



# ICO

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# Determination of risk of Keratoconus development in a population of possible at-risk children 7–18 years of age.

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## PURPOSE

The original purpose of this pilot study was to collect tomography scans on children and adolescents from a large urban low-income community to determine whether this is a population at-risk for keratoconus. The scans were completed on as many patients seen for a comprehensive eye exam at the IEI at Princeton Clinic, Chicago. The study began in 2017 and as of April 2019, 4204 Pentacam scans have been attempted. The study goal is to determine which individuals are at-risk for keratoconus based on the Pentacam tomography analysis. The initial description of the study was presented at AAO 2018. The data contained herein represents the initial stages of review, the number of scans attempted and completed. In the original methodology, the process was to have two expert reviewers blindly interpret the scans with some basic information and categorize the risk of keratoconus. We will share the demographics of the subject pool.

## METHODS

Each subject participated if they could complete the tomography scan. Subjects with significant corneal astigmatism were targeted. The tomography maps were reviewed and those that were considered valid were included in the analysis. Acceptable scans were considered at high-risk based on the criteria:

- Values of the Belin-Ambrosio A, B, or C > 1
- Final D >1.6.

The data collected included refractive error based on cycloplegic autorefraction.

In this initial part of the study, two blind reviewers who were considered experts in the field of keratoconus (one MD and one OD) provided feedback on groups of 8-10 scans at a time. They were provided with the following information along with the scans. All identifying information was removed prior to forwarding the data and scans to the reviewers.

The data that was included is as follows:

Subject Number	Pach Thin	Thin Pachy: (C)
Capture Diameter	Prog Index	IOP
BAD QS	Front E Thin	Sphere
Final D	Back E Thin	Cylinder
Asymmetry	ARC: (A)	Axis
ART-max	PRC: (B)	Best VA

The reviewers were requested to make a decision based on their knowledge and expertise and were not provided any specific guidelines for reviewing the data. We asked that they independently determine whether the subject scans were one of the following:

Normal  
Abnormal not Keratoconus  
Keratoconus Suspect  
Keratoconus

Once the primary reviewers returned their decision, subjects on which the reviewers disagreed were sent to a third reviewer.

## RESULTS

2,109 subjects had tomography scans attempted on both eyes of which 3861 total scans were valid, 14 had readable scans on only one eye. Subjects were 44.7% (942) male, 4-22 years of age (median 12 yrs), 61.6% Black, and 34.7% were Hispanic. For those that were readable, 7.2% (278) were identified as at-risk for keratoconus based on values A, B or C >1. 17.6% (687) had final D > 1.6 while 4.7% (182) showed both A, B, & C > 1 and final D >1.6. The data presented on the initial reviews covers the first 74 scans that were found to be readable.

Comparisons of the decisions by the 2 primary reviewers on the 74 subjects:

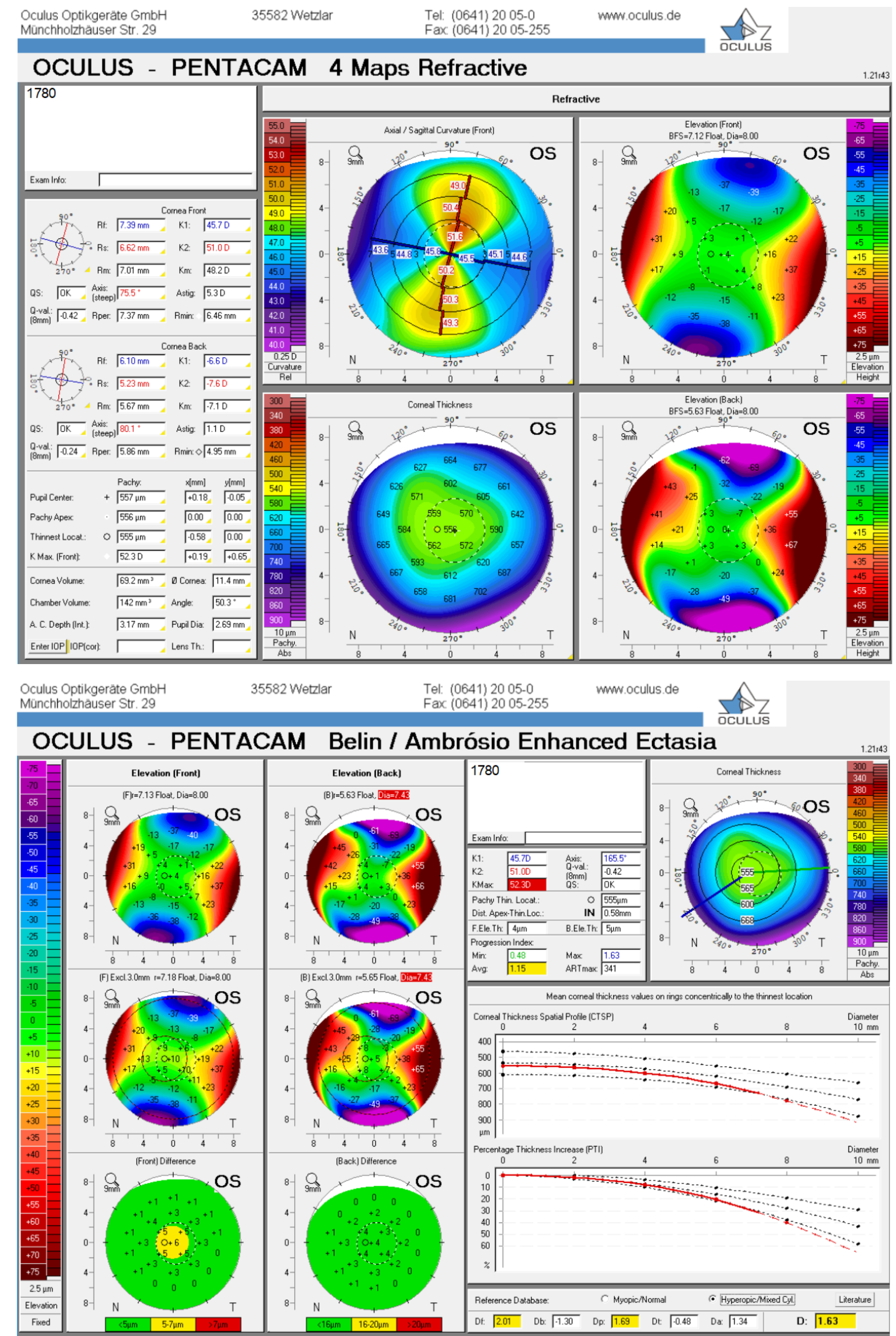
The reviewers agreed that 23 of the scans should be labeled as keratoconus and 14 should be keratoconus suspect. The reviewers did not agree on the remainder of the scans (37). The table below shows the decisions of the reviewers on all scans. The yellow cells represent agreement between the two primary reviewers.

	Reviewer 1			
Reviewer 2	Normal	Abnormal but not Keratoconus	Keratoconus Suspect	Keratoconus
Normal				1
Abnormal but not Keratoconus				
Keratoconus Suspect			14	11
Keratoconus	1		23	23

Review of the decisions of all three reviewers when Reviewer 1 & 2 did not agree on the risk of keratoconus.

Reviewer 1	Reviewer 2	Reviewer 3	# of subjects
Keratoconus Suspect	Keratoconus	Abnormal Not Keratoconus	1
Keratoconus Suspect	Keratoconus	Keratoconus	1
Keratoconus Suspect	Keratoconus	Keratoconus Suspect	13
Keratoconus Suspect	Keratoconus	Normal	7
Keratoconus Suspect	Normal	Normal	1
Normal	Keratoconus	Keratoconus Suspect	1

Example of a subjects that elicits variable interpretations:



Patient Number	Capture Diameter	BAD QS	Final D	Asymmetry	ART-max	Pach Thin	Prog Index	Front E Thin
1780	8.00/7.43	OK	1.63	10	341	555	1.15	4

Back E Thin	ARC: (A)	PRC: (B)	Thin Pachy: (C)	IOP	H/M	Sphere	Cylinder	Axis	Best VA
5	2.1	2.1	0.1	UTT	H	4.50	-6.75	166	50

## CONCLUSION

The study has encountered several challenges. The reviewers found it difficult to interpret the data simply by the information that was provided as well as the time required was longer than expected yielding a slower response rate. With the conclusion of this first group of subjects, the reviewers will be provided additional information in an effort to allow the reviewers to increase the efficiency and feel that they have all the information needed to judge the scans accurately. With the additional guidance, we are hoping that we can arrive at a more consistent outcome for those subjects truly at-risk.

The population studied is predominantly African American and Hispanic, many with significant astigmatism. The results suggest these individuals may be at higher risk for developing keratoconus based on the Pentacam values of A, B, C and final D. The data suggests a higher than expected prevalence then suggested in the literature for children and adolescents. Longitudinal studies need to monitor the subjects over time to see how many will actually convert to the diagnosis of keratoconus and what factors will contribute to the disease.

## ADDITIONAL COMMENTS

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 International Keratoconus Academy  
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