Corneal Sensitivity Across Keratoconus Stages: A Pilot Study

Sensibilidade Corneana Nos Diferentes Estadios De Queratocone: Um Estudo Piloto

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ABSTRACT

INTRODUCTION: Keratoconus is a progressive, non-inflammatory ectatic corneal disorder characterized by stromal thinning, irregular astigmatism, and visual impairment, with a substantial impact on quality of life. Beyond structural and biomechanical alterations, growing evidence indicates that keratoconus also involves changes in corneal innervation, such as reduced sub-basal nerve density, increased tortuosity, and stromal nerve thickening. These neural changes have been associated with reduced corneal sensitivity, and some studies suggest a correlation between sensitivity loss and disease severity. Given the critical role of corneal nerves in ocular surface homeostasis, wound healing, and tear production, assessing corneal sensitivity across different keratoconus stages may provide valuable insights into disease pathophysiology and progression.

METHODS: Keratoconus diagnosis was performed using Pentacam HR (Oculus, Germany). Corneal sensitivity was assessed using the Brill esthesiometer, a recently developed device that provides precise, reproducible, and operator-independent measurements, with improved clinical applicability compared to traditional contact-based methods. Keratoconus severity was classified according to the Amsler–Krumeich system and the ABCD grading system. Group differences in sensitivity were analyzed using the Kruskal–Wallis test, and correlations between disease stage and sensitivity were explored with Spearman's rank correlation coefficient.

RESULTS: Twenty patients were included (40% female; mean age 25.8 ± 8.1 years; range 13–43). Keratoconus stages were distributed as follows: stage I – 50%, stage II – 30%, stage III – 10%, and stage IV – 10%. Median corneal sensitivity was 2.60 (IQR: 2.1). No statistically significant differences in sensitivity were found across stages (p>0.05). The correlation between sensitivity and disease stage was weak and not significant (rho = 0.23, p=0.32). Only one patient reported contact lens use, limiting subgroup analysis.

CONCLUSION: This study found no significant association between keratoconus severity, as classified by the Amsler–Krumeich system, and corneal sensitivity. Nonetheless, these results contribute to the ongoing investigation of neurosensory involvement in keratoconus and highlight the potential of the esthesiometer as a practical and reliable tool for evaluating corneal sensitivity.

KEYWORDS: Disease Progression; Keratoconus; Cornea.

RESUMO

INTRODUÇÃO: O queratocone é uma ectasia progressiva da córnea, não inflamatória, caracterizada por adelgaçamento estromal, astigmatismo irregular e comprometimento visual, com impacto na qualidade de vida. Evidências crescentes demonstram também alterações na inervação corneana, como redução da densidade das fibras nervosas sub-basais, aumento da tortuosidade e espessamento dos nervos estromais. Estas alterações têm sido associadas à diminuição da sensibilidade corneana, e alguns estudos sugerem uma correlação entre a perda de sensibilidade e a gravidade da doença. Considerando o papel dos nervos corneanos na homeostase da superfície ocular, a avaliação da sensibilidade corneana em diferentes estadios do queratocone poderá fornecer informações relevantes sobre a fisiopatologia e progressão da doença.

MÉTODOS: O diagnóstico foi realizado através do Pentacam HR (Oculus, Alemanha). A sensibilidade corneana foi avaliada com o estesiómetro de Brill, um dispositivo recente que fornece medições precisas, reprodutíveis e operador independente, com melhor aplicabilidade clínica que os métodos de contacto tradicionais. A gravidade do queratocone foi classificada com o sistema de Amsler–Krumeich e classificação ABCD do Pentacam. O teste de Kruskal–Wallis permitiu a análise de diferenças entre grupos quanto à sensibilidade, e foram exploradas as correlações entre o estadio da doença e a sensibilidade pelo coeficiente de correlação de Spearman.

RESULTADOS: Foram incluídos vinte pacientes (40% do sexo feminino; idade média de 25,8 ± 8,1 anos; amplitude de 13–43 anos). A distribuição por estadios de queratocone foi a seguinte: estádio I – 50%, estádio II – 30%, estádio III – 10% e estádio IV – 10%. A mediana da sensibilidade corneana foi de 2,60 (IQR: 2,1). Não foram observadas diferenças estatisticamente significativas na sensibilidade entre os estádios (p>0,05). A correlação entre sensibilidade e estadio da doença foi não significativa (rho = 0,23; p=0,32). Apenas um paciente referiu uso de lentes de contacto, o que limitou a análise de subgrupos.

CONCLUSÃO: Este estudo não encontrou associação significativa entre a gravidade do queratocone, e a sensibilidade corneana. Todavia, estes resultados contribuem para a investigação relativa ao envolvimento nervoso no queratocone e destaca o potencial do estesiómetro de Brill como uma ferramenta para a avaliação da sensibilidade corneana.

PALAVRAS-CHAVE: Córnea; Progressão da Doença; Queratocone.

INTRODUCTION

Keratoconus (KC) is the most common corneal ectatic disease. It is a progressive, non-inflammatory corneal disorder characterized by central or paracentral stromal thinning and steepening, leading to irregular astigmatism and visual impairment, with a substantial impact on quality of life.

The prevalence of KC is approximately 1.38 per 1000 individuals, with rates reaching up to 5% of the population in some regions of the world, such as the Middle East. It affects both sexes and typically manifests around puberty, progressing until the third or fourth decade of life, when it stabilizes. Although its exact etiology is still unknown, some environmental factors such as sunlight exposure, dry weather and eye rubbing have been identified as contributors to its pathogenesis, alongside genetic predisposition.[1–4]

The corneal epithelium is densely innervated, with sensitivity related to the number of stromal nerve fibers. In addition to protecting the cornea by triggering reflex responses to external stimuli, corneal nerves also maintain ocular surface homeostasis through the release of trophic factors and the activation of brainstem circuits that regulate tear production and blinking.[5–7]

Recent advances in in vivo corneal confocal microscopy have demonstrated pronounced microstructural alterations in the corneal nerves of patients with KC, including reduced sub-basal nerve density, increased tortuosity, thickening, and disorganization of both sub-basal and stromal nerve plexuses. These findings, supported by immunohistochemical studies, indicate that corneal nerves play an active role in the pathophysiology of the disease. However, whether these neural alterations represent primary changes or secondary effects of stromal remodeling remains unclear. Considering the crucial role of corneal innervation in maintaining epithelial integrity, tear film stability, and corneal homeostasis, investigating corneal sensitivity across different stages of keratoconus may provide valuable insights into its neurosensory involvement and disease progression.[8–12]

Traditionally, corneal sensitivity has been assessed using the Cochet–Bonnet aesthesiometer, regarded as the clinical gold standard due to its simplicity, portability, and

long-standing use. However, its contact-based mechanism carries a risk of epithelial injury and is influenced by operator technique and environmental factors, potentially limiting its precision and reproducibility. Over the years, several other instruments have been developed to measure corneal sensation and innervation, including the Belmonte Non-Contact Aesthesiometer and the Swiss Liquid Jet Aesthesiometer. Despite offering higher precision and control of stimulus parameters, these devices are relatively expensive, require specialized training, and are not easily adaptable to routine clinical settings.[13,14]

Until recently, available corneal aesthesiometers presented a trade-off between accessible and intuitive devices that lacked precision and accuracy, and highly precise devices that demanded greater expertise and complex equipment. The Brill non-contact esthesiometer appears to have been designed to address these limitations, offering a safe, portable, and operator-independent method for assessing corneal sensitivity. Preliminary studies suggest that it provides measurements with good agreement and comparable range to the Cochet–Bonnet.

Central corneal sensation is reported to be significantly reduced in KC patients compared to normal controls, with further reductions observed in contact lens wearers. While some studies associate reduced corneal sensitivity with KC severity, others report no significant correlation after adjusting for contact lens wear, indicating conflicting evidence.[12,15–18] Given the crucial role of corneal innervation in ocular physiology, the present study aims to evaluate corneal sensitivity variation across different stages of KC, classified according to the Amsler–Krumeich (AK) system, using the Brill non-contact esthesiometer. The use of this device allows for standardized, reproducible, and patient-friendly assessment of corneal sensitivity, minimizing discomfort and eliminating operator-dependent variability commonly associated with traditional contact-based methods.

Figure 1. The Brill corneal esthesiometer is a portable, handheld, and non-contact device engineered for precise measurement of corneal sensitivity. Its structure features an ergonomic handle, a digital display for real-time stimulus adjustments, and an electronic positioning system that includes a camera and dual infrared LEDs for accurate alignment and distance control. The device employs a nozzle to deliver controlled pulses of air to the cornea and can be used either as a standalone handheld unit or mounted on a slit lamp. It offers five selectable pressure levels, an integrated sensor to record delivered stimulus, and operates with rechargeable battery power—streamlining assessments of corneal nerve function in both clinical and research contexts.

MATERIAL AND METHODS

STUDY DESIGN

A prospective observational study was conducted at the Ophthalmology Department of a Portuguese medical center. The study was performed in accordance with the Declaration of Helsinki.

PARTICIPANTS

Patients diagnosed with KC were invited to participate. Patients were excluded if they had any of the following: inability to provide informed consent, corneal opacities or scarring, other significant ocular diseases affecting corneal sensitivity such as diabetes, prior corneal transplant or crosslinking, or serious psychiatric conditions.

CORNEAL SENSITIVITY

Central corneal sensitivity was measured using the Brill non-contact esthesiometer (Figs. 1 and 2), which delivers calibrated air pulses to quantify sensory detection thresholds. Participants were required to cease contact lens use for a minimum of 14 days before the appointment. During testing, subjects were positioned with chin and forehead support, fixating on a distant target to ensure stability and minimize reflexive blinking. The eye to be tested first was randomly selected, with three threshold measurements taken per eye at 30 to 60-second intervals; the mean value was used for analysis. The stimulus followed an ascending-descending staircase protocol and testing was paused if the participant experienced discomfort, excessive tearing, or loss of fixation. All assessments were conducted by the same two examiners to ensure consistency, using calibrated and standardized equipment.

CORNEAL TOMOGRAPHY

Corneal tomography was obtained with Pentacam HR (Oculus, Germany). Mean central keratometry (Kmed) and thinnest corneal thickness (TCT) were registered. The severity of KC was classified according to the AK classification, a widely used system based on several parameters: corneal curvature (keratometry), corneal thickness (pachymetry), degree of myopia and astigmatism (spherical equivalent), and presence of central corneal scarring. The classification

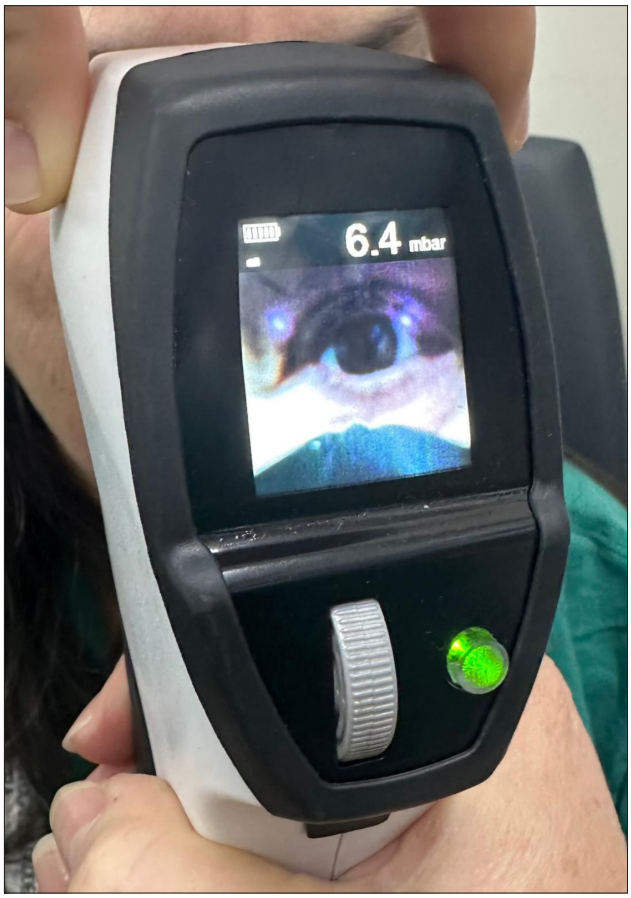

Figure 2. The Brill corneal esthesiometer in clinical use. The device is positioned in front of the patient's eye, and the integrated digital display shows real-time visualization of the ocular surface, stimulus pressure (6.4 mbar), and battery status. The ergonomic design enables single-handed operation, with a control dial for stimulus adjustment and a colored indicator light signaling device readiness. The system delivers non-contact air pulses to the cornea and uses a camera coupled with infrared LEDs for optimal alignment and precise distance control, ensuring standardization and reproducibility during corneal sensitivity assessment in both clinical and research settings.

divides KC into four stages:

- Stage I (mild): Eccentric corneal steepening, Kmed < 48D, myopia and/or astigmatism < -5D
- Stage II (moderate): Kmed <53D, TCT>400 µm, no central scarring, myopia and/or astigmatism between -5 and -8 D.
- Stage III (advanced): Kmed >53D, TCT 300-400 µm, no scarring myopia and/or astigmatism between -5 and -10D.
- Stage IV (severe): Kmed >55D, TCT<200 µm, central corneal scarring or perforation, refraction not measurable.

DATA COLLECTION

Patients were invited to participate in the study during a medical evaluation. Following their agreement, data were collected at the same time point, including demographics, and best-corrected visual acuity (BCVA) was measured with a Snellen scale and converted to logMAR for statistical purposes.

STATISTICAL ANALYSIS

Statistical analysis was performed using IBM SPSS Statistics® for Windows (version 31). Demographic and clinical variables were summarized using descriptive statistics, including means, standard deviations, medians, interquartile ranges, and frequencies as appropriate. Data from the most severe eye of each subject, based on keratometry readings, were included in the analyses. Variables were tested for normality using the Shapiro–Wilk test. Parametric tests were applied to variables with normal distribution ($p \geq 0.05$ on the Shapiro–Wilk test), while nonparametric tests were used for variables that were not normally distributed ($p < 0.05$ on the Shapiro–Wilk test). Differences in corneal sensitivity across KC stages were assessed using the Kruskal–Wallis test. Multiple pairwise comparisons between stages were conducted with appropriately adjusted post-hoc tests, with p-values corrected for multiple testing, using the Bonferroni correction. The association between corneal sensitivity and KC stage was examined using Spearman's rank correlation. Due to only one contact lens user in the sample, partial correlation was not possible to perform. A p-value less than 0.05 was considered statistically significant.

No missing data were reported. Sample size calculation or power analysis was not performed due to the exploratory nature of the pilot study.

RESULTS

DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

A total of 20 patients with KC were included in the study. The mean age was 25.85 ± 1.81 years (ranging from 13 to 43) and most patients were males (55%, n=11), with a predominance of left eyes (65%) over right eyes (35%). Me-

Table 1. Demographic and clinical characteristics of both groups.

Patients	**(n=20)**
Sex	
Male (%)	55
Female (%)	45
Age	
Mean (SD)	25.85 (1814)
Eye	
Right (%)	35
Left (%)	65
Contact Lens (%)	5
Sensitivity	
Median (IQR)	2.60 (2.1)
Severity stage (Amsler-Krumeich classification)	
Stage I (%)	50
Stage II (%)	30
Stage III (%)	10
Stage IV (%)	10

SD: standard deviation; IQR: interquartile range.

dian corneal sensitivity, as measured by the Brill esthesiometer, was 2.60 (IQR: 2.1). Based on the Amsler-Krumeich (AK) classification, 50% (n=10) of patients were categorized as stage I, 30% (n=6) as stage II, 10% (n=2) as stage III, and 10% (n=2) were classified as having the most advanced form of the disease (stage IV). Table 1 outlines demographic and clinical characteristics of the patients.

CORRELATION BETWEEN CORNEAL SENSITIVITY AND DISEASE STAGE

Spearman's rank correlation analysis showed no statistically significant association between corneal sensitivity and KC stage (ϱ=0.234, p=0.322; Table 2), indicating that corneal sensitivity did not vary appreciably across the different disease stages. Only one patient was a current contact lens user, precluding the use of partial correlation analysis to control for potential confounding effects of contact lens wear.

Table 2. Spearman's rank correlation coefficients (ϱ) between corneal sensitivity and keratoconus stage according to Amsler-Krumeich (AK).

	Correlation coefficient (ϱ)	p-value	N
Corneal Sensitivity *vs* AK Stage	0.234	0.322	20

No significant correlation was observed (p>0.05).

COMPARISON OF CORNEAL SENSITIVITY ACROSS STAGES

The distribution of corneal sensitivity by disease stage was further assessed using the Kruskal–Wallis test. The analysis revealed no statistically significant differences among the groups (H=2.958, df = 3, p=0.398). Pairwise stage comparisons, corrected using Bonferroni adjustment, also failed to identify significant differences between any pair of stages (all adjusted p>0.05; Table 3).

DISCUSSION

Evidence regarding the relationship between corneal sensitivity and KC severity remains conflicting. In this study, central corneal sensitivity was assessed using the Brill non-contact esthesiometer, a recent device that provides precise, reproducible, and operator-independent measurements while minimizing the risk of epithelial injury. This instrument offers improved clinical applicability compared to the Cochet–Bonnet aesthesiometer, considered the gold standard, which is susceptible to operator-dependent variability, environmental influences and potential corneal trauma.[13,14]

Previous studies report reduced corneal sensitivity in KC patients, with more pronounced decreases in contact lens wearers. However, associations between sensitivity and disease severity are inconsistent, likely due to differences in classification systems, small sample sizes, and diverse measurement methodologies.[12,15–19] In our study, corneal sensitivity did not vary significantly across KC stages classified by the AK system, consistent with reports indicating that reduced sensitivity may occur even in early or subclinical KC. This suggests that neural alterations can precede overt corneal thinning or topographic changes, and that sensitivity alone may not reliably reflect disease progression.[15,18,20]

Morphological changes of corneal nerves in KC include thickening, increased tortuosity, nerve sprouting, and overgrowth, primarily affecting central stromal nerves. These nerve changes are evident even in early stages and appear to worsen with disease progression, likely driven by tissue remodelling and imbalances in neurotrophic factors.[8–12,21]

Although corneal sensitivity was not found to be a useful marker for KC progression or staging, its assessment may remain clinically valuable, particularly in early detection.[8–12,21] Integrating functional sensory testing with the Brill esthesiometer and imaging modalities may improve identification of patients at risk and guide timely therapeutic interventions.[21]

This study has limitations, including a small sample size, the low number of contact lens users, and its cross-sectional design, which precludes assessment of longitudinal changes. Additionally, while the AK classification is widely accepted, it may not capture all nuances of KC severity. Future research should employ larger, longitudinal cohorts and incorporate multimodal approaches, such as *in vivo* confocal microscopy and molecular biomarkers, to provide a comprehensive understanding of corneal neurosensory alterations.

Corneal sensitivity did not significantly vary with keratoconus severity as classified by the AK system. Although morphological changes in corneal nerves are evident early

Table 3. Pairwise post-hoc comparisons between AK stages following the Kruskal–Wallis test. Adjusted p-values account for multiple comparisons.

Comparison	Test Statistic	Std. Error	Std. Test Statistic	p-value	Adjusted p-value
2 *vs* 1	0.633	3.033	0.209	0.835	1.000
2 *vs* 3	-2.333	4.796	-0.487	0.627	1.000
2 *vs* 4	-7.833	4.796	-1.633	0.102	0.614
1 *vs* 3	-1.700	4.550	-0.374	0.709	1.000
1 *vs* 4	-7.200	4.550	-1.583	0.114	0.681
3 *vs* 4	-5.500	5.874	-0.936	0.349	1.000

No statistically significant differences were found among any pair of stages (all adjusted p>0.05).

in the disease, functional sensitivity measurements alone do not reliably reflect disease progression. However, corneal sensitivity testing may still aid in the early detection of KC, particularly when integrated with imaging. Further longitudinal and multimodal research is essential to improve our understanding of neurosensory alterations and enhance clinical management of keratoconus.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

BG: Formal analysis, data collection, writing original draft, editing.

NC and AF: Data collection.

AR: Conceptualization, writing – review & editing.

JQG, EC, CT and MJQ: Writing – review & editing.

All authors have read and approved the version to be published.

BG: Análise formal, recolha de dados, redação do rascunho original, revisão.

NC e AF: Recolha de dados.

AR: Conceitualização, redação – revisão e edição.

JQG, EC, CT e MJQ: Redação – revisão e edição.

Todos os autores leram e aprovaram a versão a publicar.

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