Success Rates and Prognostic Factors in the Management of Keratoconus: A 10-Year Retrospective Cohort Study at Siriraj Hospital

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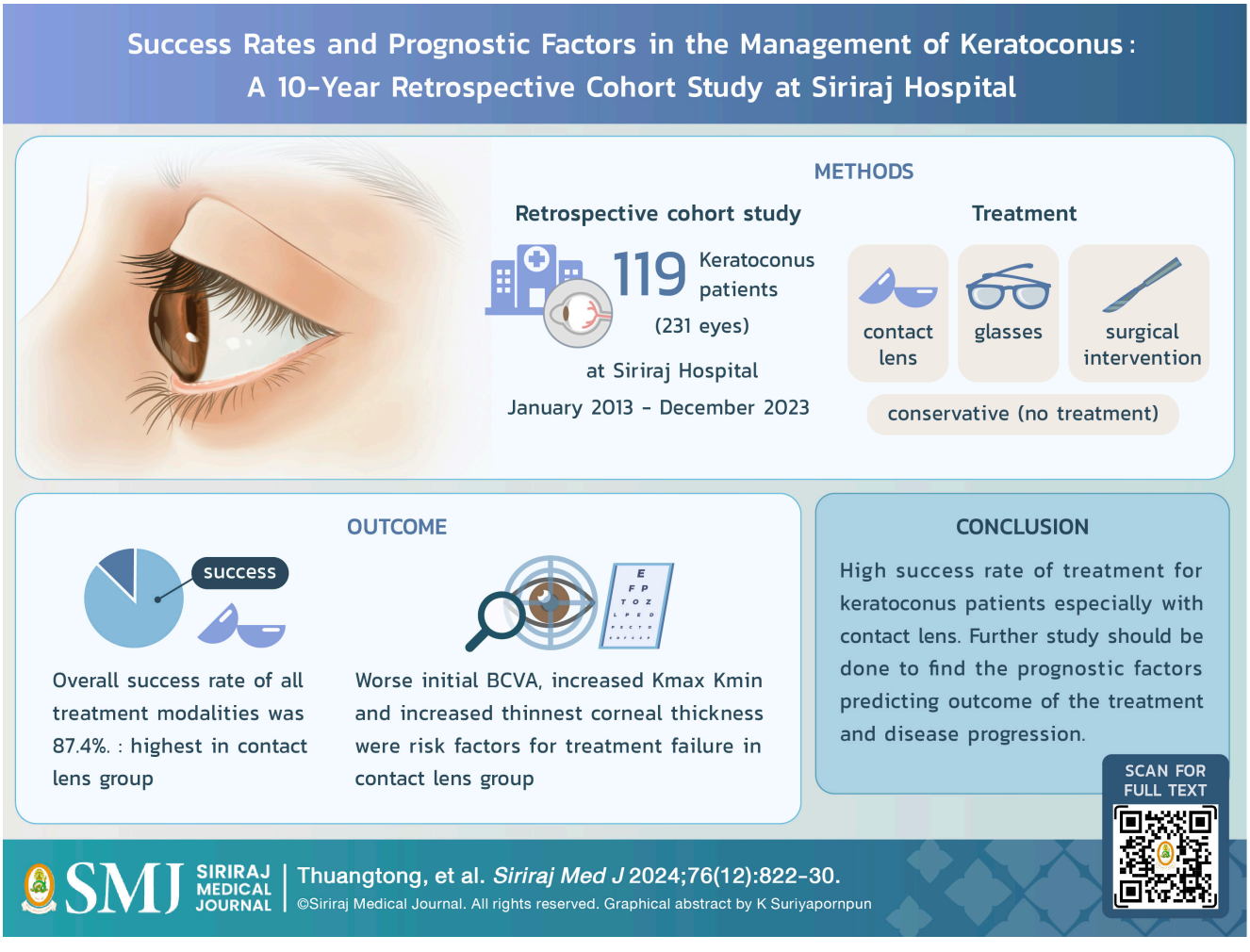

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ABSTRACT

Objective: To evaluate the success rates of different treatment modalities, identify prognostic factors associated with treatment outcomes and factors influencing disease progression in keratoconus patients.

Materials and Methods: A retrospective cohort study of keratoconus patients at Siriraj Hospital during January 2013 to December 2023 was done. Patient characteristics, symptoms and signs related to keratoconus, outcomes of corneal topography, treatment modalities, and best-corrected visual acuity (BCVA) before and after treatment were recorded. Treatment outcome was defined as a "success" when the BCVA post-treatment was equal to or better than 6/12. Progression of keratoconus was based on the Belin ABCD progression criteria.

Results: Total 119 patients (231 eyes) were analyzed. The mean age at diagnosis was 28.0 ± 9.5 years. Two hundred and sixteen eyes (93.5%) were clinical keratoconus. The overall success rate of all treatment modalities was 87.4%. Contact lenses were the most frequent treatment modality (147 eyes, 72.4%) with the highest success rate (90.5%). A worse initial BCVA, high keratometric reading and thinner cornea were risk factors for treatment failure in this group. Of 133 eyes disease progression could be evaluated (median follow-up time; 33 months) and 58 eyes (43.6%) met criteria for disease progression (median survival time; 8.8 years). No significant factors were found to be associated with disease progression.

Conclusion: Success rate in keratoconus treatment at Siriraj Hospital was 87.4%. Contact lenses were most frequently applied 72.4%. Factors associated with treatment failure were found in this group but for disease progression remained unclear due to limitations of the study.

Keywords: Keratoconus; success rate; progression; contact lens (Siriraj Med J 2024; 76: 822-830)

INTRODUCTION

Keratoconus is an eye disease characterized by protrusion and thinning of the cornea leading to astigmatism and blurred vision. While the condition commonly affects both eyes, it is often asymmetrical. Keratoconus has an incidence of approximately 2 per 100,000 individuals per year with a prevalence of 54.5 per 100,000 individuals. It can be found across all ethnicities and genders, typically manifesting during adolescence and progressing until the ages of 30–40 years old.[1,2]

In the initial stages, the treatment options[3] may include glasses or soft contact lenses to correct vision. As the condition progresses, these treatments may no longer effectively correct vision, necessitating the use of rigid contact lenses. In cases where rigid contact lenses are not suitable surgical interventions, like corneal transplantation, may be considered. Currently other treatments, such as intrastromal corneal ring segments (ICRS) implantation and collagen cross-linking (CXL), are utilized to reduce corneal curvature and increase corneal strength, respectively.[4-6] However, the contact lens remains the most popular treatment due to its convenience and non-invasiveness.[7]

Reported success rates of contact lens treatment for keratoconus range from 86.9% to 100%.[8-10] However disease progression following the treatment has been reported,[11] highlighting the increasing importance of collagen cross-linking to prevent disease progression.[1,12,13] While several studies have identified factors contributing to disease progression, investigations have not yet been conducted in a Thai population.

The aim of this study research was to analyze the success rate of keratoconus treatment at Siriraj Hospital, representing a Thai population, and to analyze prognostic factors for treatment outcome.

MATERIALS AND METHODS

Study population

The medical records of all patients aged 18 years old and older diagnosed with keratoconus and forme fruste keratoconus (ICD-10 code H18.6) between January 2013 and December 2023 at Siriraj Hospital, Mahidol University, Bangkok, Thailand were reviewed. Keratoconus was diagnosed according to the Rabinowitz criteria,[14] including central corneal power > 47.2 diopter (D), inferior–superior dioptric asymmetry over 1.2 D, sim K astigmatism > 1.5 D, and skew radial axis > 21 degrees. Forme fruste or subclinical keratoconus was diagnosed in an eye with an early stage of keratoconus with undetectable clinical findings and clinical keratoconus in the fellow eye.[15]

Patients with inconclusive diagnoses or other types of corneal ectasia were excluded. Also with patients that lost to follow-up before the treatment modalities were allocated were excluded from the treatment outcome

analysis. Furthermore, patients with less than two corneal topographic results from the Pentacam® system were excluded from the progression analysis. Approval for this study was obtained from the Siriraj Institutional Review Board [COA no. Si 628/2023 and SIRB protocol number 568/2566(IRB1)] in accordance with the principles outlined in the Declaration of Helsinki.

Data collection

Patient characteristics were recorded including age of diagnosis, sex, race, previous ocular trauma, history of atopic diseases, family history of keratoconus or other connective tissue diseases, eye rubbing, symptoms and signs related to keratoconus, such as scissoring reflex, Rizzutti's sign, Munson's sign, Fleischer's ring, and Vogt's striae, and corneal scarring. Outcomes of corneal topography including minimum keratometry (Kmin), maximum keratometry (Kmax), mean keratometry (Kmean), and thinnest corneal thickness at the time of diagnosis and at least one year follow-up were recorded. The treatment modalities, and best-corrected visual acuity (BCVA) before and after treatment were recorded.

Outcome measures

Treatment was classified into four groups: contact lenses, glasses, surgical intervention, and conservative (no treatment). The outcome was defined as a success when the BCVA post-treatment score was equal to or better than 6/12. All other outcomes were defined as failures. Additionally, in the contact lens treatment group, failure was also defined in patients who could not tolerate the contact lens even if the BCVA score equal to or better than 6/12. Progression of keratoconus was recorded if there were two or more of the followings: steepening of the anterior corneal surface, steepening of the posterior corneal surface and thinning and/or an increase in the rate of corneal thickness change from the periphery to the thinnest point. This criteria was ≥80% confidence interval (CI) (broken red line) on the Belin ABCD Progression Display as analyzed by the Pentacam® system, according to the Global Consensus on Keratoconus and Ectatic Disease published in 2015.[16]

Statistical analyses

Descriptive statistics were employed to summarize the patient and disease characteristics. Categorical data, including the success rate, were presented as numbers and percentages, while continuous data were presented as the mean ± standard deviation (SD). Due to bilateral diseases in individual patients, a generalized estimating equation (GEE) with exchangeable correlation structure was applied with binary logistic regression to determine the factors associated with the treatment outcome. The factors were analyzed between the treatment and no-treatment groups, as well as for each treatment modality separately. The median time to disease progression was analyzed using the Kaplan–Meier method. Censoring occurred when the patient was loss to follow-up or when data were missing. In addition, a mixed model for time to progression was employed to investigate the factors associated with disease progression. The statistical analysis was conducted using IBM SPSS Statistics version 29 (IBM Corp., Armonk, N.Y., USA) and Stata version 16.0.

RESULTS

A total of 319 patients with the ICD-10 code H18.6 were retrospectively reviewed. After applying eligibility criteria, data of 119 patients (231 eyes) were included in the analyses. In total 133 eyes were included for the progression analysis (Fig 1).

All the patients were Thai except for one Arabian patient. Eighty-six patients (72.3%) were male. Bilateral keratoconus was found in 112 patients (94.1%). The mean age at diagnosis was 28.0 ± 9.5 years (Table 1).

Data concerning family history of keratoconus or other corneal diseases, other comorbidities, history of atopic diseases, and even a history of eye rubbing could not be recorded consistently due to incomplete reporting in the medical records. For the available data, allergic rhinitis and allergic conjunctivitis were the most frequently associated findings.

The most common presenting symptom was blurred vision (91.1%). Therefore, signs related to keratoconus included corneal scarring, Vogt's striae, Munson's sign, Fleischer's ring, Rizzutti's and scissoring reflex were hard to described in number due to a lot of missing data.

Twenty-eight eyes were excluded due to the patients being lost to follow-up before the treatment modalities were allocated. Contact lenses were the most common treatment prescribed to the patients (147 eyes, 72.4%) followed by glasses (37 eyes, 16.7%), surgical intervention (6 eyes, 3%), and no treatment (13 eyes, 6.4%) due to the early stage of the disease or patient preference. Treatment choices were based on disease severity (corneal topography) and clinical experience.

Patients who received any treatment had a poorer initial BCVA score, higher keratometry values and lower thinnest corneal thickness compared to the no treatment group whereas the age at diagnosis did not differ significantly between the treatment groups (Table 2).

Among all the treatment modalities, surgery was preferred in patients with a poorer initial BCVA, higher keratometry values and thinner corneal thickness (Table 2). Surgery included ICRS for high astigmatism (3 eyes), deep anterior lamellar keratoplasty (DALK) for a dense central corneal scar (1 eye), and intracameral 14% C_3F_8 injection and compression sutures for corneal hydrops (2 eyes).

Contact lens treatment had the highest success rate of 90.5% followed by glasses and surgical treatment, with success rates of 81.4% and 50%, respectively (Table 2). For contact lens and glasses treatment group, the success of the treatment was determined immediate after the treatment but for the surgical group, the success of the treatment was determined at the average time of 1-3 months postoperative. Rigid gas permeable contact lenses were predominantly prescribed in the contact lens group (98.5%). The reasons for treatment failure in the contact lens group were unacceptable visual acuity (VA) (poorer than 6/12) (8 eyes, 57.1%), inability to obtain an

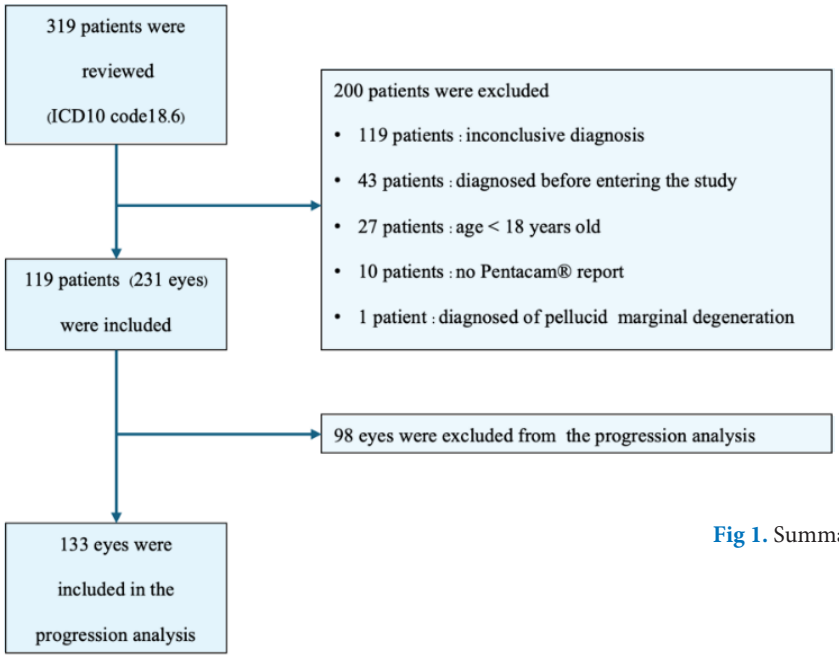

Fig 1. Summary of the study population.

TABLE 1. Characteristics of the eyes diagnosed with keratoconus in this study.

Characteristics	n = 231
Forme fruste keratoconus	15 (6.5%)
Keratoconus	216 (93.5%)
Advanced keratoconus	6 (2.8%)
Corneal hydrop	5 (2.2%)
Posterior keratoconus	4 (1.7%)
Initial BCVA (logMAR) †	0.46 ± 0.49
Kmin (D) †	48.5 ± 7.9
Kmax (D) †	53.3 ± 8.8
Kmean (D) †	50.7 ± 8.1
Thinnest corneal thickness (μm) †	460.5 ± 57.8

†Continuous variables are displayed by the mean ± SD.

Abbreviation: SD, Standard deviation; BCVA, Best-corrected visual acuity; Kmin, minimum keratometry; Kmax, maximum keratometry; Kmean, mean keratometry; D, Diopters; μm, micrometer.

TABLE 2. Success rate and baseline characteristics of the eyes in each treatment modality.

Factors	No treatment n = 13	Treatment n = 190	p-value*	Treatment modality: n (%) Treatment Contact lens n = 147	Glasses n = 37	Surgery n = 6	p-value**
Outcome							
Success	12 (92.3)	166 (87.4)	-	133 (90.5)	30 (81.4)	3 (50.0)	-
Failure	1 (7.7)	24 (12.6)	-	14 (9.5)	7 (18.9)	3 (50.0)	-
Male	12 (92.3)	134 (70.5)	-	113 (76.9)	18 (48.6)	3 (50.0)	0.002[a]
Allergy	8 (61.5)	72 (37.9)	-	60 (40.8)	15 (40.5)	0 (0.0)	0.153[a]
Corneal scarring	1 (7.7)	20 (10.5)	-	17 (11.6)	2 (5.4)	1 (16.7)	0.328[a]
Age at diagnosis (years)	26.3 ± 8.3	27.9 + 9.2	0.383	26.8 ± 8.0	32.2 ± 12.7	29.2 ± 5.6	0.043[b]
Initial BCVA (logMAR)†	0.10 ± 0.15	0.41 ± 0.4	< 0.01	0.43 ± 0.40	0.27 ± 0.30	0.97 ± 0.87	0.003[b]
Kmin (D)†	43.8 ± 1.4	48.0 ± 7.3	< 0.01	48.1 ± 6.3	45.2 ± 3.4	64.1 ± 20.1	0.002[b]
Kmax (D)†	46.9 ± 2.9	53.0 ± 8.3	< 0.01	53.1 ± 6.9	49.0 ± 4.1	73.1 ± 22.6	<0.001[b]
Kmean (D)†	45.3 ± 1.9	50.3 ± 7.6	< 0.01	50.4 ± 6.3	47.1 ± 3.6	68.2 ± 21.2	<0.001[b]
Thinnest corneal thickness (μm)†	508.9 ± 44.5	462.4 ± 51.2	< 0.01	456.0 ± 49.7	486.7 ± 75.8	468.67 ± 75.8	<0.001[b]

†Continuous variables are displayed by the mean ± SD.

*p=value between treatment and no-treatment group was calculated using Mann-Whitney U test

**p-value among baseline characteristics of each treatment modality was calculated using Fisher's exact test[a] and Kruskal-Wallis test[b]

Abbreviation: SD, Standard deviation; BCVA, Best-corrected visual acuity; Kmin, minimum keratometry; Kmax, maximum keratometry; Kmean, mean keratometry; D, Diopters; μm, micrometer

optimal position (4 eyes, 28.6%), and severe irritation (2 eyes, 14.3%). From the multivariable analysis, worse initial BCVA (OR 36.2, 95% CI: 5.7; 229.5), increased Kmax (OR 8.1, 95% CI: 1.7; 37.9), increased Kmin (OR 11.4, 95% CI: 2.6; 50.7) and increased thinnest corneal thickness (OR 1.0, 95% CI: 1.0; 1.1) were risk factors for treatment failure (Table 3).

For the glasses group, the multivariable analysis (Table 4) indicated that only an increased Kmean (OR 5.8, 95% CI: 1.3; 25.5) was the risk factor for treatment failure.

Fifty-eight eyes (43.6%) met the criteria for disease progression according to the Belin ABCD progression criteria with a mean follow-up time of 43.5 ± 33.8 months (range 1–121 months, median 33 months, IQR 55 months). Following progression, 30 eyes underwent CXL, 8 eyes underwent surgical interventions (including ICRS insertion and corneal transplantation), 12 eyes continued with their previous treatment based on patient preference, and 8 eyes continued with their previous treatment due to differing progression criteria. (The ABCD Berlin progression criteria have been implemented at Siriraj Hospital since 2020.)

In the a mixed-effect statistical analysis for binary model, no factors were significantly associated with disease progression (Table 5).

The time to progression survival curves of 133 keratoconus eyes were plotted in Fig 2. Based on Kaplan–Meier analysis, the median survival time was 105 months (8.8 years). The percentage of patients without disease progression at one year was 82.7%.

TABLE 3. Factors associated with the outcome in keratoconus patients in the contact lens treatment group.

Factors	Outcome: n (%)		Univariable analysis			Multivariable analysis		
	Success n=133	Failure n=14	OR	95% CI	p-value[b]	OR	95% CI	p-value[a]
Male	106 (79.7)	7 (50.0)	0.2	0.1;0.9	**0.033**	0.2	0.0;0.9	**0.039**
Allergy	54 (40.6)	6 (42.9)	1.1	0.3;3.9	0.919	-	-	-
Corneal scarring	13 (9.8)	4 (28.6)	3.9	1.2;13.2	**0.024**	0.9	1.0;9.2	0.961
Age at diagnosis (years)†	25.9 ± 6.0	35.1 ± 8.0	1.1	0.3;3.9	**<0.001**	0.9	0.9;1.0	0.100
Initial BCVA (logMAR)†	0.37 ± 0.30	1.00 ± 0.70	17.2	4.1;73.0	**<0.001**	**36.2**	5.7;229.5	**<0.001**
Kmin (D)†	47.9 ± 6.3	50.0 ± 6.1	1.0	0.9;1.0	**0.091**	**11.4**	2.6;50.7	**0.001**
Kmax (D)†	52.8 ± 6.7	56.7 ± 7.8	0.9	0.9;1.0	**0.042**	**8.1**	1.7;37.9	**0.008**
Kmean (D)†	50.2 ± 6.2	52.7 ± 6.3	0.9	0.9;1.0	**0.059**	0.009	0.0;0.2	**0.002**
Thinnest corneal thickness (µm)†	459.7 ± 49.4	420.7 ± 40.0	1.0	1.003;1.03	**0.009**	**1.0**	1.0;1.1	**0.042**

TABLE 4. Factors associated with the outcome in keratoconus patients in the glasses treatment group.

Factors	Outcome: n (%)		Univariable analysis			Multivariable analysis		
	Success n=30	Failure n=7	OR	95% CI	p-value[b]	OR	95% CI	p-value[a]
Male	14 (46.7)	4 (57.1)	0.7	0.1;4.6	0.738	-	-	-
Allergy	12 (40.0)	3 (42.9)	0.9	0.1;6.1	0.944	-	-	-
Corneal scarring	1 (3.3)	1 (14.3)	0.2	0.0;3.9	0.290	-	-	-
Age at diagnosis (years)†	31.6 ± 12.8	34.7 ± 12.8	1.0	1.0;1.1	0.546	-	-	-
Initial BCVA (logMAR)†	0.19 ± 0.19	0.63 ± 0.44	146.5	9.3;2,308.1	**<0.001**	73.9	0.3;19.3	0.130
Kmin (D)†	44.4 ± 2.2	49.0 ± 4.9	1.6	1.2;2.1	**0.002**	0.5	0.2;1.1	0.090
Kmax (D)†	47.9 ± 2.7	53.5 ± 5.9	1.6	1.0;2.4	**0.038**	0.5	0.2;1.8	0.327
Kmean (D)†	46.1 ± 2.3	51.3 ± 5.1	1.8	1.3;2.5	**0.001**	**5.8**	1.3;25.5	**0.021**
Thinnest corneal thickness (µm)†	495.2 ± 38.3	486.6 ± 46.5	1.0	0.96;1.00	**0.027**	1.0	1.0;1.1	0.589

†Continuous variables are displayed by the mean ± SD.

a. Statistically significant at p-value < 0.05; b. Factors with univariable p-value < 0.15 were entered into the multivariable analysis.

Abbreviation: RR, Relative risk; SD, Standard deviation; BCVA, Best-corrected visual acuity; Kmin, minimum keratometry; Kmax, maximum keratometry; Kmean, mean keratometry; D, Diopters; µm, micrometer

TABLE 5. Factors associated with progression based on the ABCD Belin progression criteria in keratoconus patients

Factors	Progression, n (%)		Univariable analysis		
	Yes n=58	No n=75	HR	95% CI	p-value[a]
Male	45 (77.6)	52 (69.3)	1.9	0.6;6.8	0.302
Age at diagnosis (years)†	26.7 ± 8.0	28.2 ± 9.0	1.0	0.9;1.0	0.305
Allergy	27 (46.6)	29 (38.7)	2.0	0.7;5.9	0.203
Initial BCVA (logMAR)†	0.39 ± 0.34	0.46 ± 0.52	0.7	0.3;1.7	0.424
Corneal scarring	6 (10.3)	11 (14.7)	0.7	0.2;2.0	0.474
Kmin (D)†	47.6 ± 4.5	48.6 ± 7.9	1.0	0.9;1.0	0.195
Kmax (D)†	52.7 ± 5.9	53.3 ± 8.0	1.0	0.9;1.0	0.698
Kmean (D)†	50.0 ± 5.0	50.7 ± 7.6	1.0	0.9;1.0	0.427
Thinnest corneal thickness (μm)†	458.3 ± 39.0	458.7 ± 58.1	1.0	0.99;1.01	0.993
ARC (mm)†	6.51 ± 0.72	6.48 ± 0.88	1.2	0.8;2.0	0.389
PRC (mm)†	4.98 ± 0.76	5.00 ± 1.00	1.2	0.8;1.9	0.378
Treatment modalities					
Contact lens	49 (87.5)	50 (66.7)	2.4	0.3;16.8	0.377
Glasses	2 (3.6)	13 (17.3)	0.2	0.0;4.0	0.310
Surgery	3 (5.4)	6 (8.0)	0.4	0.0;7.0	0.506
No treatment	2 (3.6)	6 (8.0)	Ref	-	-

†Continuous variables are displayed by the mean ± SD.

a. Statistically significant at p-value < 0.15; Ref = Reference of relative risk calculation for more than two categorical variables.

Abbreviation: HR, Hazard ratio; SD, Standard deviation; BCVA, Best-corrected visual acuity; Kmin, minimum keratometry; Kmax, maximum keratometry; Kmean, mean keratometry; D, Diopters; μm, micrometer; ARC, Anterior radius of curvature; PRC, Posterior radius of curvature; mm, millimeter.

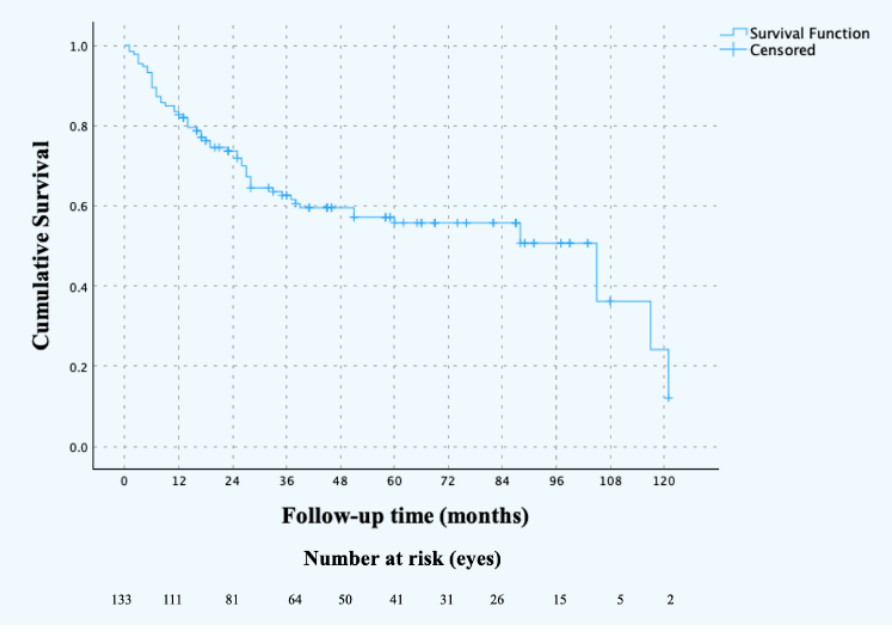

Fig 2. Kaplan–Meier plots of keratoconus disease progression in this study.

DISCUSSION

In our study, contact lenses were prescribed for 147 eyes (72.4%), followed by glasses for 37 eyes (16.7%), correlating with the results of the CLEK study, which reported a 74% utilization of contact lenses (including RGP lenses at 65%) and 16.1% for glasses. Our surgical intervention rate at initial presentation (6 eyes, 3%) was slightly lower compared to a previous study in Thailand (21.5% for corneal transplantation, 19.7% for ICRS, and 27.2% for CXL).[17]

The overall success rate of all treatment modalities was 87.4%. The success rate was observed to be higher in the contact lenses and glasses groups (90.5% and 81.4%, respectively) compared to the surgery group (50%) due to the poorer baseline characteristics, including visual acuity and keratoconus staging, in the surgery group. The success rate of contact lenses was consistent with previous studies, which have reported rates ranging from 86.9% to 100%.[8-10]

In the multivariate analysis to identify the risk factor for treatment failure, there was a difference in the risk factors in contact lens and glasses groups (worse initial BCVA, increased Kmax, Kmin and lower thinnest corneal thickness in contact lens group and only an increased Kmean in glasses group). The difference in both groups may be from the confounding by indication. Disease severity and clinical experience determined the treatment. Milder cases were treated with glasses

Binary logistic regression could not be performed to identify the risk factors in the surgical treatment group due to the limited number of patients in the present study.

According to the Global Consensus on Keratoconus and Ectatic Diseases (2015), there are no universal or definite criteria for keratoconus progression.[16] Our study opted to utilize the ABCD Berlin progression criteria due to their ability to detect disease progression early[11] and their accessibility through the "Pentacam®" application, which is widely available in Thailand.

Out of 133 eyes examined, 58 (43.6%) met the criteria for disease progression in our study. Ozalp et al.[11] demonstrated a higher percentage compared to ours (57%) using the same criteria (single baseline criteria). This discrepancy may be attributed to lower dropout rate, and the use of multiple-visit corneal topographic evaluations, which increased sensitivity in detecting progression. The mean follow-up time in their study was 53.6 months (range, 12.0-124.3 months). In comparison to other studies with different criteria, the proportion of progressors in other studies was significantly lower. For instance, between 18.6 % and 25.6% exhibited progression over the follow-up period based on criteria where topographic parameters were increased by > 1.00 D/year.[18] Additionally, 25 of 94 eyes (26.5%) showed progression of the central K ≥1.50 D, with a mean time to progression of 12 years, according to Choi et al.'s study.[19]

Although various factors have been shown to be associated with disease progression, such as a younger age, greater disease severity at baseline, and poorer best-corrected visual acuity,[1,12,18] our study did not identify any significant risk factors that could predict progression.

The limitations in our study were retrospective study, far different numbers of patients in each group, small sample size in certain treatment groups (e.g. surgical intervention) hindered the ability to perform robust statistical analyses, such as logistic regression to identify risk factors for treatment failure, incompletely collected data, which limits the study's ability to fully assess risk factors for treatment outcomes and disease progression and the variation of follow-up period that could affect the accuracy of the analysis regarding disease progression and treatment success over time. Further study should be done to find the prognostic factors predicting disease progression.

CONCLUSION

The overall success rate for all treatment modalities in keratoconus patients in Siriraj Hospital was 87.4%. Contact lenses were most frequently applied treatment (72.4%) with the highest success rates (90.5%). Treatment failure in contact lens group was associated with worse initial BCVA, increased Kmax, increased Kmin, and lower thinnest corneal thickness. No significant factors were found to be associated with disease progression.

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DECLARATION

Grants and Funding Information

This was an unfunded study.

Conflict of Interest

All authors declare no personal or professional conflicts of interest relating to any aspect of this study.

Author Contributions

Conceptualization and methodology, A.T. and T.P.; Investigation, A.T. and T.P.; Formal analysis, A.T. and T.P.; Visualization and writing – original draft, A.T. and T.P.; Writing – review and editing, A.T. and T.P.; Funding acquisition, none; Supervision, A.T. All authors have read and agreed to the final version of the manuscript.

Use of artificial intelligence

ChatGPT language model, developed by OpenAI based on the GPT-4.0 architecture was used for grammar correction.

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