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Original Article

Combined Scheimpflug-Derived Tomographic and Biomechanical Assessment Detection: A Systematic Review

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ABSTRACT

Purpose: Keratoconus is the most common corneal ectatic disease, characterized by progressive and bilateral thinning of the cornea leading to visual loss. Early diagnosis is important, particularly in preoperative screening, and the utilization of another imaging modality remains crucial. This study aimed to explore the combination of corneal biomechanical tomographic assessment derived from Scheimpflug in diagnosing subclinical keratoconus. Methods: A systematic search was conducted in MEDLINE, Google Scholar, Clinical Key, and EBSCO. Two independent reviewers selected studies and extracted data. Risk of bias was assessed using the QUADAS-2 tool in RevMan 5.4. The primary outcome measures included the Belin-Ambrosio enhanced ectasia total deviation index (BAD-D), Stiffness Parameter at First Applanation (SPA-1), Tomographic & Biomechanical Index (TBI), and Corvis Biomechanical Index (CBI). Diagnostic accuracy was categorized based on the area under the curve (AUC) as low (AUC < 0.7), moderate (0.7 ≤ AUC < 0.9), or high (AUC ≥ 0.9). Results: Twelve studies involving 3483 eyes were included BAD-D and CBI demonstrated low to moderate AUC, while TBI demonstrated moderate to high AUC. According to the QUADAS-2, common methodological limitations included inappropriate reference standards, unclear patient selection, and inconsistent exclusion criteria. Limitations include numerous issues with methodological and findings reporting, thus a meta-analysis was not conducted. Conclusion: Scheimpflug-based corneal tomographic and biomechanical assessment shows promise as an adjunctive tool for detecting subclinical keratoconus. Among the indices, TBI appears to provide the highest diagnostic performance. However, further high-quality, longitudinal studies are required to validate these findings and to develop standardized diagnostic criteria.

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Introduction

Keratoconus is a progressive corneal ectatic disorder that threatens vision, primarily leading to vision impairment in younger individual.[1] The estimated prevalence of keratoconus in the general population is 265 cases per 100,000 people, which is 10 times higher than the previously reported rates of 54.5 cases per 100,000 in the United States.[2] In the era of laser vision correction, the diagnosis of keratoconus and other ectatic corneal diseases has become increasingly important to prevent postoperative keratectasia.[3] Thus, early stage recognition of keratoconus is crucial to enhance the safety and efficacy of laser vision correction procedures.

Diagnosing subclinical keratoconus (SKC) remains particularly challenging because many topography and tomography overlap between SKC and normal eyes.[4] Moreover, there is no universally accepted definition of SKC, further complicating its diagnosis. In addition to corneal shape analysis, clinical biomechanical assessments have been proposed to improve the detection of early ectatic disease.[5] According to Roberts and Dupps, focal biomechanical abnormalities in the cornea can trigger a cycle of decompensation that leads to localized thinning and steepening (bulging), ultimately resulting in ectasia.[6]

The Corvis ST (Oculus Optikgeräte GmbH, Wetzlar, Germany) is a noncontact tonometer that measures corneal deformation using an ultra-high-speed Scheimpflug camera and a collimated air pulse of a set pressure.[7] Several derived parameters including the Corvis Biomechanical Index (CBI), Tomographic Biomechanical Index (TBI), and Stiffness Parameter at First Applanation (SPA-1) have been developed from Corvis ST data to enhance the sensitivity of keratoconus detection, particularly in its early or subclinical stages. These biomechanical indices may provide additional diagnostic value beyond tomographic paramaters such as the Belin-Ambrosio enhanced ectasia total deviation index (BAD-D).[1,7–11]

Given these advancements, this systematic review addresses a critical question in patients at risk for SKC—particularly those with keratoconus in one eye but no clinical or topographic evidence of ectasia in the fellow eye—how accurately do combined Scheimpflug-derived tomographic and biomechanical indices detect early ectatic changes in the fellow eye? This issue is clinically significant because early-stage keratoconus is often not detectable using tomographic criteria alone, yet missing these subtle changes in refractive surgery candidates may lead to iatrogenic ectasia and postoperative complications.[12] While previous studies have evaluated these indices individually, no systematic review has comprehensively assessed their diagnostic value for SKC. By synthesizing and comparing the diagnostic performance of these indices—such as BAD-D, SPA-1, TBI, and CBI—this review aims to address this gap and inform clinical decision-making by identifying which combinations of indices provide the most reliable and clinically meaningful diagnostic performance for detecting SKC.[10]

Methods

This systematic review was conducted in accordance with the PRISMA

2020 guidelines for systematic reviews and meta-analyses, and has been registered in the PROSPERO platform (registration number: CRD420250627614).

Search Strategy and Eligibility Criteria

A comprehensive literature search was performed in the following databases: MEDLINE, Google Scholar, Clinical Key, and EBSCO from March 6th to April 1st,2024. The search strategy was developed based on four categories: (i) population, (ii) intervention, (iii) comparison, and (iv) outcome. The search terms included "subclinical keratoconus", "Scheimpflug corneal biomechanical", "tomography", "early diagnosis", and their synonyms.

Table 1. Full search strategy for all databases

Source (date)	Search String	Hits	Results after removing duplicates
MEDLINE (06.03.2024)	("Keratoconus"[Mesh] OR "Subclinical keratoconus"[tw] OR "forme fruste keratoconus"[tw]) AND ("Biomechanical Phenomena"[Mesh] OR "biomechanical parameter"[tw] OR "corvis-ST"[tw] OR "tomography and biomechanical index"[tw] OR "corneal visualization Scheimpflug technolog*"[tw]) AND ("Tomography"[Mesh] OR "tomographic parameter*"[tw] OR pentacam[tw] OR "Scheimpflug technolog*"[tw])	109	
EBSCO (10.03.2024)	((Subclinical Keratoconus) OR (Forme Fruste Keratoconus)) AND ((biomechanical parameter) OR (corvis – ST) OR (tomography and biomechanical index)) AND ((tomography parameter) OR (pentacam) OR (scheimpflug technolog*)	70	
Clinical Key (24.03.2024)	)) AND ((biomechanical parameter) OR (corvis – ST) OR (tomography and biomechanical index)) AND ((tomography parameter) OR (pentacam) OR (scheimpflug technolog*)	19	
Google Scholar (01.04.2024)	((Subclinical Keratoconus) OR (Forme Fruste Keratoconus)) AND ((biomechanical parameter) OR (corvis – ST) OR (tomography and biomechanical index)) AND ((tomography parameter) OR (pentacam) OR (scheimpflug technolog*)	452	
Total		650	240

There were no restrictions regarding publication year. The full electronic search strategy for all databases is presented in Table 1. Studies had to meet the following inclusion criteria: (1) Examination of the specificity and sensitivity of Scheimpflug-based corneal biomechanical and tomography analyzers for detecting subclinical keratoconus, (2) Discussion of predefined Scheimpflug-based indices for subclinical keratoconus, and (3) Publication in English. Studies were excluded if they were inaccessible or if they focused on early keratoconus (Amsler-Krumeich stage 1 or 2) instead of subclinical keratoconus.

Study Selection and Data Extraction

Two authors (Y.S.N. and A.A.) independently conducted the literature search, reviewed titles and abstracts, evaluated full-text articles, and extracted relevant data. Disagreements were resolved through discussion among all authors until consensus was reached. Extracted data included author, publication year, country, study design, exclusion criteria, number of eyes, study characteristics, sensitivity, specificity, and Area Under Curve (AUC) values. When multiple diagnostic outcomes were reported, we extracted the primary results based on the best-reported AUC for each parameter. Only the primary diagnostic performance at baseline was considered.

For each included study, we extracted the case definition of subclinical keratoconus and the Scheimpflug-based diagnostic parameters that were evaluated. TBI is the evaluated index in all 12 studies while BAD-D, CBI, and SPA-1 serve as reference methods throughout. Supplementary Table 1 summarizes the reference standards and specific indices assessed in each study.

Quality Assessment

Two reviewers (Y.S.N and A.A.) independently assessed the quality of the included studies using the QUADAS-2 tool, which evaluates risk of bias and applicability concerns in four domains: patient selection, index test, reference standard, and flow and timing. Each domain was rated as "yes", "no", and "unclear" based on predefined criteria.

Outcome Measured

The outcome parameters analyzed in this review were diagnostic indices derived from Scheimpflug-based imaging, including BAD-D , SPA-1, TBI, and CBI. For each diagnostic parameter, we collected available measures of diagnostic, including sensitivity, specificity, and AUC. Sensitivity and specificity were used to evaluate the ability of each index to correctly distinguish eyes with subclinical keratoconus from normal eyes. AUC, derived from the receiver operating characteristic (ROC) analysis, summarized the overall discriminative accuracy of the diagnostic indices across varying decision thresholds. AUC values were analyzed and interpreted using Stata IC version 15.1 to classify diagnostic accuracy.

Results

Results of Literature Search

The initial search yielded 650 articles. After removing duplicates and irrelevant studies, 21 full-text articles were reviewed. Twelve studies met the inclusion criteria (Figure 1). Studies were excluded mainly due to differing target populations, non-peer-reviewed status, inaccessible data on sensitivity/specificity, or focus on astigmatism instead of SKC.

Countries and Study Design

Among the 12 included studies, six were conducted in China,[1,10,13–16] one each in Japan,[3] India,[9] Turkey,[17] Germany,[18] and Brazil.[11] One study was multicenter collaboration between Brazil and Italy.[7] In terms of study designs, there were four case – control studies,[3,11,14,16] four retrospective studies,[1,7,13,18] two cross–sectional studies,[9,10] and two prospective studies.[15,17]

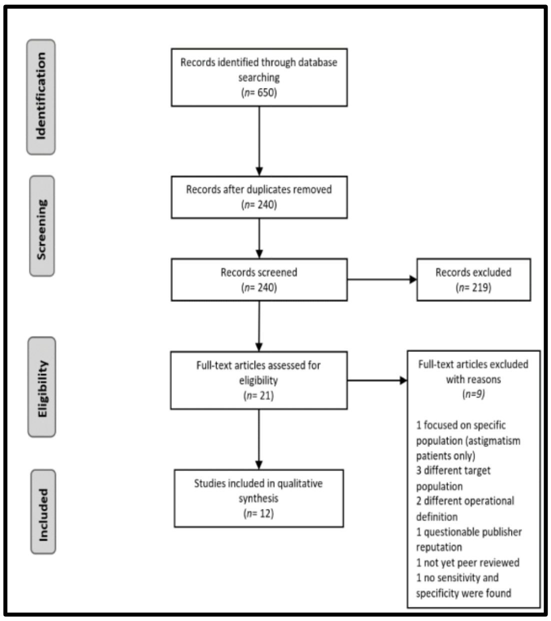

Figure 1. Flowchart of study selection. (PRISMA 2020 flow diagram showing the identification, screening, eligibility, and inclusion of studies.)

Participants' Characteristics

A total of 3483 eyes from 2920 subjects were included. Most studies compared three groups: eyes with clinical keratoconus, eyes with subclinical keratoconus, and healthy control eyes.[9–11,13–18] Two studies included only SKC eyes and healthy control eyes.[1,3] Eight studies clearly stated exclusion criteria, commonly prior ocular surgery, significant corneal scarring, other ocular diseases, or systemic diseases affecting the eye.[9,10,13–18]

Diagnostic Performance and Clinical Value

TBI parameters were reported in seven studies,[1,3,9,11,15,17,18] CBI and BAD-D were each reported in six studies,[1,3,9,15,17,18] and SPA-1 was reported in three studies.[9,15,17] Due to the limited availability of SPA-1 data, only TBI, CBI, and BAD-D were included in the AUC-based analysis, categorized as low (AUC < 0.7), moderate (0.7 ≤ AUC < 0.9), and high (AUC ≥ 0.9). In our analysis, TBI achieved a median AUC of 0.93 (95% CI: 0.91 – 0.95), BAD-D an AUC of 0.82 (95% CI: 0.79 – 0.86), and CBI an AUC of 0.76 (95% CI: 0.72 – 0.80), derived from narrative synthesis as the methodological heterogeneity between studies precluded formal meta-analytic pooling. In general, BAD-D and CBI demonstrated low to moderate diagnostic performance, whereas TBI showed moderate to high accuracy. Detailed sensitivity, specificity, and AUC values for each study are provided in Supplementary Table 2. Due to heterogeneity and incomplete reporting across studies, a meta-analysis was not conducted.

Quality Assessment

According to the QUADAS-2 evaluation, 10 of the 12 studies were judged to have a low overall risk of bias.[1,7,9–11,13,14,16–18] A study by Shizuka Koh had an unclear risk of bias in patient selection due to insufficient detail about enrollment.[3] Figure 2 summarizes the risk of bias an applicability concerns

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across all included studies. In the patient selection domain, most studies were rated low risk; however, several case-control studies recruiting exclusively from tertiary referral ectasia clinics were rated unclear, as hospital-based cohorts enriched for corneal disease may not reflect the spectrum of disease severity expected in a community refractive surgery screening setting. In the index test domain, the objective, machine-derived nature of Corvis ST and Pentacam outputs generally supported a low-risk rating, though two studies did not explicitly confirm that index test results were interpreted without knowledge of the reference standard, and were therefore unclear. Hui Zhang's study had a high risk of bias in the reference standard domain.[15] BAD-D used as the reference standard was derived from the same Scheimpflug acquisition session as the evaluated index tests, violating independence between the reference and index test and introducing potential incorporation bias. In the flow and timing domain, all studies performed index and reference tests contemporaneously and were rated low risk. Applicability concerns were generally low for the included studies.[1,3,7,9–11,13,14,16–18] However, six of twelve studies were conducted in Chinese cohorts and caution is warranted when extrapolating reported diagnostic thresholds to populations with different ethnic backgrounds, given documented variation in corneal biomechanical properties.

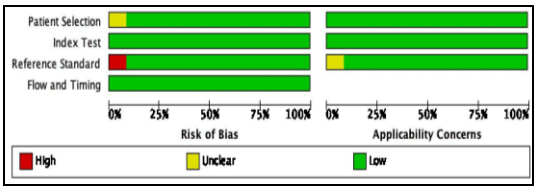

Figure 2. Summary of risk of bias and applicability concerns. (QUADAS-2 assessment showing the reviewers' judgements for each domain as percentages across all included studies.) Green = low risk, yellow = unclear risk, red = high risk.

Discussion

Keratoconus is a progressive and sight-threatening corneal ectatic disease that leads to permanent visual loss, primarily in adolescents and young adults.[1] The recent prevalence is 10-fold higher compared to the previously reported study which is 265 cases per 100,000 individuals. This could be due to the heightened sensitivity of modern corneal imaging technology.[2] However, diagnosing SKC remains one of the most challenging tasks, particularly when considering refractive surgery, as many metrics from topography and tomography imaging overlap between SKC and normal eyes.[4,19]

The cornea has nonlinear elastic and viscoelastic properties, making it a complicated anisotropic composite structure. As a result of alterations in the viscous and elastic characteristics of the cornea, specific structural changes in the corneal stroma are observed in ectasia-affected eyes. Keratoconus compromises the mechanical stability of the cornea, which gradually results in the alteration of the macroscopic morphology.[13,20] Thus, measuring corneal biomechanical characteristics is crucial for subclinical ectatic eye screening. It is theoretically plausible that integrating morphological and biomechanical tests could enhance the accuracy of KC diagnosis.

Most of the reported studies were conducted in hospital settings, and the limited prevalence of SKC made it difficult to determine the true predictive value of combining Scheimpflug biomechanical and tomographic indices. Godefrooij *et al.*[2] conducted a nationwide registry study in the Netherlands, but it addressed only keratoconus and did not consider SKC. In the general population, the prevalence is 1 in 375, which equates to 265 cases per 100,000.[2] As a result, this study could not determine the real true positive predictive value (PPV) and negative predictive value (NPV), as they rely on prevalence. Other indicators, including sensitivity, specificity, and AUC showed favourable results. In particular, TBI presented a moderate to high AUC, wheras CBI and BAD-D had low to moderate AUC. The superior diagnostic performance of TBI over CBI and BAD-D is mechanistically consistent with its construction. Unlike CBI, which is derived exclusively from corneal deformation response parameters measured by Corvis ST and BAD-D, which relies solely on tomographic deviation indices from Pentacam, TBI is machine-learning derived composite index that integrated both biomechanical and tomographic data simultaneously into a single determinant output. This dual domain integration allows TBI to capture the earliest structural and mechanical corneal changes that neither modality detects reliably in isolation which is precisely the diagnostic challenge that subclinical keratoconus presents. Although the included papers have information on sensitivity and specificity, they do not come with 95% CI, making it impossible to analyze and plot this information. Despite each study describing the same tomographic and biomechanical indices for SKC, establishing recommendations for diagnostic criteria remained challenging. First, although the studies measured the same parameter, they used different cut-off values. Furthermore, since most studies conducted a single comprehensive ophthalmological examination, it was not possible to determine how many cases of subclinical keratoconus might progress to frank keratoconus or how the corneal biomechanical characteristics might evolve.

Although most studies agree that TBI has the most valuable value to differentiate SKC and normal cornea, Guo *et al*. examined 758 eyes and reported that BAD-D and TBI showed the highest efficiency, sensitivity, and specificity to distinguish keratoconus and normal eye yet those parameters have relatively low ability to distinguish SKC and normal eyes.[14] This apparent contradiction with the overall findings of this review is likely attributable to differences in cohort composition. Guo *et al*. examined 758 eyes spanning broad spectrum from clinical keratoconus to normal and the high overall AUC reported for BAD-D and TBI was predominantly driven by strong separation between frank keratoconus and normal eyes. Moreover, a study in Japan reported that 40% of patients with normal topography and ectatic fellow eyes were regarded as having normal cornea by BAD-D, CBI, and TBI.[3] Global consensus of keratoconus and ectasia diseases has established that true unilateral keratoconus does not exist, these eyes may have been unaffected or may have showed true monocular keratoconus.[21] On the other hand, five cases of Imbornoni's study might be true unilateral keratoconus and during 3-7 years of follow-up, the patient's healthy eyes remained normal.[22]

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The study's limitation was the small number of included studies, each conducted within specific population groups such as Chinese, Brazilian, German, Indian, Turkish, and Japanese. This study also lacks horizontal or transversal follow-up to illustrate the odds of SKC progress to frank keratoconus. However, biomechanical evaluation using Corvis ST might be a useful complementary diagnostic method for detecting keratoconus in patients without topographic or tomographic abnormalities.

Other imaging technologies (e.g., Ocular Response Analyzer, Brillouin microscopy, Swept Source OCT) were not reported in this study. With the rise of multimodal imaging, it is believed that employing multiple diagnostic imaging techniques will enable clinicians to gain a better understanding of the underlying pathogenesis, disease progression, and treatment response. In refractive surgery cases, multimodal imaging may improve the safety profile and predictability of the outcome. Therefore, combining Scheimpflug-derived corneal biomechanical and tomographic indices may enable the clinician to more effectively assess patients for refractive surgery.

Conclusion

Scheimpflug-based corneal biomechanical and tomographic assessment shows promise as an adjunctive tool for subclinical keratoconus detection, particularly in preoperative refractive surgery screening. Among the indices evaluated, TBI demonstrated the highest diagnostic performance with moderate to high AUC, consistently outperforming CBI and BAD-D, which showed only low to moderate accuracy. These findings support the integration of biomechanical and tomographic data over reliance on either modality alone.

Nevertheless, the wide variability in reported sensitivity and specificity, the predominance of hospital-based case control designs, the concentration of evidence within East Asian populations, and the incorporation bias identified in Hui Zhang *et al.* collectively limit the generalizability of current thresholds and temper the apparent superiority of TBI. Until prospective, longitudinal, and ethnically diverse validation studies are available, Scheimpflug-derived TBI should be regarded as a promising adjunctive screening tool rather than a standalone diagnostic criterion, and clinical decisions should continue to integrate multimodal assessment with careful longitudinal monitoring.

Declarations

Statement on the Use of Artificial Intelligence

The authors should specify whether artificial intelligence tools were used in preparing this manuscript. If applicable, provide the tool name and its purpose, describe how the output was reviewed, and confirm that the authors take full responsibility for the final content.

Author contribution statement

Conceptualization: Yuniar Sarah Ningtiyas, Farida Moenir, Sahata P.H. Napitupulu, Dini Dharmawidiarini ; Literature search, data acquisition, and data analysis: Yuniar Sarah Ningtiyas, Amalia Azrina; Writing - original draft preparation and editing: Yuniar Sarah Ningtiyas, Amalia Azrina; Manuscript review: Yuniar Sarah Ningtiyas, Amalia Azrina, Farida Moenir, Sahata P.H.

Napitupulu, Dini Dharmawidiarini. All authors have read and agreed to the published version of the manuscript. All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Yuniar Sarah Ningtiyas and Amalia Azrina. The first draft of the manuscript was written by Yuniar Sarah Ningtiyas and Amalia Azrina. All authors commented on previous versions of the manuscript. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest

The authors declare no financial or non-financial conflicts of interest relevant to the research, authorship, or publication of this article.

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