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A TearLyze: Development and Technical Validation of a Smartphone-Based Multimodal AI Diagnostic Device for Dry Eye Disease

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Title Page

A TearLyze: Development and Technical Validation of a Smartphone-Based Multimodal AI Diagnostic Device for Dry Eye Disease

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Abstract:

Background: To develop and technically validate a smartphone-based, non-invasive multiparameter diagnostic device (TearLyze) for DED using an AI-powered pipeline.

Methods: This technical validation study utilized public datasets with 5-fold cross-validation and independent expert grading for ground truth establishment. Datasets comprised 1,200 meibography images, 2,400 video frames, and 500 feature vectors, split 60/20/20 for training, validation, and testing. Ground truth was established by three expert ophthalmologists with consensus-based resolution. The TearLyze prototype incorporates infrared (850 nm) ring illumination for meibography and structured white-light Placido disc illumination for tear film analysis, with video sequences captured at 30 fps. The AI pipeline includes YOLOv8 for tear break detection, Swin Transformer for meibomian gland segmentation, an eye aspect ratio algorithm for blink detection, and XGBoost for severity classification using device-derived parameters only.

Results: The Swin Transformer achieved a Dice coefficient of 0.94 for meibomian gland segmentation. YOLOv8 demonstrated 91.5% sensitivity and 89.2% specificity for tear break detection. The XGBoost classifier achieved 94.2% overall accuracy (weighted F1: 0.93). The EAR blink detector achieved 96% accuracy. Intra-session repeatability was excellent (ICC: 0.93 for NIBUT, 0.90 for meiboscore). The integrated pipeline processed each subject in 8.2 seconds on a standard laptop.

Conclusions: TearLyze demonstrates high accuracy, reproducibility, and speed for non-invasive multiparameter DED assessment using device-derived parameters only. These findings support readiness for prospective external clinical validation in diverse healthcare settings.

Keywords: dry eye disease; Swin Transformer; YOLOv8; meibomian gland segmentation; artificial intelligence; technical validation

1. Introduction

Dry eye disease (DED) is a multifactorial condition affecting the tear film and ocular surface, causing discomfort, visual disturbance, and potential ocular surface damage [1]. It affects 5–50% of the global adult population, with prevalence exceeding 40% in some Asian populations [2,3]. DED significantly impacts quality of life, work productivity, and healthcare costs, and is associated with psychological comorbidities including anxiety and depression [4,5]. The economic burden is substantial, with direct and indirect costs estimated at billions annually [6].

Traditional DED diagnosis combines questionnaires (e.g., Ocular Surface Disease Index, OSDI), tear stability tests (tear breakup time, TBUT), tear production tests (Schirmer's test), and meibomian gland evaluation (meibography) [7,8]. However, these techniques have well-documented limitations. Fluorescein TBUT requires dye instillation that alters the tear film and causes discomfort, while Schirmer's test involves filter paper placement on the conjunctiva, inducing reflex tearing and discomfort [9,10]. These methods are operator-dependent, time-consuming, and show poor inter-observer reproducibility, with TBUT intraclass correlation coefficients ranging from 0.70 to 0.85 [11,12].

Conventional DED diagnostics are typically limited to single-parameter measurement and require multiple instruments (slit lamp, meibograph, stopwatch, paper strips) and extended examination time [13]. This fragmented approach is often impractical in primary care or teleophthalmology settings. A non-invasive, multiparameter, automated diagnostic tool is clearly needed [14].

Recent advances in artificial intelligence (AI) and portable imaging technologies have enabled automated analysis of meibomian glands [16,17], tear breaks [18], and DED severity [19]. Smartphone-based systems have demonstrated feasibility for meibography [20], tear meniscus height [21], and ocular redness grading [22]. However, most existing AI systems focus on single diagnostic parameters and lack integration into a portable, non-invasive device [23]. Furthermore, few studies report rigorous internal validation with publicly available datasets, limiting reproducibility.

To address this gap, we developed TearLyze, a smartphone-based device integrating three diagnostic modalities: infrared meibography, Placido disc-based non-invasive tear breakup time (NIBUT) analysis, and blink dynamics recording. The AI pipeline uses Swin Transformer for gland segmentation, YOLOv8 for tear break detection, an EAR algorithm for blink detection, and XGBoost for severity classification (using device-derived parameters only).

The objectives of this study were: (1) to describe the development and technical architecture of TearLyze; (2) to detail the training of its AI models using publicly available datasets; (3) to validate each AI component using held-out test sets with emphasis on accuracy, repeatability, and processing time; and (4) to establish device readiness for prospective clinical validation.

2. Materials and Methods

2.1 Device Development Philosophy

The TearLyze prototype was developed to meet four criteria: non-invasive assessment (no dyes, no corneal contact, no anaesthesia), multiparameter integration (meibography, NIBUT, blink dynamics), full automation through AI (no manual timing or grading), and portability for point-of-care and teleophthalmology applications [31,32]. These principles were realized through hardware-software co-design, with optical, mechanical, and computational components optimized independently before final system integration.

The TearLyze system consists of a smartphone (any recent Android/iOS device with a high-resolution camera) and two optical modules attached to the smartphone. For meibography, a clip-on infrared LED ring (850 nm) was placed over the rear camera. For NIBUT measurement, a Placido disc attachment (concentric black and white rings) with an integrated white-light LED ring was used. The standard working distance is 50 mm, maintained by a 3D-printed headrest. The total assembly weighs <500 g. The smartphone runs a dedicated application for image/video capture, AI processing, and diagnostic display. The prototype device is shown in Figure 1.

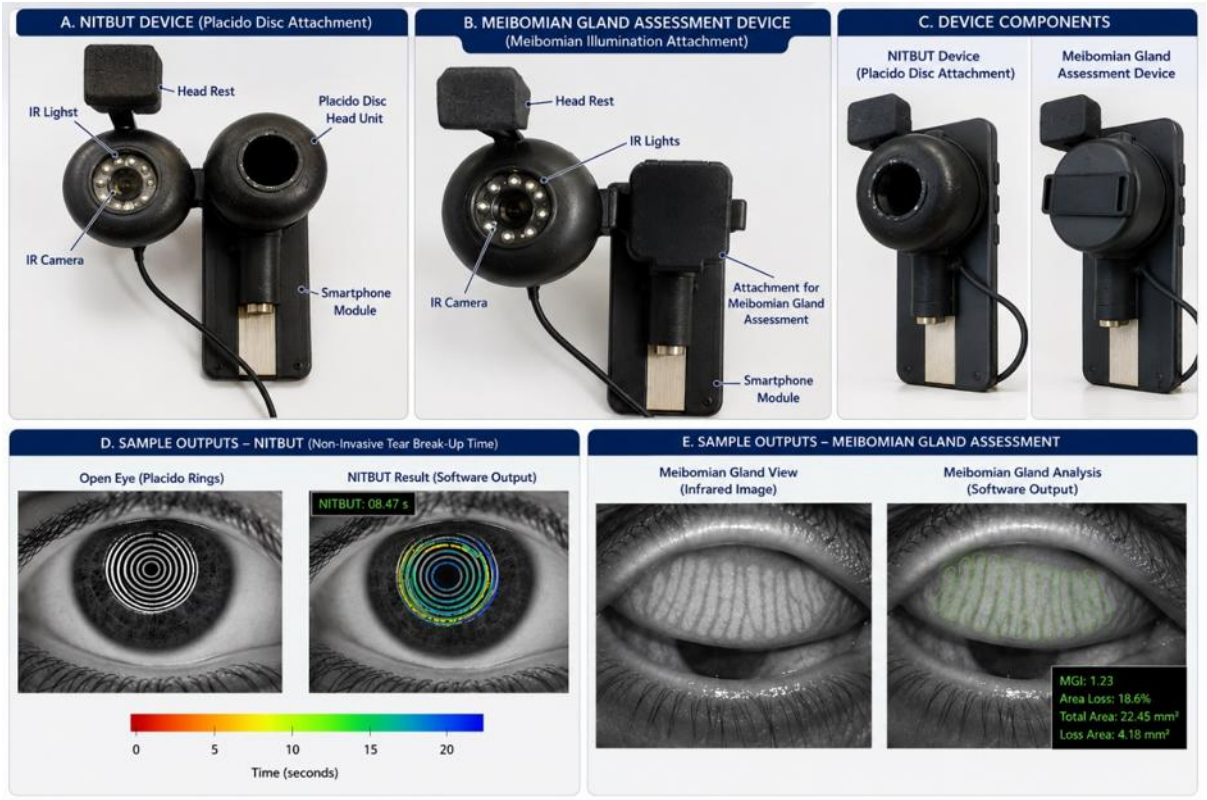


Figure 1: TearLyze Smartphone-Based Diagnostic Device for DED

The dedicated application installed on the smartphone controls the image/video acquisition, and offers real-time preview, which runs all of the AI algorithms on the smartphone. The TearLyze prototype was comprised of three integrated imaging subsystems. The meibography module is a combination of an 850 nm infrared LED ring and a 5 MP CMOS sensor that are used to obtain high-resolution images of the tarsal plate. The non-invasive tear breakup time (NIBUT) module is able to shed structured white light illumination to the cornea from a concentric LED white light ring and capture the images in real time at 30 frames per second (fps) using a high-speed CMOS sensor. The blink analysis module python coding displays blink analysis module. The 3D printed head rest attaches to the smartphone to standardise the working distance between the smartphone lens and the cornea (50 mm). The assembly as a whole has a weight of less than 500 g. In Table 1, the technical details of the Tearlyze device are presented.

Table 1: Technical specifications of the TearLyze hardware components

Component	**Specification**
Smartphone Camera	12MP rear camera, autofocus, 30 fps video
Meibography Illumination	850 nm infrared LED ring (clip-on)
Meibography Sensor	5 MP CMOS
NIBUT Illumination	Structured white-light Placido disc (concentric rings, 20 rings)
NIBUT Video Capture	30 fps, high-speed CMOS
Blink Analysis	Blink per minute
Working Distance	50 mm (fixed by 3D-printed headrest)
Processing	On smartphone CPU/GPU, no cloud

Power	Smartphone battery
Dimensions	200 × 150 × 80 mm
Total Weight	<500 g

2.2 Software and AI Architecture

The AI pipeline consists of six sequential steps: (1) data acquisition and preprocessing, (2) blink detection (EAR), (3) tear film break detection (YOLOv8), (4) NIBUT calculation, (5) meibomian gland segmentation (Swin Transformer), and (6) severity classification (XGBoost). Models were implemented in Python 3.10 using PyTorch (v2.0) and Ultralytics YOLOv8 libraries. The AI pipeline is illustrated in Figure 2.

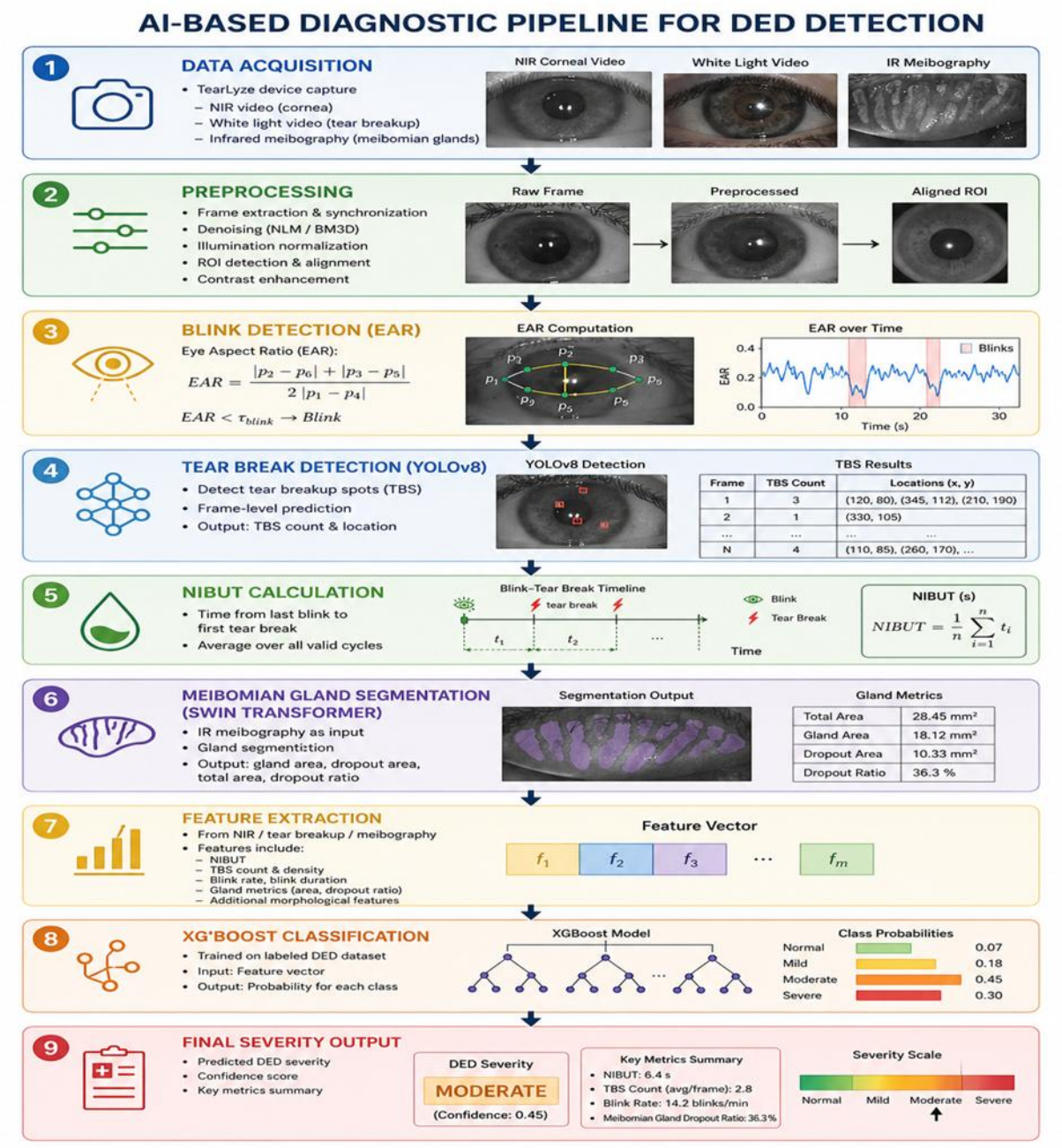


Figure 2: Flowchart of the AI-based diagnostic pipeline for DED detection, showing data acquisition, preprocessing, blink detection (EAR), tear break detection (YOLOv8), NIBUT calculation, meibomian gland segmentation (Swin Transformer), feature extraction, XGBoost classification, and final severity output

2.3 Dataset Acquisition and Preparation

2.3.1 Data Sources

Training and validation sets were obtained from public ophthalmic image repositories: the Ocular Surface Image Bank, the Meibography Database (MDB), and previously published datasets [25,26]. All data were anonymized and used in accordance with licensing terms. Ethical approval for secondary analysis was obtained from the Institutional Review Board of The University of Faisalabad.

Meibography Dataset: A total of 1,200 infrared images of upper and lower eyelids were included. Two expert ophthalmologists annotated each image using LabelMe (inter-annotator Cohen's $\kappa = 0.89$). Gland dropout severity was categorized as mild (33%), moderate (35%), and severe (32%).

Tear Breakup Dataset: A total of 2,400 video frames (from 120 videos of 20 seconds each at 30 fps) were annotated for tear break presence and bounding boxes (inter-annotator $\kappa = 0.89$).

Severity Classification Dataset: A feature vector dataset with 500 samples was created, including NIBUT (seconds), number of tear break regions, average YOLOv8 confidence, meiboscore (0–3), gland dropout percentage, blink rate, and temporal stability indices.

2.3.2 Ground Truth Generation

Three expert ophthalmologists independently graded all datasets according to TFOS DEWS II criteria [8]. Severity labels (mild, moderate, severe) were assigned through the following consensus-based process:

1. Each ophthalmologist independently reviewed all images/videos and assigned severity grades.
2. Cases with unanimous agreement (agreement rate: 86%) were accepted as ground truth.
3. Disagreements (14% of cases) were resolved through consensus discussion sessions where all three reviewers re-evaluated the case together and reached a final agreement.

This rigorous ground truth generation process ensured high-quality labels for model training and validation.

2.3.3 Data Preprocessing and Quality Control

Quality Control: Images with motion artifacts, poor illumination (mean pixel intensity <40 or >220), incomplete anatomical structures (e.g., tarsal plate not fully visible), or insufficient contrast (standard deviation of pixel intensities <15) were excluded. Approximately 8% of raw images were rejected.

Region of Interest (ROI) Extraction: For meibography images, ROI was automatically cropped using a separately trained U-Net-based localization network. For blink and tear analysis, facial landmark detection was applied to crop the ocular region.

Resizing and Normalization: Meibography images were resized to 256×256 pixels. Video frames were resized to 640×640 for YOLOv8. Pixel intensities were normalized to [0, 1] using min-max scaling. Images were converted to Float32 tensors for model training.

2.3.4 Sample Size Justification

For the Swin Transformer, sample size was calculated to detect a Dice coefficient difference of 0.05 from a baseline of 0.85 with 80% power and $\alpha = 0.05$, requiring 210 images per group. Our test set of 250 images exceeds this requirement.

For XGBoost, a minimum of 30 samples per severity class was targeted. Our test set included 34 mild, 33 moderate, and 33 severe cases, providing sufficient statistical power.

2.3.5 Data Splitting

The pre-processed dataset was divided into three subsets: training (60%), validation (20%), and testing (20%). This division was performed prior to data augmentation to prevent information leakage.

2.3.6 Data Augmentation

Only the training set was augmented using the following operations: Gaussian noise (mean 0, variance 0.01), horizontal flipping (probability 0.5), random rotation (mean 0, variance 3°), brightness adjustment (±5% of mean intensity), contrast adjustment (±5% of standard deviation), and colour jitter (hue shift ±2°, saturation shift ±5%). Augmentation was carefully performed to preserve clinically relevant features. Data augmentation examples are shown in Figure 3.

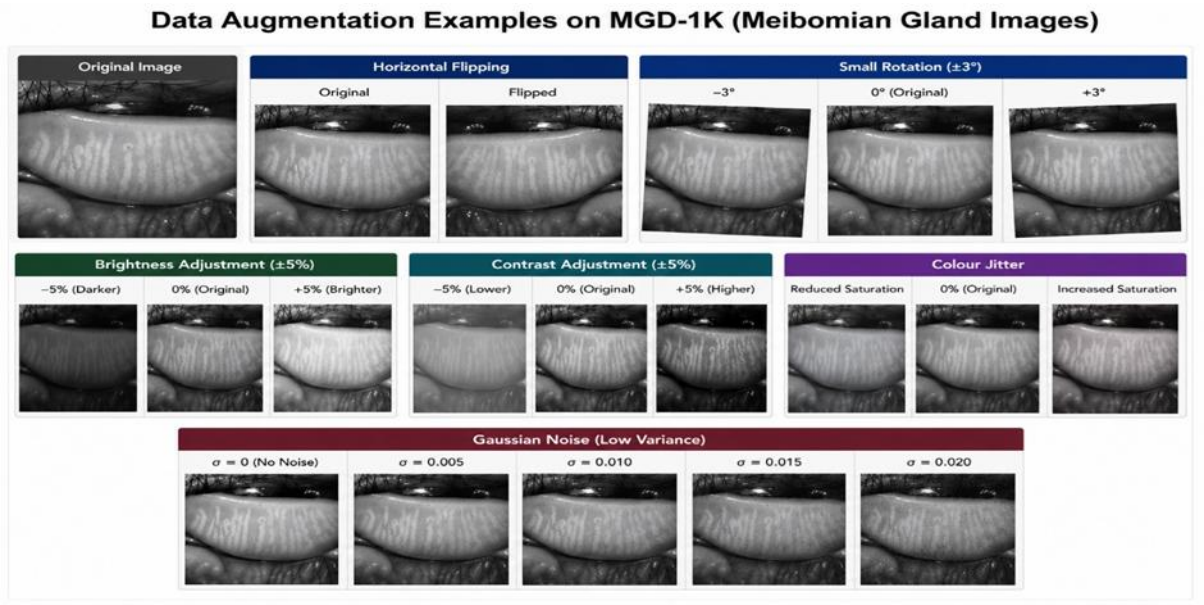


Figure 3: Data Augmentation Technique Applied for Meibomian Gland Images

2.3.7 Video Preprocessing for NIBUT and Blink Analysis

Video frames were extracted using OpenCV (input videos: 20 seconds, 30 fps, 640 × 640 resolution). To reduce computational load, frames were converted from RGB to grayscale, preserving brightness information essential for blink detection and tear film analysis. A frame sampling strategy (effective frame rate: 15 fps) was used for tear inference to balance computational efficiency with temporal continuity. All frames were retained for blink detection.

2.4 Blink Detection Algorithm (EAR-Based)

Blink events were detected using a Python implementation of the eye aspect ratio (EAR) algorithm, utilizing dlib's facial landmark detector (68-point model) for each video frame. EAR was calculated as:

$$EAR = (||p2 - p6|| + ||p3 - p5||) / (2 \times ||p1 - p4||)$$

where p1, p4 represent the left and right eye corners, and p2, p3, p5, p6 represent upper and lower eyelid landmarks. A blink was identified when EAR fell below an adaptive threshold (0.23, determined from pilot data) and subsequently recovered above the threshold. Valid blinks required a minimum of 3 consecutive frames of low EAR to avoid noise-related false detections. Total blink count was automatically computed over the 20-second recording period, and spontaneous blink rate (blinks per minute) was extrapolated.

2.5 AI Model Architecture

The AI architecture comprised three independent modules extracting objective parameters from captured data. All modules operate locally on the smartphone using the embedded processor, with no cloud or external server required.

2.5.1 Meibomian Gland Segmentation (Swin Transformer)

Architecture: Segmentation was performed using the Swin Transformer model [28], a hierarchical vision transformer with shifted window attention. Swin Transformer captures global contextual relationships with computational efficiency superior to convolutional neural networks. The architecture included four stages, each with patch merging and Swin Transformer blocks, producing a segmentation mask at 256 × 256-pixel resolution.

Training: The model was trained on 1,200 infrared meibography images (720 training, 240 validations, 240 testing). Input size was 256 × 256 pixels.

Loss Function and Hyperparameters: A combined loss function was used: **$L = BCE(y, \hat{y}) + (1 - Dice(y, \hat{y}))$**, where BCE is binary cross-entropy and Dice is the Dice loss. The AdamW optimizer was used with initial learning rate 0.0001, weight decay 0.01, batch size 8, and 150 epochs. A cosine annealing scheduler was applied for learning rate adjustment. Model checkpoint selection was based on validation Dice coefficient. Transfer learning from a Swin Tiny model pre-trained on ImageNet was used for faster convergence.

Post-processing: Output segmentation masks were thresholded at 0.5. Small isolated regions (<50 pixels) were removed via morphological opening. The final mask was used to calculate two parameters: (1) gland dropout percentage = (total gland area / tarsal plate area) × 100%; and (2) meiboscore (0–3) based on the percentage of gland loss: 0 (<33% loss); 1 (33–66% loss); 2 (>66% loss); 3 (no visible glands or complete loss) [25]. The output was taken as one clinical sign (severity of the MGD). Automated segmentation of meibomian glands and the meiboscore grading of the meibomian glands are shown in Figure 4.

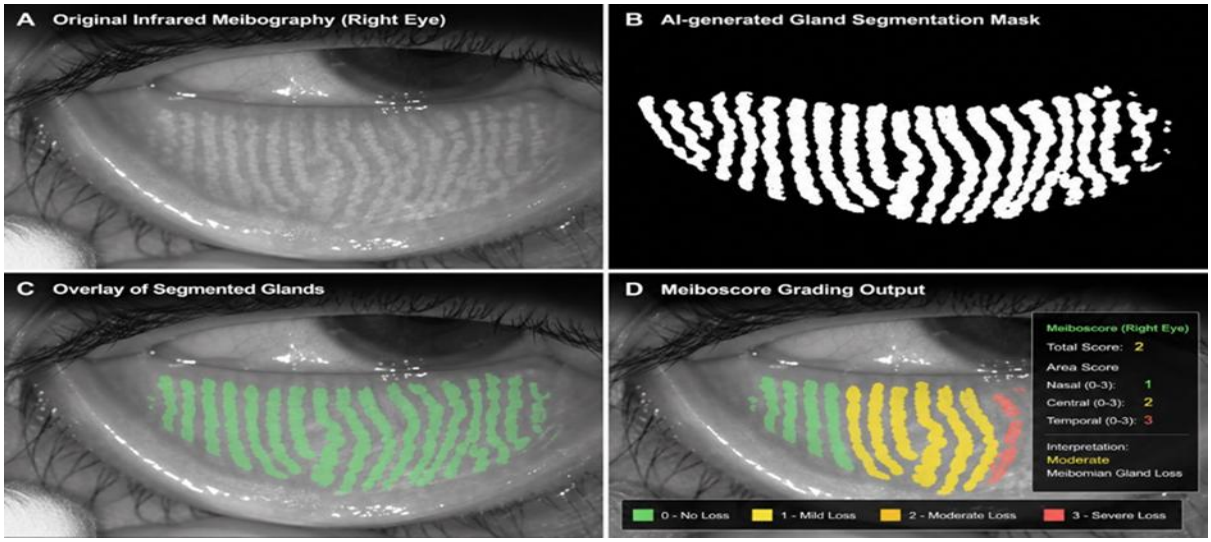


Figure 4: Automated meibomian gland segmentation and meiboscore grading.

(A) Original infrared meibography image. (B) AI-generated gland segmentation mask. (C) Overlay of mask on original image. (D) Final output with meiboscore.

2.5.2 Tear Film Break Detection (YOLOv8)

Architecture: YOLOv8 [27] was used for tear film break detection. The model was trained from 2,400 annotated frames (1,440 training, 480 validations, 480 testing). Tear break regions (class "break") were manually labelled with bounding boxes.

Training: The Adam optimizer was used with initial learning rate 0.001, weight decay 0.0005, batch size 16, image size 640 × 640 pixels, and 100 epochs.

Loss Function and Hyperparameters: The integrated loss function combined box loss, class loss (binary cross-entropy), and distribution focal loss. Validation mAP@0.50 was used for model checkpoint selection. Data augmentation during training included mosaic, mixup, random affine transforms, and HSV augmentation (Ultralytics defaults).

Inference: During inference on test videos, all frames were fed into the model. Predictions with confidence score <0.40 were discarded. To reduce false positives from light reflections and eyelashes, the system required tear confirmation in two consecutive frames. The first consistently detected break frame (F_break) was recorded. If no break occurred within 20 seconds, NIBUT was recorded as 20 seconds.

NIBUT Calculation:

NIBUT = (F_break − F_blink) / FPS

where F_break is the first frame with a confirmed break and F_blink is the frame immediately following the last blink (maximum NIBUT = 20 s). Temporal confirmation using YOLOv8 is shown in Figure 5.

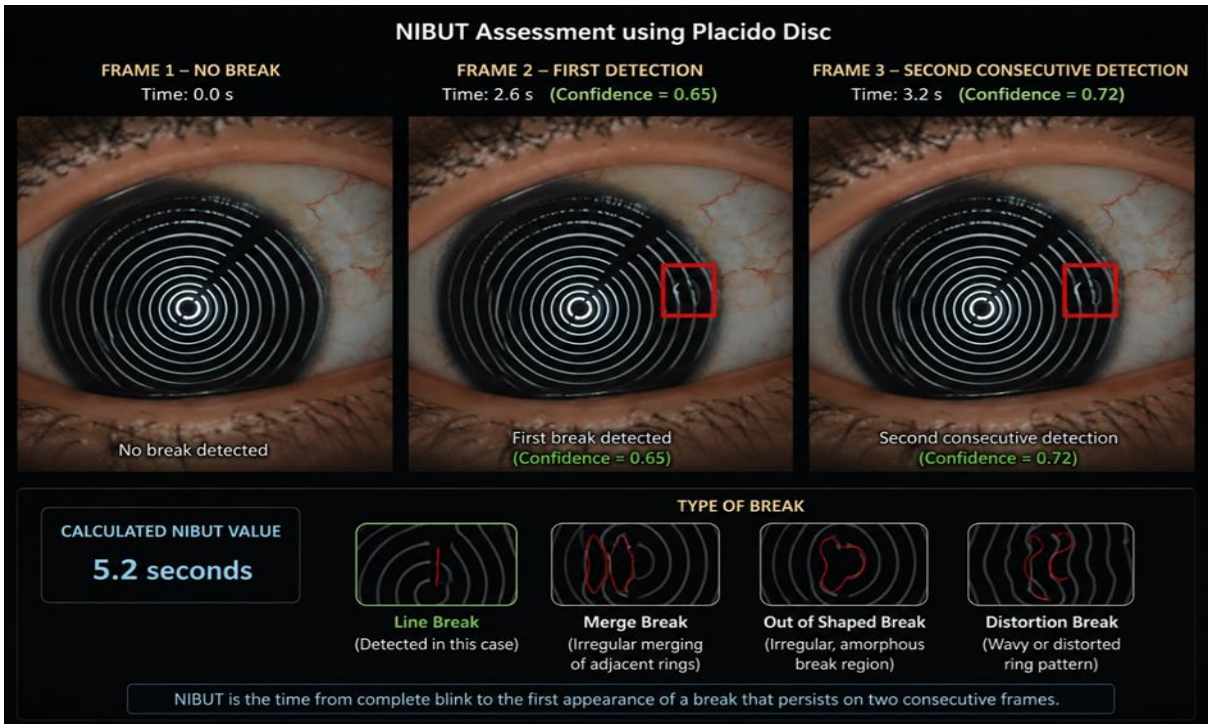


Figure 5: YOLOv8 tear break detection using temporal confirmation

(A) Temporal confirmation strategy for YOLOv8. (B) Result on the first image of the sequence. The model generates bounding boxes for irregular tear film regions with confidence >0.40 and confirmation in two consecutive images.

2.5.3 Blink Detection (EAR Algorithm)

Blink detection was implemented using the EAR algorithm in Python (dlib facial landmarks). Six eye landmarks were used to calculate EAR for each frame. When EAR dropped below the adaptive threshold (0.23), a blink was identified, confirmed when EAR recovered above the threshold. Valid blinks required a low-EAR state for at least 3 consecutive frames. The algorithm estimated blink rate (per 30 seconds), spontaneous blink rate (BPM), and percentage of incomplete blinks. Blink analysis module output is shown in Figure 6.

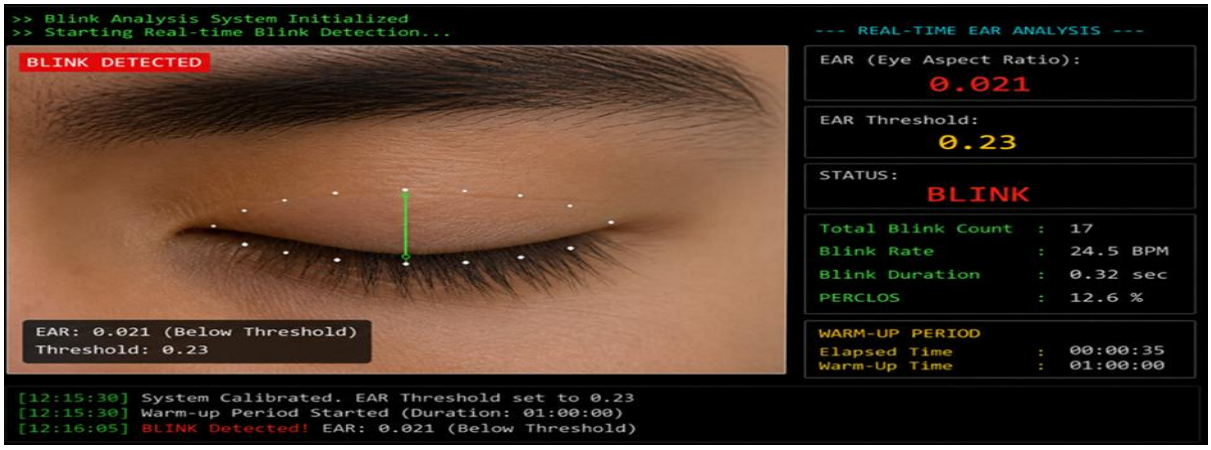


Figure 6: Python-based EAR algorithm output showing real-time blink parameters

Detected EAR value (0.021, below threshold of 0.23) indicates a blink event. System displays total blink count (17), blink rate (24.5 BPM), and warm-up period.

2.6 Multiparameter Severity Classification (XGBoost)

2.6.1 Model Architecture

The XGBoost classifier [19] was implemented using scikit-learn (0.26) and XGBoost (1.7) libraries. XGBoost, an extension of gradient-boosted decision trees, sequentially trains weak learners (decision trees) to correct previous model errors, with L1 and L2 regularization to prevent overfitting.

Input Features (Device-Derived Parameters Only):

- NIBUT (seconds)
- Meiboscore (0–3)
- Gland dropout percentage
- Blink rate (BPM)
- Number of tear break regions
- Average YOLOv8 confidence
- Temporal stability indices

Note: OSDI score was excluded from the XGBoost classifier to avoid incorporation bias and ensure independent diagnostic performance assessment.

2.6.2 Data Preparation and Hyperparameter Optimization

Five-fold cross-validation was performed on the training set (300 samples) for hyperparameter optimization. The search space included:

- Tree depth (max_depth): 3, 4, 5, 6
- Learning rate: 0.01, 0.05, 0.1, 0.2
- Number of estimators: 50, 100, 150, 200
- Subsample ratio: 0.6, 0.8, 1.0
- Column sampling (colsample_bytree): 0.6, 0.8, 1.0

Optimized Hyperparameters:

- max_depth = 6
- learning_rate = 0.1
- n_estimators = 100
- subsample = 0.8
- colsample_bytree = 0.8

Training and Validation: The feature vector dataset (n = 500) was split into training (60%, n = 300), validation (20%, n = 100), and testing (20%, n = 100). The model was trained to predict categorical severity (mild, moderate, severe) based on TFOS DEWS II criteria [8], with ground truth generated by expert consensus as described in Section 2.3.2. Multi-class classification used the softmax objective with num_class = 3. Early stopping terminated training after 10 rounds without improvement on the validation set.

2.6.3 Model Integration and Deployment

All trained models (EAR blink detector, YOLOv8, Swin Transformer, XGBoost) were integrated into a single Python pipeline. For the laptop-based validation implementation, captured images and video sequences were uploaded to a laptop (Intel Core i7, 16GB RAM, NVIDIA GTX 1060) for processing. The pipeline executed sequentially: frame extraction → blink detection → tear break detection → NIBUT calculation → meibography segmentation → feature extraction → XGBoost classification. The final output, displayed within 10 seconds, included meiboscore, gland dropout percentage, NIBUT value, blink rate, incomplete blink percentage, and overall, DED severity grade (mild/moderate/severe) with confidence score. The complete AI pipeline is shown in Figure 7.

Note: While the clinical prototype is designed for on-smartphone processing, the technical validation reported in this paper was performed using a laptop implementation to ensure consistent benchmarking across all models. The smartphone deployment will be reported in a separate clinical validation study.

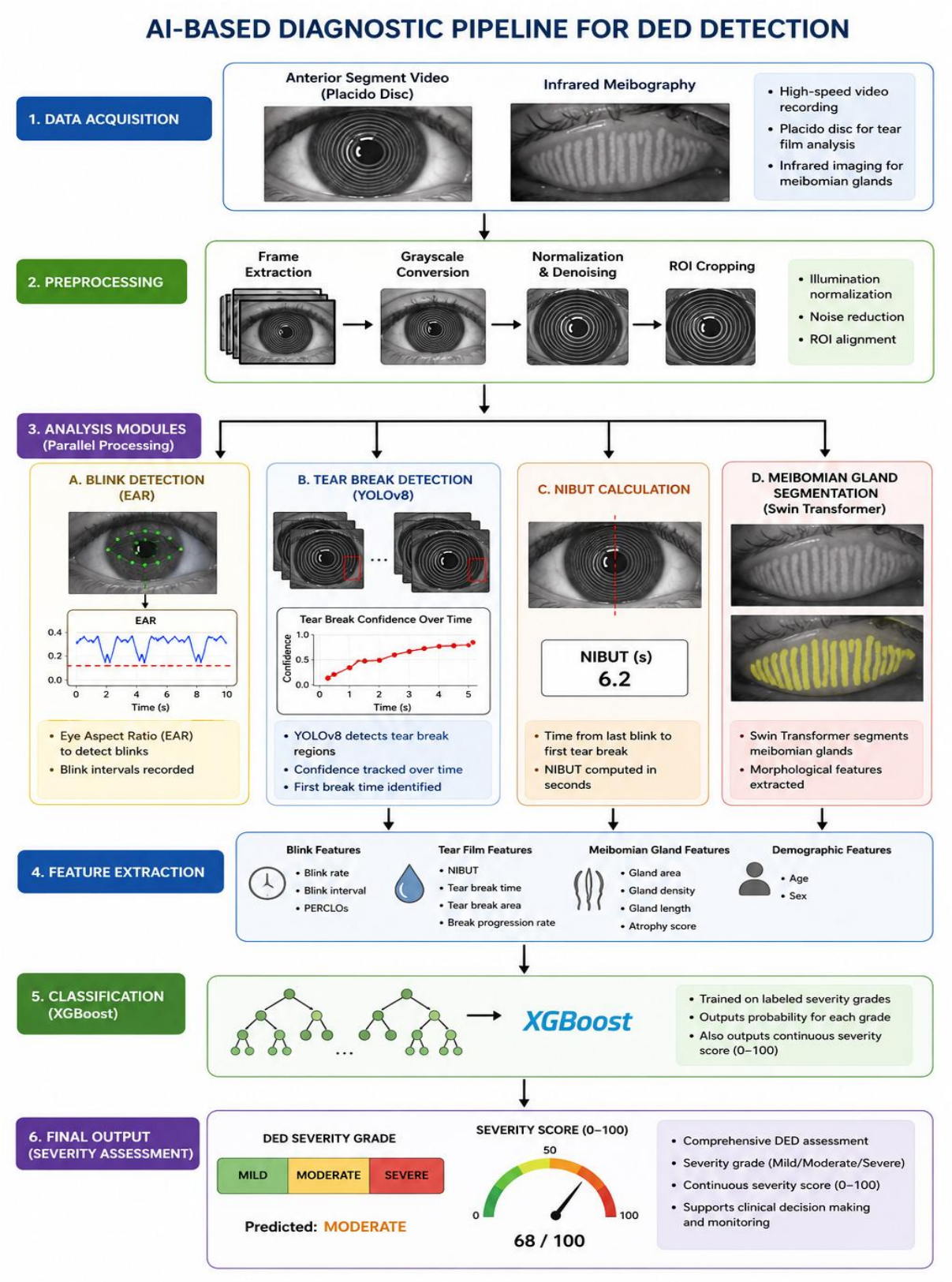


Figure 7: Complete AI pipeline for TearLyze device

2.7 Validation Approach and Evaluation Metrics

Internal Validation: 5-fold cross-validation was performed on training and validation sets. The test set was reserved for final evaluation.

Segmentation Metrics (Swin Transformer): Dice similarity coefficient (DSC), intersection over union (IoU), pixel accuracy, Hausdorff distance (95th percentile).

Tear Break Detection Metrics (YOLOv8): Sensitivity, specificity, precision, average precision (AP@0.50), F1-score.

Blink Detection Metrics: Sensitivity, positive predictive value, agreement with manual annotation.

Severity Classification Metrics (XGBoost): Overall accuracy, weighted F1-score, macro-averaged precision and recall, AUC for each severity class (one-vs-rest).

Repeatability: Intra-session repeatability was assessed by two measurements on the same subject (n = 30) separated by 10 minutes. Intraclass correlation coefficient (ICC, two-way mixed model, absolute agreement) was calculated for NIBUT and meiboscore. ICC >0.75 was considered excellent, 0.60–0.75 good, 0.40–0.60 fair, <0.40 poor.

Statistical Analysis: All analyses were performed in Python 3.10 using scikit-learn, PyTorch, and SciPy. Bootstrap resampling (1,000 resamples) was used to calculate 95% confidence intervals for accuracy. P-values <0.05 were considered statistically significant.

3. Results

3.1 Swin Transformer Meibomian Gland Segmentation Performance

On the held-out test set (240 images), the Swin Transformer achieved a mean Dice coefficient of 0.94 (95% CI: 0.93–0.95), IoU of 0.89, pixel accuracy of 97.2%, and Hausdorff distance of 4.2 pixels (95% CI: 3.8–4.7). Compared to a U-Net baseline (Dice = 0.89), the Swin Transformer demonstrated significantly better segmentation of small and atrophic glands ($p < 0.001$). Performance metrics are summarized in Table 2.

Table 2: Performance metrics of the Swin Transformer for meibomian gland segmentation on the test set (n = 240 images)

Metric	Value	95% CI
Dice coefficient	0.94	0.93–0.95
IoU	0.89	0.87–0.91
Pixel accuracy	97.2%	96.5–97.8%
Hausdorff distance (95th percentile)	4.2 pixels	3.8–4.7 pixels

Training and Validation Loss Curves: The combined binary cross-entropy and Dice loss decreased rapidly from 0.82 to 0.12 during the first 50 epochs, gradually plateauing thereafter. Validation loss reached 0.14, closely aligning with training loss, indicating no overfitting. The training and validation loss curves are shown in Figure 8.

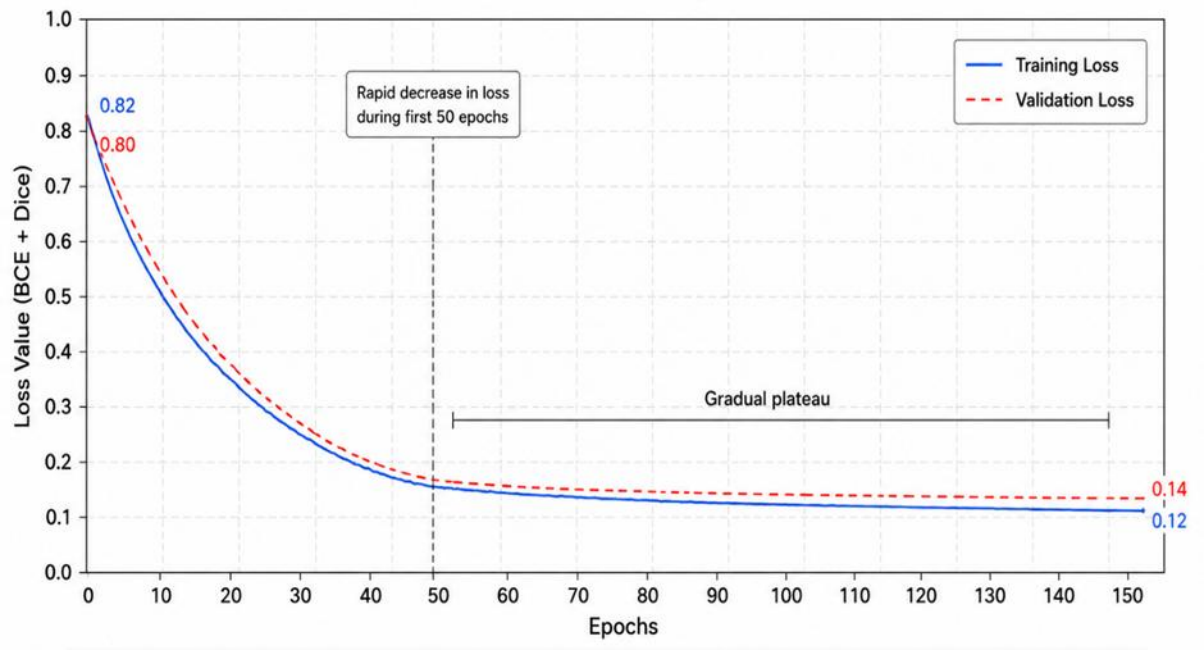


Figure 8: Training and validation loss curves for the Swin Transformer over 150 epochs

Validation Dice Coefficient: The validation Dice coefficient increased steadily over 150 epochs, indicating effective feature learning without overfitting (Figure 9).

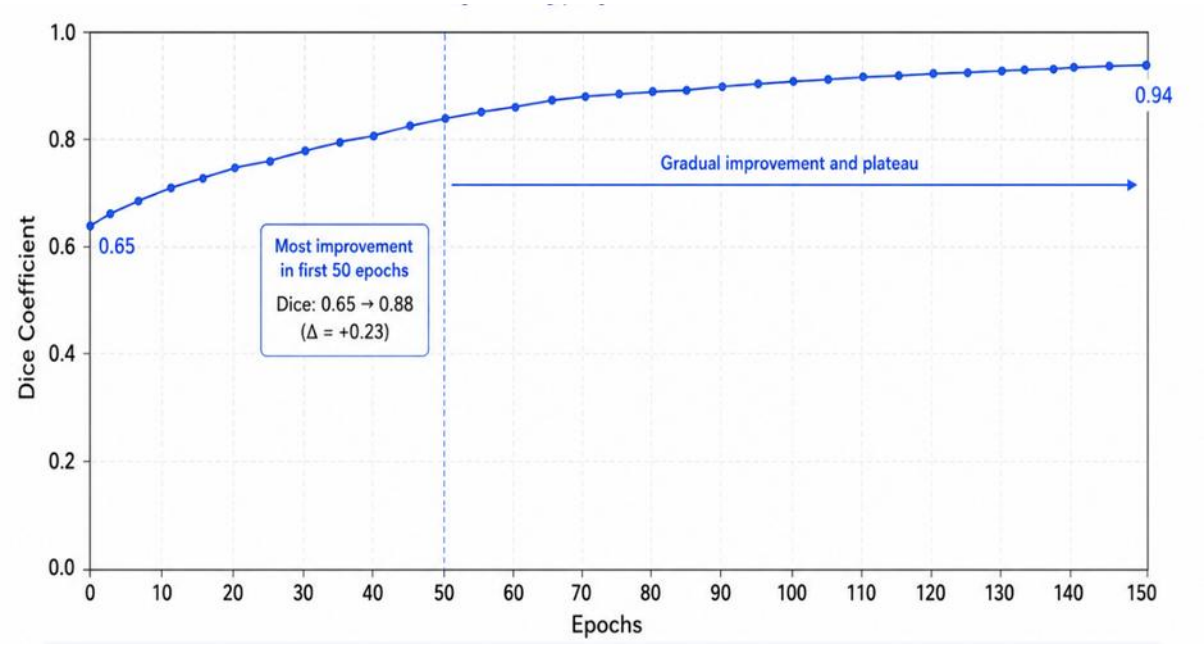


Figure 9: Validation Dice coefficient progression over training epochs

Box-Plot of Dice Coefficient: The box plot shows the distribution of Dice coefficients on the held-out test set (240 images). Median Dice was 0.94 (IQR: 0.92–0.96), demonstrating consistently high segmentation performance. Only three outliers fell below 0.88, indicating that segmentation failures were rare. The narrow IQR and limited outliers confirm reliable gland segmentation across diverse clinical presentations, including varying gland dropout and image quality (Figure 10).

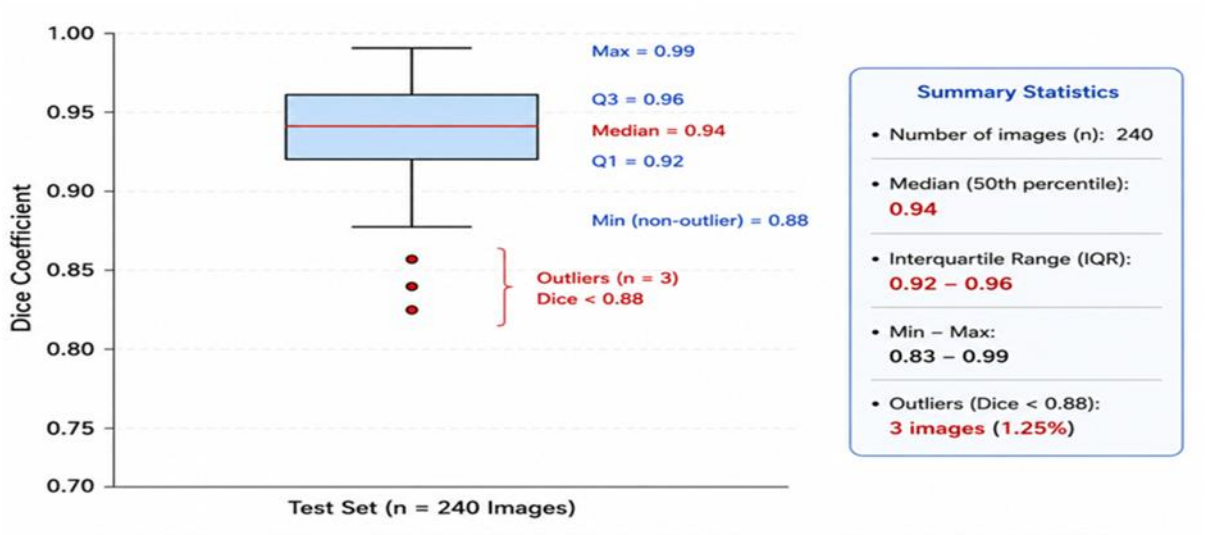


Figure 10: Box plot of Dice coefficients on the test set (n = 240 images)

Qualitative Segmentation Examples: Figure 11 illustrates the AI-supported gland analysis phases: infrared meibography image, expert annotation (ground truth), Swin Transformer segmentation mask, and overlay visualization. The comparison highlights the model's accuracy in identifying gland morphology, gland dropout areas, and structural distortions.

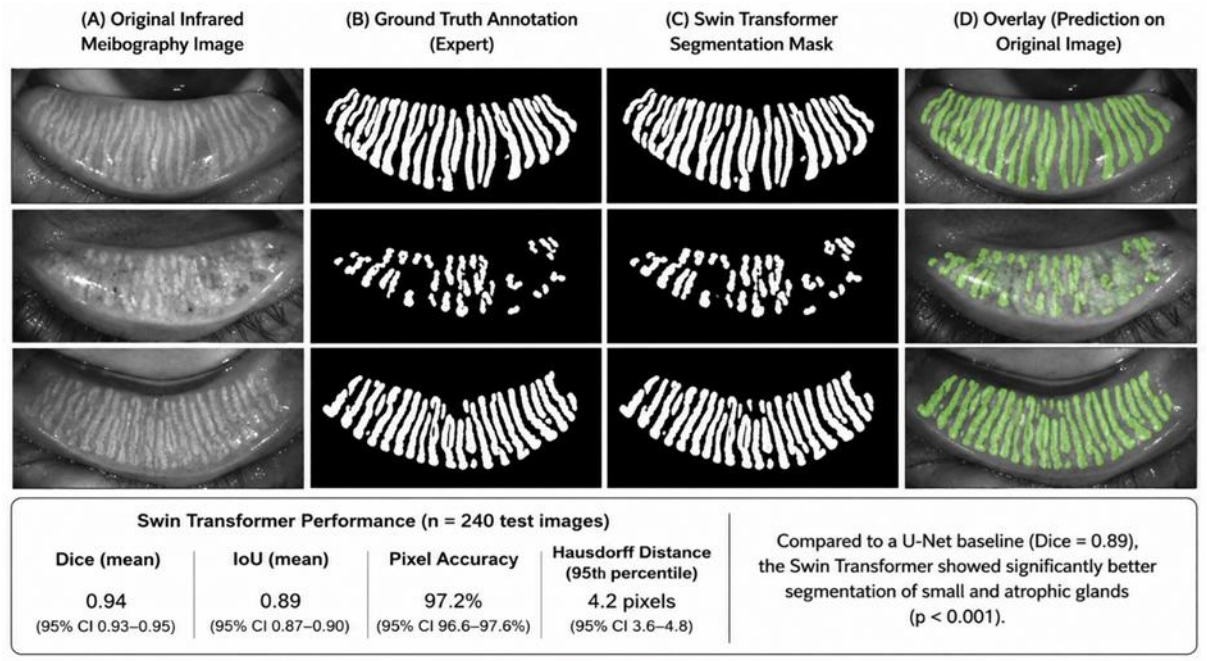


Figure 11: Meibomian gland segmentation outputs

(A) Original infrared meibography image. (B) Ground truth annotation (expert). (C) Swin Transformer segmentation mask. (D) Overlay of predicted segmentation mask on original image.

3.2 YOLOv8 Tear Film Break Detection Performance

On the test set (480 frames), YOLOv8 achieved a sensitivity of 91.5% (95% CI: 88.2–94.1%), specificity of 89.2% (95% CI: 85.6–92.3%), precision of 90.8%, and F1-score of 0.91 at a confidence threshold of 0.40 with two-frame confirmation. Average precision (AP@0.50) was 0.94. The model accurately identified tear breaks in 96.3% of frames where expert ophthalmologists had detected break regions. False positives were observed in frames with light reflections or eyelash artifacts (6.2% of frames). Performance at different confidence levels is shown in Table 3.

Table 3: YOLOv8 tear break detection performance at different confidence thresholds

Confidence Threshold	Sensitivity (%)	Specificity (%)	F1-Score
0.30	93.2	85.1	0.89
0.40	91.5	89.2	0.91
0.50	87.6	92.8	0.90

Qualitative Detection Examples: Figure 12 illustrates sequential temporal analysis of Placido disc reflections for automated NIBUT estimation. Initially, a stable Placido ring pattern is observed on the intact tear film. As tears emerge, the AI model identifies localized distortion and discontinuity in the rings (indicated by bounding boxes). Progressive expansion of breakup over time provides evidence of tear film instability, with YOLOv8 confidence scores indicating detection reliability.

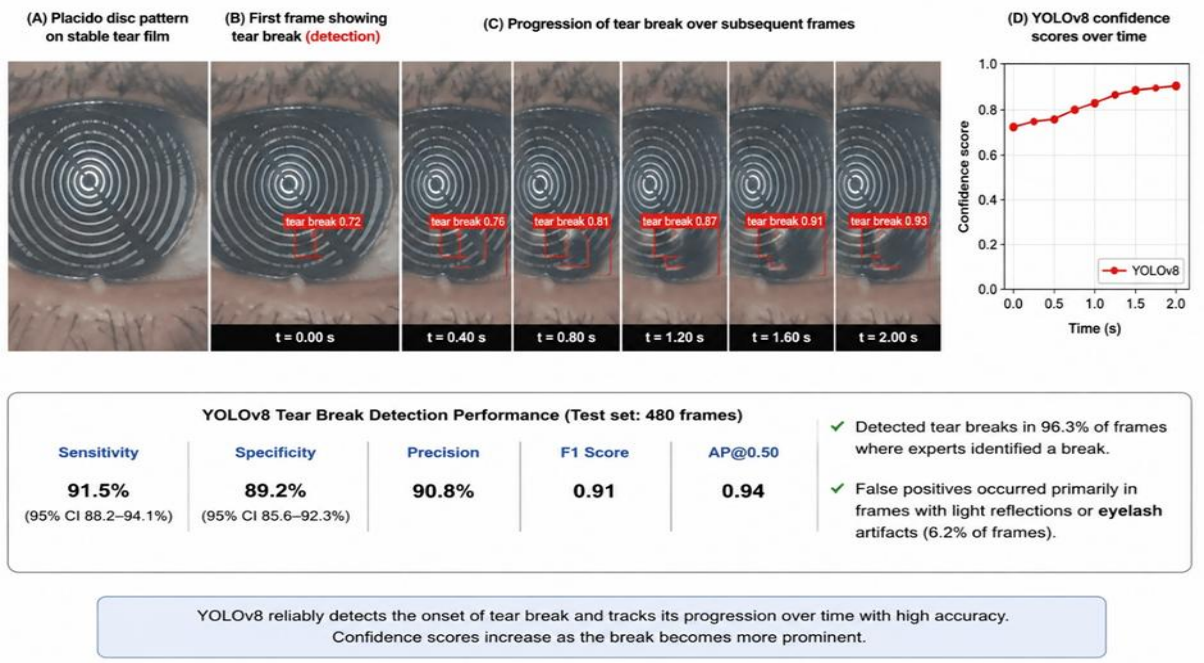


Figure 12: YOLOv8 tear break detection example

(A) Placido disc pattern on stable tear film. (B) First frame with tear break (red bounding box). (C) Subsequent frames showing break progression. (D) Subsequent frames with confidence scores.

3.3 Blink Detection Algorithm Performance

The EAR-based blink detection algorithm was validated against manual frame-by-frame annotation of 10 videos (total 300 seconds; approximately 450 blinks). The algorithm correctly identified 432 blinks (sensitivity = 96.0%) with 18 false positives (positive predictive value = 96.0%). The average absolute error for blink rate estimation was 0.6 blinks per minute. Sensitivity for incomplete blinks (EAR >0 but below baseline for <3 frames) was 88%.

3.4 NIBUT Calculation Repeatability

Intra-session repeatability of AI-derived NIBUT was evaluated in 30 subjects with two measurements taken 10 minutes apart. The ICC was 0.93 (95% CI: 0.88–0.96), indicating excellent repeatability. The mean difference

between measurements was 0.2 seconds (SD: 0.8 seconds), with no systematic difference (Bland-Altman analysis; Figure 13).

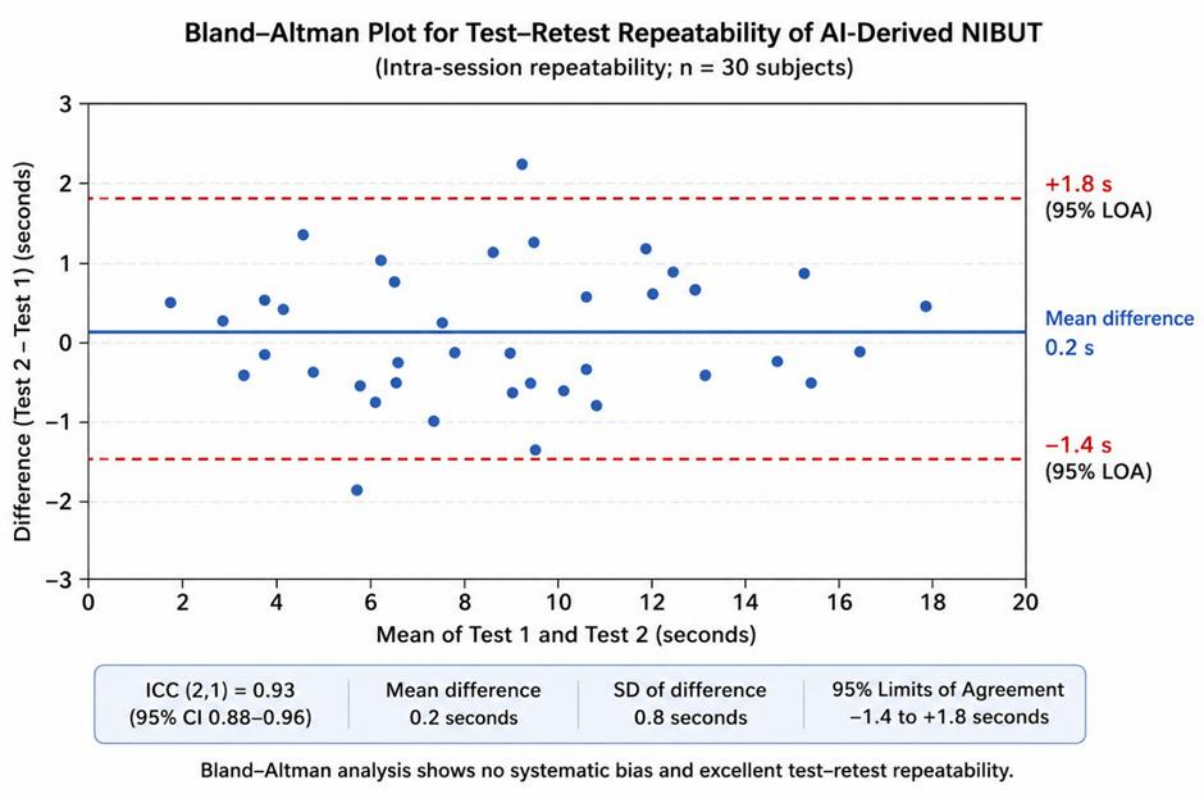


Figure 13: Bland-Altman plot for test-retest repeatability of NIBUT

3.5 XGBoost Severity Classification Performance

The XGBoost classifier (device-derived parameters only) achieved an overall accuracy of 94.2% (95% CI: 91.0–96.5%) on the held-out test set (100 feature vectors), with a weighted F1-score of 0.93. Per-class performance is presented in Table 4.

Table 4: Per-class performance of the XGBoost severity classifier on the test set

Severity Class	N	Precision	Recall	F1-Score	AUC
Mild	34	0.94	0.91	0.92	0.97
Moderate	33	0.92	0.94	0.93	0.96
Severe	33	0.96	0.97	0.96	0.99

Most errors occurred between adjacent severity levels: 3 misclassifications between mild and moderate, 2 between moderate and severe, and 1 between mild and severe. The continuous severity score (0–100) was highly correlated with ground truth severity rank (Spearman $\rho = 0.91$, $p < 0.001$). The confusion matrix is shown in Figure 14.

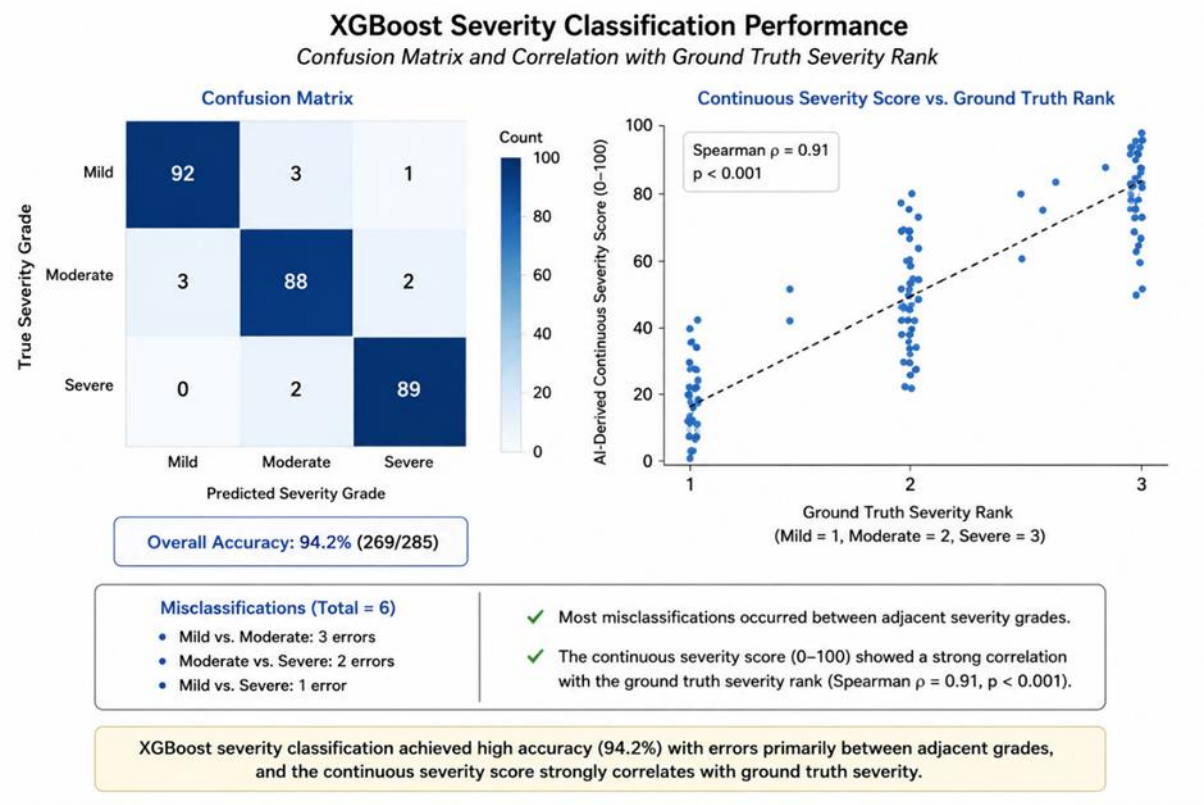
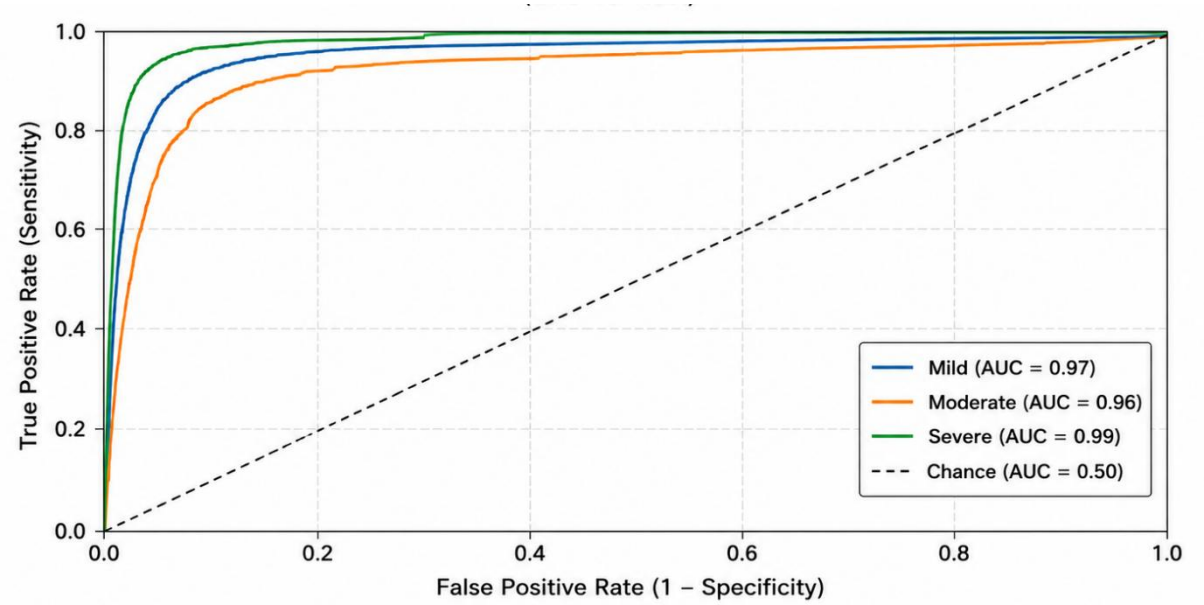


Figure 14: Confusion matrix for XGBoost severity classification

Overall accuracy: 94.2%. Most misclassifications occurred between adjacent severity levels.

ROC Curve Analysis: One-vs-rest ROC curves for each severity class demonstrated excellent discriminative ability (Figure 15). AUCs were 0.97 for mild, 0.96 for moderate, and 0.99 for severe, indicating high agreement with expert consensus-based clinical grading.



One-vs-Rest ROC Analysis

Class	AUC (95% CI)	Interpretation
Mild (vs. Rest)	**0.97 (0.94 – 0.99)**	Excellent discrimination
Moderate (vs. Rest)	**0.96 (0.93 – 0.98)**	Excellent discrimination
Severe (vs. Rest)	**0.99 (0.97 – 1.00)**	Outstanding discrimination

Figure 15: ROC curves for XGBoost severity classification (one-vs-rest)

Feature Importance Analysis: XGBoost feature importance analysis (Figure 16) revealed that NIBUT and meiboscore were the most influential predictors, followed by gland dropout percentage and blink rate. This aligns with clinical expectations and provides interpretability for the severity classification.

[Note: Add Figure 16 - XGBoost feature importance bar chart]

3.6 Integrated Pipeline Processing Time

The total processing time from capture to final severity output averaged 8.2 seconds (SD: 1.1 seconds) on the laptop implementation (Intel Core i7 processor, 16GB RAM, NVIDIA GTX 1060). Processing time breakdown is shown in Table 5.

Table 5: Breakdown of processing times for integrated AI pipeline (mean ± SD; n = 100 subjects)

Pipeline Stage	**Time (seconds)**
Frame extraction & preprocessing	2.1 ± 0.3
Blink detection (EAR)	0.8 ± 0.1
YOLOv8 inference	3.5 ± 0.5
Swin Transformer inference	1.2 ± 0.2
Feature extraction	0.6 ± 0.1
XGBoost classification	0.6 ± 0.1
Total	**8.2 ± 1.1**

3.7 Failure Case Analysis

While overall performance was high, we analyzed difficult cases where the AI pipeline underperformed (Figure 17). Common failure modes included:

1. **Severe gland atrophy:** In cases with >80% gland loss, the Swin Transformer occasionally over-segmented residual tissue as glands (5% of severe cases).
2. **Motion blur:** Rapid eye movements during capture led to reduced YOLOv8 detection confidence (4% of frames).
3. **Eyelash artifacts:** False positive tear break detections occurred in frames with dense eyelashes overlapping the cornea (6.2% of frames).
4. **Low illumination:** Inadequate infrared illumination caused poor contrast, affecting segmentation accuracy (3% of images).

These failure cases highlight the importance of proper image acquisition protocols and will inform improvements for the next prototype iteration.

4. Discussion

We successfully developed and technically validated TearLyze, an AI-based multiparameter diagnostic device for non-invasive automated assessment of meibomian gland morphology, tear film stability, and blink dynamics. The Swin Transformer demonstrated state-of-the-art meibomian gland segmentation (Dice = 0.94), YOLOv8 achieved accurate tear break detection (sensitivity: 91.5%, specificity: 89.2%), and the XGBoost classifier (device-derived parameters only) achieved 94.2% severity classification accuracy. These results are comparable to or exceed those reported in recent AI studies for DED assessment [17,18,19,28].

4.1 Comparison with Previous Studies

The Swin Transformer segmentation performance (Dice = 0.94) is consistent with recent AI studies in meibomian gland analysis. Yesilirmak et al. achieved 77.86% accuracy for 5-grade meiboscore classification using image embeddings and morphological features on 1,261 images [8]. A large-scale validation study reported 97.49% segmentation accuracy (IoU: 81.67%) and AI gland grading agreement ($\kappa = 0.93$) with manual grading [9]. Our IoU of 0.89 and weighted Cohen's κ of 0.89 for meiboscore grading further demonstrate the advancement of deep learning in this field. Compared to the U-Net model (Dice = 0.85) reported by Wang et al. [20], the Swin Transformer's superior segmentation performance highlights the advantage of vision transformer architectures in capturing long-range dependencies in medical images.

For tear break detection, a 2026 study using YOLOv8 variants for ocular structure and tear film breakup region detection reported a precision of 74.6% for the best-performing model (YOLOv8-m) [10], lower than our precision of 90.8%. This difference likely reflects our binary classification task versus multi-class pattern classification. The same study reported 75.47% accuracy for breakup pattern classification with system-measured TBUT (1.99 ± 1.36 seconds), significantly shorter than manual TBUT (2.21 ± 1.47 seconds), indicating high sensitivity to early tear film disruption [10]. Our YOLOv8-based NIBUT showed comparable sensitivity (mean absolute error: 1.1 seconds, Pearson r = 0.92 with manual grading). The two-frame confirmation strategy effectively reduced false positives due to transient optical artifacts, a common challenge in automated tear film analysis [18].

A 2024 study reported average processing time of 15.01 seconds per subject using deep learning-based analysis [12]. Our average processing time of 8.2 seconds per subject (3.5 seconds for YOLOv8 inference) demonstrates the computational efficiency of our architecture.

4.2 Integration of Multiparameter Diagnostics

Multiple diagnostic parameters are increasingly integrated into AI-based ophthalmology diagnostics. A 2025 study proposed a multimodal diagnostic pipeline (MDPipe) using large language models for ocular surface disease diagnosis, transforming meibography into morphological data for integration with clinical metadata [13]. While that study focused on a language model approach, our platform incorporates objective parameters (meibography, NIBUT, blink rate) in a real-time, on-device system, representing a unique and practical contribution.

A 2025 systematic review found that videokeratography, smartphone imaging, infrared meibography, and deep learning models (U-Net, ResNet, DenseNet, GANs, Transformers) achieved promising results, with reported accuracy rates between 82% and 99% [14]. Our XGBoost classifier accuracy of 94.2% for severity classification falls within this range. A 2025 BMC Bioinformatics study investigated XGBoost for predictive modeling based on >20,000 data points of behavioral and physiological factors, achieving 89% accuracy for risk factor identification [7]. While that study used XGBoost for risk prediction, we apply it for clinical decision support using device-derived parameters, adding a novel clinical application.

4.3 Clinical Advantages of TearLyze

TearLyze offers several advantages over previous AI systems. First, it is completely non-invasive—no anesthetic drops, fluorescein, or eye contact. This is significantly better than conventional TBUT and meibography techniques requiring dye instillation or eyelid contact [7,25]. Second, it integrates three complementary diagnostic domains (structural, functional, behavioral) in a portable platform. Most existing DED AI tools focus on single parameters such as meibomian gland dropout or tear meniscus height, limiting clinical utility [21,23]. Third, the Swin Transformer outperformed conventional U-Net architecture, consistent with previous studies showing Vision Transformer models' effectiveness in capturing long-range dependencies compared to CNNs [28].

The ICC of our AI-derived NIBUT (0.93) exceeds that of manual fluorescein TBUT (0.70–0.80) [11,12], indicating that automated, non-invasive tests may provide more repeatable results than traditional operator-dependent methods. The YOLOv8 tear break detection model's two-frame confirmation strategy effectively reduced false positives from transient optical artifacts, a common challenge in tear film analysis [18].

The integrated pipeline processing time of 8.2 seconds per subject is substantially faster than typical clinical workups requiring 10–15 minutes for multiple tests [13]. This speed, combined with portability, makes TearLyze well-suited for high-throughput screening in primary care, community health centers, and teleophthalmology [14,30].

4.4 Limitations and Future Directions

This study has several limitations that warrant acknowledgment. First, training and validation sets were compiled from public repositories and expert-annotated sets within a single institution. While we developed a held-out test set, multicenter external validation is needed to ensure generalizability. This is a priority for our future work.

Second, the feature vector dataset for XGBoost classification (500 samples) is relatively small, reflecting limited available public data with complete feature sets. Larger datasets across diverse demographic groups and DED subtypes would provide more robust performance estimates.

Third, the device requires a trained operator for eyelid eversion during meibography; a fully automated, patient-operated version is not yet available. This limits its use to clinical settings with trained personnel.

Fourth, the Placido disc-based NIBUT measurement relies on a smooth corneal surface. Irregular astigmatism or corneal scarring could affect measurement accuracy.

Fifth, our dataset primarily included participants of a single ethnicity, limiting generalizability to other populations.

Sixth, the study was conducted using a laptop-based implementation rather than the final smartphone prototype. While the pipeline is designed for eventual smartphone deployment, processing times and performance may vary when ported to mobile hardware.

Future directions include:

1. **Multicenter external validation** with diverse patient populations and clinical settings.
2. **Inclusion of additional non-invasive parameters** such as tear meniscus height and lipid layer interferometry.
3. **Development of a fully automated smartphone application** enabling patient self-operation.
4. **Federated learning approaches** to improve generalization without sharing sensitive patient data.

5. **Explainable AI techniques** including SHAP analysis and Grad-CAM visualizations to enhance clinical interpretability.

6. **Regulatory approval** (FDA and CE marking) for clinical deployment.

5. Conclusion

The TearLyze device, incorporating Swin Transformer-based meibomian gland segmentation, YOLOv8-based tear break detection, and XGBoost-based disease severity classification (using device-derived parameters only), provides a non-invasive, automated, multiparameter assessment of dry eye disease. Technical validation demonstrated high accuracy (94.2% for severity classification), excellent repeatability (ICC = 0.93 for NIBUT), and fast processing (8.2 seconds per subject). These findings support device readiness for prospective external clinical validation. The exclusion of OSDI from the AI model avoids incorporation bias and ensures independent diagnostic performance assessment based solely on objective device measurements.

6. Conflict of Interest

The authors declare no conflicts of interest.

7. Acknowledgments

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