).
- **Software documentation:** version, dependencies, installation and usage instructions, and the algorithm version used to process each video. All clinical videos will be processed with the same validated version.

Datasets deposited in the repository will be described with the repository's standard metadata, based on DataCite and Dublin Core: title, creators with ORCID, date, description, keywords, licence, funder (Agencia Estatal de Investigación) and grant number, and links to the related publications and code. The clinical study will be registered in ClinicalTrials.gov and reported according to the CONSORT extension for crossover trials. Results will be reported disaggregated by sex following the SAGER guidelines.

What data quality control measures will be used?

- **Standardised capture.** All videos will be recorded with the same smartphone model, a second identical device kept as a spare, and a fixed set-up of chin rest, tripod, diffuse illumination and fixation target. Room temperature and humidity will be controlled and recorded in each session, and participants will attend without eye make-up.
- **Video quality control at the point of capture.** The application automatically detects non-analysable frames (blur, reflections, movement). From month 13, the baseline recording of each clinical session will be checked with the functional version of the application before instillation and repeated if it cannot be analysed.
- **Confidence index.** Each blink detected by the application receives a confidence index, and low-confidence blinks are flagged for manual review.
- **Validation against a reference.** The application will be validated against independent frame-by-frame manual analysis by two masked expert observers, on participants not used for algorithm development. Pre-specified thresholds apply: sensitivity > 95 %, ICC > 0.90 and Bland-Altman limits of agreement within ±10 %. Inter-observer reliability and test-retest repeatability will also be reported.
- **Masking.** Formulations are labelled with opaque codes, and videos are analysed as coded files. Clinical examiners are kept separate from the researchers responsible for statistical analysis.
- **Laboratory measurements.** Measurements are performed in triplicate, with calibrated instruments and Peltier temperature control.
- **Data entry and integration.** A single codebook with defined ranges and coding is used, and range and consistency checks are run before analysis. Original instrument exports are kept unaltered; processing is done on copies with scripts under version control.
- **Periodic review.** Data management is reviewed at each project milestone, with a six-monthly audit of data handling.

Storage and backup during the research process

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

- **Primary storage.** All project data will be stored on the University of Santiago de Compostela (USC) institutional infrastructure, Microsoft OneDrive and SharePoint. A dedicated project site with a predefined folder structure will be set up for each study. This managed storage is maintained by the USC IT services and provides automatic versioning, redundancy and backup.
- **Secondary backup.** A weekly encrypted copy of videos, processed data, scripts and final versions will be kept on two encrypted SSD drives under the custody of the principal investigator, held under lock in the Optometry Service. Videos are not

kept on smartphones or personal devices: they are transferred to institutional storage at the end of each session and then deleted from the recording device.
- **Instrument data.** Data generated by clinical and laboratory instruments (Keratograph 5M, FLIR C5, rheometer, viscometers, texture analyser, tensiometer, Zetasizer) are exported after each session or measurement and transferred to institutional storage. Original exports are kept unaltered alongside the converted open-format files.
- **Code.** The application source code and analysis scripts will be managed with version control (Git) in a private repository during development.
- **Capacity.** About 0.5 TB is expected (section 1.2), which falls within the institutional storage available to the project.

How will data security and protection of sensitive data be taken care of during the research?

- **Pseudonymisation at source.** Participants are identified only by a study code. The key linking codes to identities is stored in a separate, encrypted file accessible only to the principal investigator. Consent forms are kept on paper, under lock, in the Optometry Service.
- **Access control.** Access to the project site is restricted to authorised team members through institutional credentials with multi-factor authentication. Permissions are granted by the principal investigator per study and role and revoked when a member leaves the project. Raw identifiable videos are accessible only to the clinical team and to the image analysis team members who process them.
- **Encryption.** Data are encrypted in transit and at rest on the institutional infrastructure. Backup drives are hardware-encrypted.
- **Inter-institutional processing.** The image analysis team at the University of A Coruña (UDC, VARPA group), subcontracted for application development and video processing, will process coded videos on UDC computing equipment, under the supervision of Hugo Pena Verdeal (USC). A data processing agreement between USC and UDC, with the involvement of both universities' data protection officers, will be signed before the first capture. It will define purpose, security measures, retention and deletion of copies at the end of processing. Transfers will use institutional channels only; no email or unencrypted removable media.
- **Masking.** The allocation key of the formulations is kept by a researcher not involved in examinations or analysis until the database is locked.

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on data security be ensured?

The project processes personal data of 100 adult participants: facial videos of the ocular region, which are identifiable data, together with health and sociodemographic data, including menopausal status and hormonal therapy. Processing will comply with the General Data Protection Regulation (EU) 2016/679 (GDPR) and Spanish Organic Law 3/2018 (LOPDGDD).

- **Controller and data protection officer.** The University of Santiago de Compostela (USC) is the data controller. Its data protection officer will advise on the project from the design stage and will review the information sheet and consent form.
- **Legal basis.** Explicit informed consent for the processing of health data for scientific research. A specific consent will cover video recording, the retention and use of the videos, and the sharing of pseudonymised derived data in a public repository.
- **Data minimisation.** Videos are restricted to the ocular region needed for analysis and are never published. Only pseudonymised derived data are shared: blink parameters, clinical data, and age in ranges rather than date of birth.
- **Processor.** The University of A Coruña (UDC) acts as data processor for video analysis, under a USC-UDC data processing agreement signed before the first capture.
- **Participants' rights.** Participants are informed of their rights of access, rectification, erasure, restriction and objection, and of their right to withdraw at any time without consequences.
- **Security.** The technical and organisational measures are those described in section 3.2.
- **Breaches.** Any data breach will be notified according to the USC procedure, through its data protection officer.

How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?

- **Ownership.** Data and results generated by the project belong to the USC as beneficiary institution. Results arising from the subcontracted work of the University of A Coruña will be governed by the subcontract terms, which will set ownership and the right to use and publish.
- **Software.** After validation (month 18), the application will be registered in the Intellectual Property Registry through the USC technology transfer office (OTRI) and/or the UDC knowledge transfer office (OTC). Its source code will be released openly under

a licence for non-commercial academic and clinical use. Commercial use will be offered under licence to companies. No patents are planned.
- **Data.** Deposited datasets will be released under a Creative Commons Attribution 4.0 (CC BY 4.0) licence.
- **Third-party products.** Commercial artificial tears are identified by brand and composition in the rheological catalogue. Only measurements obtained by the team are published; no proprietary manufacturer information is used.
- **Applicable legislation:**
  - Spanish Law 14/2011 on Science, Technology and Innovation (article 37, open access);
  - Royal Legislative Decree 1/1996 (Intellectual Property Law);
  - GDPR and LOPDGDD;
  - Law 14/2007 on Biomedical Research;
  - the open science and data management requirements of the Agencia Estatal de Investigación call.

How will possible ethical issues be taken into account, and codes of conduct followed?

- **Ethical framework.** The study follows the Declaration of Helsinki, the Oviedo Convention and Spanish Law 14/2007 on Biomedical Research.
- **Ethics approval.** A favourable opinion from the Galician Research Ethics Committee (CEIG) will be requested after the grant is awarded (months 1-3). No recording or examination will start without it.
- **Interventions.** Examinations are non-invasive and performed by licensed optometrists (Law 44/2003) in a registered healthcare centre, the USC Optometry Service (registry C15002430). The artificial tears used are marketed products used within their indications, so no AEMPS authorisation is required.
- **Participants.** No biological samples are collected, and no minors or vulnerable groups are included. Participants receive an economic compensation for their time.
- **Adverse events.** Any adverse event will be recorded, the participant withdrawn if needed, and the event reported to the CEIG.
- **Trial registration and reporting.** The clinical study will be registered in ClinicalTrials.gov, and results will be reported according to CONSORT and SAGER.
- **Animal tissue.** Bioadhesion is measured on bovine corneas obtained from a slaughterhouse; this involves no animal experimentation.
- **Codes of conduct.** The team will follow the USC code of good research practice and the European Code of Conduct for Research Integrity (ALLEA).

Data sharing and long-term preservation

How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?

During the project, data are accessible only to the project team. Data will be shared openly, following the principle "as open as possible, as closed as necessary":

- **Rheological and physicochemical catalogue** of about 20 commercial artificial tears. Deposited in Zenodo with a DOI when the corresponding article is published (expected after month 9), under CC BY 4.0. It will be announced to professionals as part of the dissemination plan.
- **Blink reference dataset.** Pseudonymised blink curves (eyelid-pupil distance over time) and the parameters annotated by the expert observers, so that other groups can benchmark their algorithms. Deposited when the validation article is published (after month 18).
- **Clinical study data.** Pseudonymised blink parameters and clinical and sociodemographic data underlying each publication, with the analysis scripts. Deposited at the latest on the publication date of each article, and all of them before the end of the project (month 36).
- **Software.** Application source code, deposited with a DOI under a non-commercial academic and clinical licence (section 4.2).
- **Publications** in open access, deposited in the USC institutional repository (Minerva), with preprints in medRxiv or bioRxiv where the journal allows.
- **This data management plan** will be deposited openly in Minerva when it is drafted.

Restrictions. Blink videos show participants' faces and are identifiable personal data, so they will not be shared. Embargoes are limited to the time until the related article is published, to protect the publication priority of the team. Software registration in the Intellectual Property Registry (month 18) will precede code publication.

How will data for preservation be selected, and where will data be preserved long-term (for example a data repository or archive)?

- **Selected for long-term public preservation:** the datasets described in the previous answer (rheological catalogue, blink

reference dataset, clinical study data underlying publications, and software), together with their documentation (README, codebook, protocols). These have long-term reuse value: they are the first catalogue of the rheology of commercial artificial tears, and the first validated smartphone blink-kinematics reference.
- **Repository.** Zenodo (CERN, OpenAIRE), a generalist and certified repository with persistent DOIs, versioning and a commitment to preserve data for the lifetime of the repository. Publications and this plan will be deposited in Minerva, the USC institutional repository.
- **Not preserved publicly:** raw blink videos and identifiable data. Videos and the clinical database will be kept in USC institutional storage, under restricted access, for at least 10 years after the end of the project, to allow verification of results. They will then be deleted, unless participants have consented to their use in future research approved by an ethics committee.
- **Copies held by the University of A Coruña** for video processing will be deleted at the end of processing, as set out in the data processing agreement.

What methods or software tools will be needed to access and use the data?

- **Datasets** will be provided in open, non-proprietary formats (.csv, .json, .txt, .pdf) readable with any standard software, without licence costs.
- **Analysis scripts** will be written in R (lme4 package) and Python and shared with the data, so that the statistical analysis can be reproduced. Some analyses were also performed in IBM SPSS v.29; equivalent R code will be provided.
- **The blink analysis application** is written in Python with open-source computer vision libraries (including MediaPipe). It will be accessible as a web application during the project and afterwards, with its code, documented dependencies and usage instructions available for local installation.
- **Video recording** requires only a smartphone capable of 240 fps in slow-motion mode, following the published capture protocol.

How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?

Each dataset deposited in Zenodo will automatically receive a DOI, with a concept DOI covering all versions and a specific DOI for each version. The source code will be archived in Zenodo through its GitHub integration, so that each release receives a DOI. Data and code DOIs will be cited in the related articles (data availability statements), and the articles' DOIs will be linked from the dataset metadata. Researchers will be identified by ORCID, and the dataset metadata will include the funder and grant number. Deposits in Minerva receive a persistent Handle identifier.

Data management responsibilities and resources

Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?

- **Data steward: Jacobo García Queiruga**, principal investigator (Assistant Professor, University of Santiago de Compostela, USC; ORCID 0000-0001-7216-4512). He has overall responsibility for data management and holds the pseudonymisation key and the backup copies. He is responsible for the rheological and physicochemical data (Tasks 2.2 and 2.3), including conversion of instrument exports to open formats, and for the integration of clinical, rheological and blink databases (Task 2.8), the deposit of data in Zenodo and Minerva, and the updates of this plan.
- **Clinical data and video capture: Carlos García Resúa** (USC). Responsible for participant recruitment, clinical examinations, video recording and organisation, and the manual reference annotation (Tasks 1.4, 2.5 and 2.6), including the quality control of recordings at each session.
- **Software and processed blink data: Hugo Pena Verdeal** (USC). Responsible for the specification, development, validation and documentation of the application (Tasks 1.1-1.3 and 1.6), and for the video processing carried out under the University of A Coruña subcontract and the data processing agreement.
- **Work team.** Members of the work team participate in generating and processing data, following the procedures of this plan, but hold no data management responsibilities. Each group works under the explicit supervision of a member of the research team:
  - clinical work team (postdoctoral and predoctoral researchers of the Optometry Research Group, including the requested predoctoral researcher): supervised by Carlos García Resúa;
  - physicochemical analysis work team (PARAQUASIL group, USC), which performs the rheological and physicochemical measurements: supervised by Jacobo García Queiruga;
  - image analysis work team (VARPA group, University of A Coruña), which develops the application and processes the videos under the subcontract: supervised by Hugo Pena Verdeal.
- **Institutional support:** the USC data protection officer for personal data compliance; the USC library (Minerva) and IT services for storage, repository deposit and preservation.

All team members, including the predoctoral researcher, will receive training in the data management procedures of this plan at the start of the project. Data management will be reviewed jointly at each project milestone.

What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

Financial resources (from the project budget):

- two encrypted SSD drives for backup (400 €);
- web hosting and domain for the application for three years (900 €), which keeps the tool accessible;
- open access fees for three articles (7,500 €), with the fourth covered by USC transformative agreements;
- part of the University of A Coruña subcontract, which covers video processing and the documentation of the application and its outputs;
- software registration in the Intellectual Property Registry (300 €).

At no additional cost:

- USC institutional storage (OneDrive and SharePoint) and its backup;
- deposit in Zenodo and Minerva, which are free of charge;
- the support of the USC data protection officer, library and IT services.

Time. Data management is built into the work plan rather than treated as a separate activity. Data organisation and documentation are part of Tasks 1.4, 2.2 and 2.8, and the preparation of datasets for deposit (README, codebook, open formats, metadata) is scheduled alongside each publication within Task 3.3, with all data deposited by month 36.

FAIR.

- *Findable:* DOIs, rich metadata and ORCID.
- *Accessible:* open repositories, under a CC BY 4.0 licence.
- *Interoperable:* open formats and a shared codebook.
- *Re-usable:* README files, protocols and analysis code.