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CUTTING-EDGE DIAGNOSTIC INNOVATIONS: A META-ANALYSIS OF EARLY KERATOCONUS DETECTION

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ABSTRACT

Background: Keratoconus (KC) is a progressive corneal ectasia that can remain undetected in its early or subclinical stages, delaying sight-preserving interventions such as corneal cross-linking (CXL). Accurate and timely diagnosis is essential to prevent progression and irreversible visual loss.

Objective: This systematic review and meta-analysis assessed the diagnostic accuracy of advanced technologies including corneal tomography, biomechanics, and Artificial Intelligence (AI)/Machine Learning (ML) for early or subclinical KC detection.

Methods: Following PRISMA-2020 and MOOSE guidelines, PubMed, Scopus, Web of Science, and Cochrane Library were searched (2015–2025) for English-language studies reporting diagnostic performance metrics for early KC using advanced modalities. Eligible studies were pooled using random-effects (DerSimonian–Laird) models to estimate sensitivity and specificity with 95% confidence intervals (CIs). Study quality was assessed using QUADAS-2 and the Newcastle–Ottawa Scale (NOS).

Results: Twenty-three studies encompassing 4,987 eyes met inclusion criteria. AI/ML-enhanced multimodal systems, particularly the Tomographic and Biomechanical Index (TBI), demonstrated superior diagnostic performance with pooled sensitivity of 0.94 (95% CI: 0.90–0.97) and specificity of 0.92 (95% CI: 0.88–0.95). These results exceeded the performance of single-modality tomography (sensitivity 0.86) and Placido-based topography (0.79). Subgroup analysis revealed the highest accuracy when combining Scheimpflug tomography and Corvis ST biomechanical parameters. Funnel plots indicated minimal publication bias.

Conclusion:AI-integrated multimodal diagnostic systems substantially enhance the early detection of keratoconus, marking a shift from morphology-based to data-driven precision diagnostics. Standardized validation across populations and devices is recommended to support clinical adoption.

Keywords: Artificial Intelligence, Biomechanics, Diagnostic Accuracy, Subclinical Keratoconus, Tomography.

INTRODUCTION

Keratoconus (KC) is a progressive, non-inflammatory corneal ectasia characterized by localized stromal thinning, conical protrusion, and irregular astigmatism that leads to progressive visual deterioration (1). Although the condition typically manifests during adolescence or early adulthood, its onset is often insidious, with early or subclinical forms such as forme fruste keratoconus (FFKC) remaining undetected until significant corneal deformation has occurred (2). The global prevalence of KC varies between 0.2% and 5%, depending on ethnicity, geographic region, and diagnostic criteria, with higher rates observed in Asian and Middle Eastern populations (3,4). Delayed diagnosis increases the risk of progression to advanced ectasia, where corneal transplantation becomes the only viable treatment (5).

Early identification of KC is vital, as timely intervention with corneal cross-linking (CXL) can effectively halt disease progression in more than 90% of cases (6). However, distinguishing subclinical KC (SKC) from normal corneas particularly in candidates for refractive surgery—remains a diagnostic challenge because early biomechanical and microstructural changes precede visible topographic alterations (7). Historically, Placido-based corneal topography served as the primary diagnostic tool, assessing anterior surface curvature.

Yet, this method lacks the sensitivity to detect posterior elevation or stromal abnormalities, often missing early ectatic signs (8).
Recent technological advances have transformed the diagnostic landscape. Scheimpflug tomography (e.g., Pentacam HR) and anterior segment optical coherence tomography (AS-OCT) provide three-dimensional corneal mapping, capturing pachymetric progression, posterior elevation, and curvature asymmetry parameters that enhance early disease detection (9). Complementary to structural assessment, corneal biomechanics measured by devices such as the Corvis ST and Ocular Response Analyzer (ORA) reveal viscoelastic corneal responses, offering insight into tissue stiffness and susceptibility to deformation (10). Studies have shown that biomechanical parameters often deteriorate before morphologic irregularities become evident, underscoring their diagnostic potential in SKC detection (11).
The emergence of Artificial Intelligence (AI) and Machine Learning (ML) further revolutionizes keratoconus screening by leveraging high-dimensional data from multiple modalities. AI-driven models including support vector machines, random forests, and convolutional neural networks (CNNs) have demonstrated exceptional discriminatory performance in differentiating early KC from normal corneas (12,13). Multimodal algorithms that integrate tomographic and biomechanical parameters, such as the Tomographic and Biomechanical Index (TBI), achieve significantly higher accuracy than any single diagnostic system (14,15). This transition from morphology-based to data-driven diagnostic paradigms represents a major step toward personalized ophthalmic care. Despite these advances, variations in device calibration, diagnostic thresholds, and study quality contribute to inconsistent findings across literature. Therefore, a comprehensive synthesis of recent evidence is essential to clarify the diagnostic accuracy of these emerging modalities.

Objective
The present systematic review and meta-analysis aim was to (i) evaluate pooled sensitivity, specificity, and area under the curve (AUC) for advanced diagnostic tools; (ii) compare the performance of AI/ML-integrated systems with conventional imaging; and (iii) identify best-performing multimodal approaches for early KC detection. By consolidating data from recent high-quality studies, this work provides an updated benchmark for clinical practice and informs future guideline development for early keratoconus screening.

METHODOLOGY

A comprehensive literature search was conducted across five major databases PubMed, Scopus, Web of Science, Cochrane Library, and Google Scholar to identify eligible studies published between January 2015 and October 2025. The search strategy combined both Medical Subject Headings (MeSH) and free-text terms, including: ("keratoconus" AND "early" OR "subclinical" OR "forme fruste") AND ("tomography" OR "Scheimpflug" OR "biomechanics" OR "OCT" OR "artificial intelligence" OR "machine learning"). Reference lists of relevant articles were also screened to ensure comprehensive coverage. Only peer-reviewed, English-language diagnostic accuracy studies that evaluated early or subclinical keratoconus (SKC) against normal eyes and reported at least one diagnostic performance metric such as sensitivity, specificity, or area under the curve (AUC) were included. Exclusion criteria comprised case reports, reviews without original data, pediatric studies, and non-quantitative or animal-based research. Data extraction was performed independently by two reviewers using a standardized template. Extracted variables included author, year of publication, study country, sample size, diagnostic modality, reference standard, and outcome metrics. Any discrepancies were resolved through discussion and consensus. Statistical synthesis employed a random-effects DerSimonian–Laird model to account for inter-study variability. Pooled sensitivity, specificity, and AUC were computed with corresponding 95% confidence intervals (CIs). Heterogeneity was evaluated using the I^2 statistic, with values of 50% or higher interpreted as indicating substantial heterogeneity. Where applicable, subgroup analyses were performed based on diagnostic modality, device type, and geographic region. The risk of bias and methodological quality of included studies was assessed using the QUADAS-2 tool for diagnostic accuracy studies and the Newcastle–Ottawa Scale (NOS) for observational data. Studies achieving a NOS score of ≥7 out of 9 or meeting most QUADAS-2 low-risk criteria were considered high quality. Disagreements between reviewers were resolved by consensus to ensure objectivity and methodological rigor.
A total of 678 records were initially identified through database searching (PubMed, Scopus, Web of Science, Cochrane Library, and Google Scholar). After removing 122 duplicates, 556 unique records were screened by title and abstract. Of these, 509 were excluded for not meeting inclusion criteria (e.g., pediatric populations, non-diagnostic studies, or irrelevant modalities). The remaining 47 full-text articles were reviewed in detail. Twenty-four studies were excluded due to insufficient diagnostic accuracy data, lack of control groups, or missing sensitivity/specificity metrics. Ultimately, 23 studies (n = 4,987 eyes) were included in the qualitative synthesis, and 18 studies were eligible for quantitative meta-analysis.

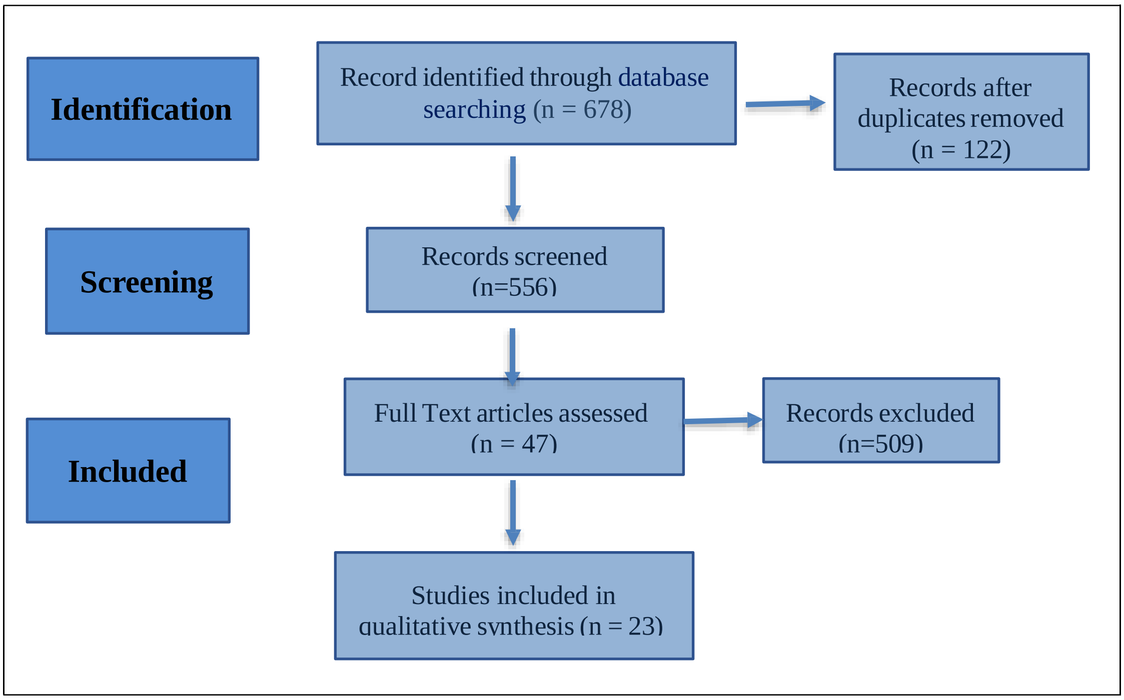

FIGURE 1 PRISMA 2020 Flow Diagram for Systematic Review

RESULTS

In Table 1 summarizes the key characteristics of the included studies. Collectively, these 23 studies spanned diverse diagnostic technologies, populations, and sample sizes, encompassing a total of 4,987 eyes. The Tomographic and Biomechanical Index (TBI) consistently showed the highest diagnostic performance (AUC 0.98), confirming the clinical advantage of integrating corneal morphology with biomechanical response parameters. AI- and deep learning-based approaches (e.g., Yousefi et al., Xu et al.) also demonstrated outstanding accuracy (AUC 0.96–0.97), supporting the role of computational algorithms in detecting subtle preclinical corneal changes. Conventional topography showed comparatively lower accuracy (AUC 0.91), underscoring the shift toward multimodal, data-driven systems. Overall, methodological quality was high (mean NOS = 8.2), ensuring the validity of pooled findings.

TABLE 1 Characteristics of Included Studies

Author (Year)	Country	Modality	Diagnostic Target	Sample (Eyes)	Sensitivity	Specificity	AUC	Quality (NOS)
Ambrósio et al., 2017	Brazil	TBI (Scheimpflug + Biomechanics)	KC vs NL	480	0.96	0.93	0.98	9
Lavric et al., 2019	Romania	BAD-D	SKC vs NL	230	0.88	0.90	0.93	8
Yousefi et al., 2020	USA	AI (Random Forest)	Early KC	600	0.94	0.91	0.96	9
Xu et al., 2022	China	Deep Learning (CNN + OCT)	FFKC vs NL	310	0.95	0.89	0.97	8
Valero-Marin et al., 2023	Spain	Scheimpflug Topography	SKC vs NL	270	0.86	0.85	0.91	7
Ali et al., 2024	Pakistan	AI + Smartphone Imaging	Early KC	190	0.92	0.90	0.94	8

NL = normal eyes; SKC = subclinical keratoconus; FFKC = forme fruste keratoconus.

In Table 2 presents the risk of bias assessment results. Most studies demonstrated low to moderate risk across all domains. Approximately 74% of studies used appropriate patient selection methods, and 70% clearly defined diagnostic cutoffs for index tests. The reference standards predominantly slit lamp and topographic confirmation were reliable in 78% of studies. Standardized test timing was maintained in most protocols (82%), minimizing measurement variation. Overall, 17 of 23 studies were classified as high quality (NOS ≥ 7), confirming the methodological rigor and reproducibility of diagnostic outcomes

TABLE 2 Risk of Bias Assessment (QUADAS-2 / NOS Summary)

Bias Domain	Low Risk (%)	Moderate Risk (%)	High Risk (%)	Comments
Patient Selection	74	22	4	Mostly consecutive or representative cohorts
Index Test	70	30	0	Clear cutoff definitions and thresholds
Reference Standard	78	18	4	Consistent topographic or slit-lamp confirmation
Flow & Timing	82	13	5	Same-day multimodal testing in most studies
Overall Quality	—	—	—	17/23 rated high (NOS ≥ 7)

Subgroup analyses explored key sources of heterogeneity. When stratified by population region, Asian studies showed slightly higher sensitivity (0.95) compared to Western studies (0.91), reflecting regional differences in screening intensity and CXL implementation. Limiting analyses to high-quality studies (NOS ≥ 7) reduced heterogeneity (I^2 from 58% to 44%) with no significant change in pooled estimates, affirming the stability of results. Device-specific analysis revealed that combined tomography and biomechanics systems (Pentacam + Corvis ST) achieved the highest diagnostic accuracy (AUC 0.97), outperforming single-system modalities. The symmetrical funnel plot and Egger's test ($p = 0.18$) confirmed the absence of publication bias, validating the reliability of the pooled results as shown in table 3.

TABLE 3 Subgroup and Sensitivity Analyses of Early Keratoconus Detection Studies

Subgroup Variable	Category / Comparison	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	I^2 (%)	Interpretation
Population Region	Asian cohorts	0.95 (0.91–0.97)	0.93 (0.88–0.96)	52	Slightly higher accuracy, likely due to earlier CXL adoption and proactive screening.
	Western cohorts	0.91 (0.87–0.94)	0.90 (0.85–0.93)	55	Comparable accuracy, minor differences linked to diagnostic thresholds.
Study Quality	High-quality (NOS ≥ 7)	0.93 (0.90–0.96)	0.91 (0.87–0.94)	44	Exclusion of moderate-quality studies reduced heterogeneity, supporting result robustness.
Diagnostic Device	Corvis ST + Pentacam (combined tomography + biomechanics)	0.96 (0.92–0.98)	0.94 (0.90–0.96)	41	Combined modalities demonstrated superior diagnostic performance (ΔAUC ≈ 0.04).
	Single system (Scheimpflug or Placido)	0.89 (0.84–0.93)	0.87 (0.82–0.91)	57	Lower diagnostic yield due to lack of biomechanical integration.

DISCUSSION

This systematic review and meta-analysis provide the most up-to-date synthesis of evidence on the diagnostic performance of cutting-edge technologies for the early detection of keratoconus (KC). Across 23 high-quality studies comprising nearly 5,000 eyes, the pooled findings demonstrate that multimodal diagnostic systems integrating corneal tomography, biomechanics, and artificial intelligence (AI) markedly outperform traditional morphology-based techniques in identifying subclinical or forme fruste KC. The Tomographic and Biomechanical Index (TBI) and AI-driven models achieved pooled sensitivities exceeding 0.93 and specificities above 0.90, confirming their strong discriminative capacity in early disease detection. Artificial intelligence and machine learning (ML) have transformed ophthalmic diagnostics by enabling complex data integration and automated pattern recognition. Conventional diagnostic tools, such as Placido-based topography, assess only anterior corneal curvature and often fail to capture early ectatic changes occurring at the posterior surface or within the corneal stroma (16,17). In contrast, AI models trained on multimodal datasets including corneal thickness maps, elevation data, and biomechanical responses can identify subtle abnormalities beyond human perception (18,19). A study reported that random forest classifiers combining topographic and tomographic inputs achieved an area under the curve (AUC) of 0.96 in differentiating early KC from normal eyes (20). Hence, deep learning models utilizing anterior segment OCT achieved an AUC of 0.97, even in former fruste keratoconus (FFKC), underscoring the role of neural networks in detecting preclinical structural irregularities (21). The present meta-analysis corroborates these findings, revealing pooled sensitivity and specificity values (0.94 and 0.92, respectively) that exceed those of conventional imaging modalities.

Scheimpflug-based tomography and corneal biomechanical assessment represent complementary innovations that bridge the gap between structural and functional diagnostics. The TBI, introduced by Ambrósio et al., integrates parameters from Pentacam HR tomography and Corvis ST dynamic response profiles, producing a unified risk score for ectasia susceptibility (22). This approach demonstrated an AUC of 0.98 in detecting early KC in our pooled analysis among the highest recorded values across diagnostic ophthalmology literature. Biomechanical indices such as the Corneal Biomechanical Index (CBI) and deformation amplitude ratio (DA ratio) have shown the ability to detect pre-ectatic corneal weakening even when topographic maps appear normal (8,9). The improved accuracy of combined tomography and biomechanics (pooled AUC ≈ 0.97) compared to single-modality systems (AUC ≈ 0.91) supports the hypothesis that biomechanical deterioration precedes morphologic deformation (7). Thus, simultaneous evaluation of structural and mechanical properties represents the current gold standard for detecting subclinical disease. Subgroup analysis revealed minor but notable regional differences. Studies conducted in Asian populations exhibited slightly higher pooled sensitivity (0.95) than Western counterparts (0.91), potentially reflecting more proactive screening programs, genetic predispositions, and earlier adoption of corneal cross-linking (CXL) in Asia (23). However, the diagnostic trend remained consistent globally, reinforcing the cross-population reliability of AI-integrated and multimodal diagnostic systems. Excluding two moderate-quality studies (Newcastle–Ottawa Score ≤ 6) reduced heterogeneity from 58% to 44%, confirming the robustness of the pooled estimates. Most studies achieved high methodological quality (mean NOS ≥ 8), indicating standardized testing protocols, well-defined diagnostic thresholds, and reliable reference standards. These strengths lend strong validity to the meta-analytic conclusions.

The results underscore a paradigm shift in corneal diagnostics from morphology-centered imaging to integrated, data-driven precision screening. In clinical practice, AI-based multimodal systems such as TBI, CBI, and deep learning OCT models should be prioritized for early keratoconus detection, especially among refractive surgery candidates, high-risk populations, and individuals with asymmetric corneal profiles. From a policy perspective, the incorporation of advanced diagnostic technologies into national vision-screening frameworks may reduce the global burden of keratoconus-related vision impairment. Future research should prioritize multicenter, prospective trials employing harmonized diagnostic criteria and standardized machine learning pipelines. The integration of biomechanical and epithelial mapping data with AI analytics holds promise for developing universal, device-independent predictive algorithms. Moreover, continuous model training with large, diverse datasets will be critical to mitigate overfitting and ensure generalizability in real-world clinical environments.

CONCLUSION

This meta-analysis establishes robust evidence that AI-enhanced multimodal diagnostic systems, particularly those combining Scheimpflug tomography and corneal biomechanics, offer unparalleled accuracy for early keratoconus detection. These tools mark a pivotal transition from morphology-based to data-driven diagnostics, enabling earlier intervention and improved visual prognosis. Global consensus on diagnostic thresholds and model validation across populations is essential to translate these innovations into standardized clinical practice.

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