Development of a Clinical Decision Support System for Cataract Surgery Planning Using Swept-Source Optical Biometry

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Conflict of Interest Statement
The authors declare no conflicts of interest.

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INTRODUCCIÓN

Cataract surgery is one of the most frequently performed surgical procedures worldwide and represents the main intervention for the management of visual impairment caused by lens opacification. Despite continuous advances in surgical techniques and technology, intraoperative complications such as posterior capsule rupture, zonular weakness, and difficulties associated with dense or mature cataracts remain relevant challenges that may compromise visual outcomes. **1,2** The selection of the surgical approach and intraoperative strategy continues to rely largely on surgeon experience and subjective assessment of cataract characteristics.

Currently, cataract density and severity are commonly assessed using clinical grading systems such as the Lens Opacities Classification System III (LOCS III). However, this classification presents limitations, including interobserver variability and the inability to fully characterize the structural properties of the crystalline lens that influence surgical complexity.**3**

Swept-source optical coherence tomography (SS-OCT) has emerged as a non-invasive imaging technology capable of providing detailed structural information regarding the lens and anterior segment. The ARGOS biometer (Alcon Laboratories, Inc., Fort Worth, TX, USA) incorporates SS-OCT technology and allows evaluation of parameters such as lens thickness, anterior chamber depth, and optical reflectivity patterns. **4,5**

Previous studies have demonstrated associations between objective optical coherence tomography (OCT) derived measurements and parameters related to cataract hardness, including nuclear opacity, phacoemulsification time, and energy requirements. However, a standardized tomographic classification integrating SS-OCT lens patterns with surgical decision-making has not yet been established. **6,7**

The aim of this study was to evaluate the association between SS-OCT lens patterns obtained using the ARGOS swept-source optical biometer and the surgical approach selected during cataract surgery, assessing their potential role as a clinical decision support tool for preoperative planning.

Background: Clinical decision-making gaps exist in choosing the best surgical approach for cataract surgery. Despite technological advances, the choice of technique still largely depends on the surgeon's experience and subjective judgment, which can reduce accuracy and raise the risk of intraoperative complications.

Unmet Medical Need: There is a need to parameterize the surgical approach in cataract surgery using swept-source optical coherence tomography (SS-OCT) imaging to provide an objective and reliable tool for selecting the most appropriate surgical technique. Incorporating parameters obtained from SS-OCT would enable preoperative identification of patients at higher surgical risk, predict procedural complexity, and reduce intraoperative complications, thereby supporting a safer, more efficient, and personalized approach.

Scientific Rationale: Cataracts are the leading cause of preventable blindness in developing countries. Although technological advances have improved surgical safety, intraoperative complications remain a significant clinical challenge because they can compromise postoperative vision and require reintervention. Traditionally, the assessment of surgical difficulty is performed clinically and subjectively, using scales such as the Lens Opacities Classification System III (LOCS III). However, this method exhibits inter-observer variability and lacks objectivity. In this context, anterior segment

optical coherence tomography (ASOCT) has emerged as a promising tool for evaluating the structural parameters of the lens and anterior chamber that can influence the choice of surgical technique and the risk of complications. State-of-the-art equipment, such as the ARGOS biometer (Alcon Laboratories, Inc., Fort Worth, TX, USA), enables rapid and precise acquisition of detailed measurements of the eye, including anterior chamber depth, lens thickness, and axial distances. Several studies have demonstrated that certain SS-OCT-derived characteristics are associated with an increased risk of intraoperative complications, including posterior capsule rupture, and can influence the choice of surgical technique (1). However, there is currently no classification that integrates clinical assessment (LOCS III) with objective OCT-SA parameters to establish a systematic, personalized presurgical risk model that optimizes the selection of the surgical approach and improves visual outcomes in cataract surgery (1).

HYPOTESIR

Using swept-source optical coherence tomography (SS-OCT) with the Argos biometer allows for identifying specific optical patterns in the lens that relate to the level of opacity and density. It is believed that these patterns, which have been observed and empirically classified into Types I-V, can accurately predict the best surgical approach—whether chop, stop and chop, divide and conquer, or extracapsular—thus improving the safety and success of the procedure. These wave patterns are newly described; they were established through clinical observation and linked to the Lens Opacities Classification System (LOCS) and surgical results.

Argos aids in analyzing SS-OCT measurements. The image from the Argos manual shows (c) an OCT image and (d) a one-dimensional representation of the OCT signal. Using these measurements, different patterns for various types of cataracts have been identified.

Type I (juvenile or V pattern) is a clear lens characterized by two prominent anterior and posterior wave peaks, with a central dip; it can be treated with phacoemulsification using only vacuum aspiration.

Type II (plateau or M pattern) is a lens with a cataract classified as NO3NC3 or NO4NC4 (LOCS III). It features two prominent anterior and posterior wave peaks and multiple intralenticular peaks in the mid- or nuclear zone due to increased central reflectivity caused by nuclear changes in the lens. It can be treated with phacoemulsification.

Type III (decline pattern) is a hypermature cataract classified as NO6NC6 according to the LOCS III system. It features a prominent anterior peak that gradually decreases along the nucleus, with the loss of the prominent posterior wave peak caused by the fusion of all lens layers. This requires cataract extraction through an extracapsular approach.

The literature shows SS-OCT is a noninvasive, reproducible, and highly sensitive tool for measuring lens morphology, assessing lens layer density, opacity, and reflectivity before surgery. These features relate to surgical difficulty, phacoemulsification time, and complication risk. Studies with single-segment OCT (IOLMaster 700) found a high ($r=0.86$) correlation between nuclear reflectivity and nuclear opalescence per LOCS III, also correlating with phacoemulsification time and energy. Research with intraoperative OCT (iOCT) classifies white cataracts and predicts capsular complexity, aiding surgical approach.

Preoperative OCT-SS (Argos) classification aids in characterizing cataracts (I-V) and predicting surgical approach, enhancing risk assessment, surgeon prep, and tool selection. Validating these patterns fosters a reproducible, cost-effective system

integrated into routine biometry, improving safety, efficiency, and reducing complications. ARGOS parameters and LOCS III guide surgical decisions, though their impact on timing decision remains uncertain.

However, Argos biometer users often assess IOL calculations without accounting for integral risk considerations in premium IOL selection based on cataract type. Therefore, if we include SS-OCT lens criteria, we can consider surgical risk and surgical planning techniques, which help optimize operating room efficiency and improve patient safety by managing energy, fluidics, and phacodynamics.

Additionally, it incurs no extra costs when requesting additional tests and is easily reproducible across different centers.

III. STUDY DESIGN

An observational, analytical, single-center, ambispective study will be conducted, aimed at the development and internal validation of a preoperative prediction tool for surgical complexity in cataract surgery. The study will evaluate the ability of a classification of lenticular patterns obtained using swept-source optical coherence tomography (SS-OCT), integrated into the ARGOS biometer, to predict the surgical approach required during cataract extraction and determine whether this information provides additional predictive ability beyond conventional clinical assessment using the Lens Opacities Classification System III (LOCS III).

The analytical and predictive nature of the study is based on the fact that the main predictor, corresponding to the lenticular tomographic pattern, will be determined preoperatively, and its relationship with the surgical outcome will subsequently be evaluated. The design will be ambispective because it will include procedures performed before the formal initiation of the study, evaluated retrospectively, and procedures prospectively included during the recruitment period. Surgical management will be determined by the treating surgeon according to routine clinical practice, without experimental treatment assignment by the investigators.

Population and Unit of Analysis

For the establishment of the reference group with clear crystalline lenses, patients who underwent optical biometry using the ARGOS device for indications other than cataract, such as myopia monitoring, will be included to characterize the Type I pattern. These patients were not included in the statistical analysis of the study.

The study population will consist of patients older than 40 years with an indication for crystalline lens extraction and preoperative biometry performed using ARGOS, including acquisition of SS-OCT images of the crystalline lens. Patients in whom both the preoperative tomographic pattern and the surgical outcome can be adequately determined will be eligible.

Patients undergoing combined cataract surgery with glaucoma, corneal, or retinal procedures; those with a history of ocular trauma capable of significantly altering anterior segment anatomy; and subjects with ocular conditions that prevent the acquisition of reliable tomographic images will be excluded.

Preoperative Assessment and SS-OCT Classification

The preoperative assessment will include demographic and clinical variables, visual acuity expressed on the logMAR scale, cataract classification using LOCS III, and biometric parameters obtained using ARGOS. Whenever possible, quantitative variables

will be retained on their original scale, avoiding unnecessary dichotomization that could reduce the available information and statistical efficiency.

Lenticular images obtained using SS-OCT will be classified according to tomographic patterns I, II, and III previously defined by the research group. Before the final analysis, an operational manual will be established to unequivocally describe the morphological criteria required to assign each image to one of the three patterns, including reflectivity characteristics, intralenticular signal distribution, configuration of the peaks corresponding to the anterior and posterior surfaces of the crystalline lens, and other relevant features. Procedures for classifying borderline images, images with overlapping characteristics, studies affected by artifacts, and non-interpretable studies will also be defined in advance.

Tomographic classification will be performed by trained observers blinded to the surgical procedure performed, intraoperative complications, and final outcome. Preferably, each image will be independently evaluated by two observers. In cases of disagreement, the final classification will be obtained through consensus or adjudication by a third expert evaluator.

Reproducibility and Blinding

Given that the proposed tomographic classification constitutes a new stratification tool, its interobserver reproducibility will be evaluated using percentage agreement and Cohen's kappa coefficient with a 95% confidence interval. If the patterns are considered ordinal categories with a previously justified clinical and morphological progression, weighted kappa will be used; otherwise, unweighted kappa will be employed. Additionally, a random sample of images will be reevaluated after a predefined interval to estimate intraobserver reproducibility.

Bidirectional blinding will be maintained. The surgeon will select the surgical approach and technique according to their usual clinical assessment, without knowledge of the experimental classification obtained using SS-OCT. Conversely, the investigators responsible for classifying the images will be unaware of the technique used and the surgical outcome. This strategy will aim to reduce the risk of incorporation bias and prevent knowledge of the outcome from retrospectively influencing tomographic classification.

Primary Outcome

The primary outcome will be the need for a complex surgical approach during cataract extraction. The operational definition of complexity will be established before the analysis and documented in the study manual, using objective criteria derived from the operative record and, when possible, the surgical recording. This definition may not be modified after the relationship between SS-OCT patterns and outcomes is known.

For the primary analysis, the outcome will be expressed as a dichotomous variable distinguishing a conventional approach from a complex approach. This strategy will allow clinically interpretable estimation of the predictive performance of the tomographic classification.

The specific surgical technique—including the different modalities of phacoemulsification, extracapsular extraction, or other previously defined approaches—will be retained as a multicategorical secondary outcome. The need for conversion from the initially planned technique will also be recorded when this information is available.

To reduce the influence of individual surgeon preferences, cases in which complexity cannot be directly determined using the predefined criteria will be reviewed by expert evaluators blinded to the SS-OCT classification. Discrepancies will be resolved through consensus or adjudication by a third evaluator.

Study Variables

The main predictor will be the SS-OCT tomographic pattern I–III. The LOCS III classification will constitute the main conventional clinical predictor and will allow evaluation of whether the information derived from ARGOS provides incremental predictive ability beyond routine clinical assessment.

Age, sex, laterality, logMAR visual acuity, relevant ocular comorbidities, available biometric parameters, and surgeon identity will also be recorded. Inclusion of the surgeon will allow control for potential systematic differences in the selection of the surgical approach among operators.

Secondary outcomes will include the specific surgical technique, need for conversion, available phacoemulsification energy parameters, intraoperative complications, and technical feasibility of ARGOS images. Artifacts, acquisition failures, and unclassifiable studies will be considered indicators of image quality and technical feasibility, whereas clinical safety will be evaluated through surgical complications.

Sample Size

The initial sample size calculation was performed by comparing two independent proportions, considering an expected frequency of complex surgical approaches of 20% and 50% between the comparison groups, a two-sided significance level of 0.05, and a statistical power of 80%. This calculation determined a minimum of 78 patients, to which 10% was added to compensate for losses or incomplete information, resulting in an initially estimated sample size of 86 subjects.

However, because the primary objective is the evaluation of a predictive tool, sample adequacy will also be assessed according to the effective number of patients experiencing the primary outcome, the precision of diagnostic performance measures, and the amount of information available for multivariable modeling. The complexity of the statistical model will be restricted according to the number of events to reduce the risk of overfitting.

Statistical Analysis

Statistical analysis will be performed using Stata version 18. Before inferential analysis, a database quality control process will be conducted, including identification of duplicate records, verification of ranges and units, consistency between clinical and surgical variables, detection of outliers, assessment of missing data, and verification of participant eligibility.

Qualitative variables will be described using absolute and relative frequencies. Quantitative variables will be summarized using mean and standard deviation when they exhibit an approximately symmetric distribution, and median and interquartile range when they exhibit substantial skewness. The choice of descriptive measures will be based on the observed distribution and the clinical nature of each variable, rather than exclusively on formal normality tests. The main estimates will be accompanied by 95% confidence intervals.

Initially, the association between SS-OCT tomographic patterns and the surgical approach will be explored using contingency tables. Pearson's χ^2 test will be used when its assumptions are met. In the presence of small expected frequencies, appropriate exact tests or Monte Carlo simulation methods will be employed. These analyses will be considered measures of association and will not be interpreted in isolation as evidence of predictive ability.

For the binary primary outcome, the performance of the predictive rule derived from the SS-OCT pattern will be evaluated using sensitivity, specificity, positive predictive value,

negative predictive value, positive likelihood ratio, negative likelihood ratio, and overall proportion of correct classification, all accompanied by 95% confidence intervals. The rule determining which patterns represent a high risk of requiring complex surgery will be defined before the final analysis and may not be selected afterward for the purpose of maximizing observed performance.

Predictive values will be interpreted considering the frequency of the outcome in the study population, as they depend on prevalence or pretest probability. For the multicategorical analysis, a confusion matrix will be constructed between the predicted approach and the reference approach. When the number of cases per category permits, class-specific performance measures will be calculated using a one-versus-rest approach.

Multivariable Predictive Modeling

A logistic regression model will be constructed using the need for complex surgery as the dependent variable. The SS-OCT tomographic pattern will be the main predictor of interest, and only covariates previously defined based on their clinical and epidemiological relevance will be included, avoiding automatic variable selection strategies based exclusively on p-values.

Initially, a reference clinical model consisting of LOCS III and prespecified clinical predictors will be developed. Subsequently, an expanded model incorporating the ARGOS SS-OCT pattern will be constructed. Comparison between the two models will determine whether tomographic information provides additional predictive ability beyond that obtained through conventional clinical assessment.

Because the choice of surgical approach may vary among operators, surgeon identity will be incorporated as a fixed effect when the number of events allows stable estimation. The distribution of surgical techniques and the primary outcome according to surgeon will also be described.

The magnitude of associations will be expressed using odds ratios with 95% confidence intervals. Nevertheless, the evaluation of predictive utility will be based primarily on the individual probabilities estimated by the model. In the presence of a limited number of events, complete or quasi-complete separation, or coefficient instability, penalized regression methods will be considered.

Model Performance and Internal Validation

Predictive performance will be evaluated through discrimination and calibration. Discrimination will be quantified using the area under the ROC curve or C-statistic with a 95% confidence interval. Calibration will be evaluated by comparing predicted probabilities with the observed frequency of the outcome using calibration plots and, when possible, estimates of the calibration intercept and slope.

To establish the incremental value of ARGOS, the clinical model based on LOCS III will be compared with the expanded model through changes in discrimination, calibration, and overall model fit. When appropriate, the comparison may be complemented by a likelihood ratio test for nested models.

The final model will undergo internal validation using bootstrap, preferably with 1,000 resamples, to estimate and correct the optimism arising from evaluating the model in the same cohort used for its development. The sample will not be arbitrarily divided into training and validation subsets, as this strategy would considerably reduce statistical efficiency in a moderately sized sample.

The validation obtained in the present study should be interpreted as internal validation. Widespread clinical implementation of the classification will subsequently require

external validation in an independent cohort, ideally from other centers and involving different surgeons.

Secondary Outcomes and Handling of Missing Data

Quantitative parameters related to phacoemulsification will be analyzed only in procedures in which this technique was used. When statistical assumptions are reasonably met, linear regression will be used; in the presence of markedly skewed distributions, transformations or generalized linear models with appropriate distributions and link functions may be employed.

The proportion of non-interpretable images, images affected by artifacts, or images with acquisition failures will be reported as a measure of technical feasibility. Its relationship with cataract severity will be explored, because the differential exclusion of denser cataracts could introduce selection bias.

For each variable, the number and percentage of missing data will be reported. When their frequency is minimal, a complete-case analysis may be performed. If the proportion of missing data is relevant and the mechanism is compatible with data missing at random, multiple imputation by chained equations may be considered, complemented by sensitivity analyses.

Multiplicity, Interpretation, and Sensitivity Analysis

Inferential tests will be two-sided, and a statistical significance level of $\alpha = 0.05$ will be used for the primary hypothesis. Secondary outcomes and non-prespecified analyses will be explicitly identified as exploratory. When a family of secondary comparisons exists, adjustment for multiplicity using procedures such as the Holm method will be considered.

Interpretation of the results will not be based exclusively on the p-value. Priority will be given to the magnitude of associations, predictive performance measures, precision reflected by their confidence intervals, and clinical relevance.

Before final database closure, consistency between ARGOS images, clinical information, operative records, and available surgical recordings will be verified. Finally, sensitivity analyses will be performed to evaluate the robustness of the results, including analyses restricted to patients with complete information, exclusion of images of borderline quality, and, when sample size permits, evaluation of model performance across different surgeons.

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