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Impact of scleral contact lens use on rate of corneal transplantation for keratoconus

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Abstract

Purpose: To evaluate the association of scleral contact lens (SCL) use on the risk for keratoplasty for people with keratoconus (KCN).

Methods: The electronic health records of patients receiving eye care at the University of Michigan Kellogg Eye Center between August 1, 2012 and December 31, 2018 were reviewed. Patients with a diagnostic code of KCN or corneal ectasia, no previous history of keratoplasty, and for whom data was available for both eyes were included. Using a multivariable Cox regression model, associations between SCL use and keratoplasty were tested adjusted for sociodemographic factors, maximum keratometry (MaxK), and current contact lens (CL) use.

Results: 2,806 eyes met inclusion criteria. CL use in each eye was 36.2% with no CL, 7.2% soft, 33.9% rigid gas permeable (RGP), and 22.7% scleral. A total of 3.2% of eyes underwent keratoplasty. In the adjusted model, SCL or RGP CL use significantly lowered the hazard of undergoing keratoplasty (HR=0.19, 95% CI 0.09-0.39, p<0.0001 and HR=0.30, 95% CI 0.17-0.52, p<0.0001, respectively), when compared to no CL use. Factors associated with increased risk of keratoplasty were black race as compared to white (HR=1.87, 95% CI 1.10-3.16, p=0.02), younger age (HR=0.92 per 5-year increment, 95% CI 0.86-0.99, p=0.032), and lower socioeconomic status (HR=1.08 per 5-point increase in Area Deprivation Index, 95% CI 1.03-1.13, p=0.0008). Keratoplasty was not associated with gender, insurance, or MaxK.

Conclusions: Physicians should maximize the use of scleral or RGP CL as patients who successfully use CL have almost one fifth risk of undergoing keratoplasty.

Keywords

keratoconus; penetrating keratoplasty; scleral contact lenses

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Keratoconus (KCN) is a bilateral, non-inflammatory corneal ectasia with onset often in adolescence that can profoundly affect vision and quality of life.[1] Management options include eyeglasses, soft or rigid gas permeable (RGP) contact lenses (CL), intrastromal corneal ring segments, and most recently, collagen cross-linking. Despite these management options, patients with KCN carry an estimated 10-20% lifetime risk of needing a corneal transplant,[2] and KCN remains the foremost indication for primary penetrating keratoplasty (PK) and deep anterior lamellar keratoplasty (DALK) in the United States.[3]

The benefit of scleral CL (SCL) and RGP CLs across patients with differing severity of KCN is not fully understand. RGPs are the most commonly employed CL design in patients with KCN and can delay the need for keratoplasty.[4–7] However, patients with KCN and advanced ectasia can be difficult to fit successfully due to the highly irregular corneal surface. The resultant poor vision, discomfort, and incident corneal scarring often lead patients to proceed with surgical intervention. SCLs offer a distinct advantage over RGPs. These large-diameter hard CLs vault over the cornea and rest on the peri-limbal conjunctiva. This design maintains comfort while neutralizing refractive error, even in cases of severe ectasia. These lenses have recently become more available to patients because of improved materials and fitting strategies.[8,9] However, little research has been done on the impact of SCLs on rates of keratoplasty in KCN. The goal of this study was to evaluate the association of SCL use on the need for keratoplasty (PK or DALK) for patients with all severities of KCN.

Methods

Data Source:

This study was approved from the University of Michigan International Review Board (IRB). Data was captured from patients receiving eye care between August 1, 2012, and December 31, 2018. The data source used was the Sight Outcomes Research Collaborative (SOURCE) Ophthalmology Data Repository, which captures EPIC electronic health record (EHR) data of all patients receiving eye care included in the repository (EPIC Systems Corporation). Data include patient demographics, diagnoses identified by International Classification of Diseases ICD-9 and ICD-10 billing codes, and structured and unstructured (free-text) data from all clinical encounters.

Inclusion and Exclusion Criteria:

Participants were identified who had an ICD-9 or ICD-10 diagnostic code of KCN or corneal ectasia (Supplemental Table 1). All participants received at least two diagnoses of KCN or corneal ectasia on two separate dates to exclude “rule-out” cases. Patients with a previous history of keratoplasty (PK, DALK, and endothelial keratoplasty) were excluded. Only participants with data from both eyes were included. Records were tracked and censored at time of keratoplasty or at the end of the study period.

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Analysis:

Variables analyzed included current use of a soft, RGP, or scleral CL at the eye level. Current CL use was defined as use at the most recent office visit, or office visit just prior to any keratoplasty. SCL included full-diameter scleral, mini-scleral, and Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) designs. RGP CLs included small-diameter, corneal-bearing RGP, hybrid, and piggy-back designs. Other variables analyzed were maximum corneal keratometry value (MaxK), age, sex, race, health insurance status, and socioeconomic level. MaxK value was assessed using the most recent topographic or tomographic test, or the test just prior to any keratoplasty. MaxK values were manually extracted via review of scanned images in each patient's EHR. Tomography and topography performed at the University of Michigan were done using the Pentacam (Oculus) and Orbscan (Bausch & Lomb), but if data was only available from outside records, keratometry from those notes was extracted from the electronic health record. Socioeconomic level was measured using the Area Deprivation Index (ADI).[10] ADI is an index from 0 to 100 based on zip code of residence and represents the socioeconomic deprivation experienced by a neighborhood, with a higher score representing more severe deprivation.

Statistical Analysis:

Descriptive analysis was performed for continuous variables (mean, standard deviation) and categorical variables (frequency, proportion). A multivariable Cox regression model assessed the association between current use of a SCL (key predictor) and need for keratoplasty (primary outcome) at the eye level. Models were adjusted for current use of a soft or RGP CL, MaxK, sociodemographic factors and to account for within-person correlation (between two eyes).

Results

A total of 2,806 eyes met inclusion criteria. Average age at index date was 45.1 ± 16.0 years, 61.2% were male, and 67.6% were white, 20.2% black, and 12.2% other race. CL use at most recent office visit or the office visit just prior to keratoplasty was: 1016 (36.2%) eyes with no CL, 202 (7.2%) soft, 951 (33.9%) RGP, and 637 (22.7%) scleral.

A total of 90 eyes (3.2%) of 81 participants underwent keratoplasty during the study period, with characteristics displayed in Table 1. Of the 90 eyes which underwent keratoplasty, 65 (72.2%) were PK and 25 (27.8%) were DALK. Participants who underwent keratoplasty were significantly younger (39.8 vs. 45.2 years, p=0.001), more likely to be black (40.0% vs. 19.5%, p<0.001), more likely to have an unknown insurance status (46.7% vs. 30.0%, p=0.002), and had a higher ADI, representing worse socioeconomic status, (62.6 vs. 48.9, p<0.001). Those eyes also had a steeper MaxK (58.1 vs 54.7 diopters, p=0.008) and a significantly lower percentage were currently wearing an RGP (20.0 vs. 34.4%) or SCL (8.9% vs. 23.1%) (p<0.0001).

A multivariable Cox regression model was performed adjusted for all variables (Table 2). SCL and RGP CL use was associated with a decreased risk of keratoplasty. Participants who used SCL underwent keratoplasty at one fifth the rate (HR=0.19, 95% CI 0.09-0.39,

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p<0.0001) when compared to no CL use. RGP use had one-third the rate keratoplasty (HR=0.30, 95% CI 0.17-0.52, p<0.0001) when compared to no CL use.

Factors associated with increased risk of keratoplasty were black race as compared to white (HR=1.87, 95% CI 1.10-3.16, p=0.02), younger age (HR=0.92 per 5-year age increase, 95% CI 0.86-0.99, p=0.032), and lower socioeconomic status (HR=1.08 per 5-point increase in ADI score, 95% CI 1.03-1.13, p=0.0008). There was no significant association of gender, insurance status, or MaxK with keratoplasty.

Discussion

In this study, we reviewed records of 2,806 eyes of patients with KCN. The multivariable model approach of analysis allowed evaluation of the association of SCL and RGP CL use with keratoplasty. Those who successfully wore SCL or RGP CLs had significantly lower risk of undergoing keratoplasty compared to those wearing no CLs. Being black, younger, and living in a neighborhood with more socioeconomic deprivation was associated with increased risk of keratoplasty, even after controlling for insurance status.

The importance of rigid material CLs in the management of KCN is well-established. RGPs, which rest on the corneal surface, are the most commonly employed design and can delay the need for surgery.[4–7] Our study supports that patients with RGPs had a decreased likelihood of corneal transplantation. RGPs were the most common type of CLs used and patients with RGPs had one-third the rate of keratoplasty compared to no CL use. However, clinicians know that patients with advanced ectasia can be difficult to fit successfully in RGPs due to the highly irregular corneal surface.

Patients with advanced disease can now be fit with SCLs and obtain better comfort.[8,11,12] By vaulting over the corneal surface, patients who have previously failed RGPs can be successfully fit with SCLs. Thus, more patients have the opportunity for visual rehabilitation without corneal transplantation surgery. In this study, successful SCL users had one-fifth the risk of keratoplasty compared to non-CL users. SCLs, when used with appropriate lens hygiene, offer many advantages over keratoplasty, including avoidance of intra-operative surgical morbidity, post-operative risk of infection, rejection, and wound dehiscence, and need for long term topical steroid drops.[1]

There has been relatively little research in this area. Dr. Koppen et al in Belgium report that successfully fitting patients with SCLs enabled them to halve the rate of keratoplasty in their KCN population.[13] They retrospectively identified eyes with severe KCN, which they defined as maxK ≥ 70 diopters, and found that 40 eyes were successfully fit with SCLs with continued use after at least 6 months of follow-up. They conclude that, if not for SCLs, these 40 eyes would have undergone keratoplasty, thereby increasing the rate of keratoplasty from the observed 28 of 1692 eyes (1.65%) to 68 of 1692 eyes (4.02%) over the study period. Though compelling, their conclusion is based on assumptions about how patients would hypothetically have been managed. It also fails to consider the impact of other sociodemographic factors.

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Patients may face barriers to SCL use,[8,9,12,13] including limited access to experienced optometric providers and difficulty affording the lenses depending on insurance coverage. Patients need good dexterity for CL insertion and removal and must maintain good lens hygiene to minimize risk of infectious keratitis. Not all patients are SCL (or RGP) candidates due to the presence of corneal scarring (for instance from prior hydrops) that may limit vision despite good fit and comfort with a CL. Whether these factors affected our patient population's ability or desire to wear SCL could not be captured by the chosen method of analysis.

The results show that black race, younger age, and living in a neighborhood with more socioeconomic deprivation was associated with increased risk of keratoplasty. Although KCN affects all races, it appears to do so differentially. Woodward et al, in an analysis of 16,053 patients in a nation-wide health care claims database, found that black persons had 57% higher odds higher odds of KCN as compared to whites.[14] Tuft et al, in a 7-year analysis of 2723 patients, found that blacks had an increased risk of progression to keratoplasty as compared to whites and Asians.[15] Other studies have found variations in KCN prevalence among races, ethnicities, and geographic location.[16,17] The reasons for these findings are likely multifactorial. KCN is thought to have a genetic predisposition, with a "second hit" or environment event eliciting clinical progression.[18] Strong familial aggregation of disease has been noted and several possible genomic loci have been identified.[16,19] In addition, race and ethnicity may affect an individual's access to health care and the subsequent diagnosis and management of diseases. Further research on how race affects rates of keratoplasty in patients with KCN is needed.

Younger age at time of KCN diagnosis has been linked to faster progression of disease as well as higher risk of keratoplasty. Ferdi et al, in a meta-analysis of 41 publications on the natural progression of KCN, found that younger patients demonstrate greater progression and steepening of Kmax at 12 months.[20] Tuft et al found that individuals younger than 18 underwent keratoplasty sooner than did those older than 18.[15] Finally, Reeves et al, in a 5-year analysis of 131 eyes, found that patients age 30 or younger had a sevenfold increased risk of keratoplasty compared with ages over 40.[21] These findings are not uniform across the literature. Pouliquen et al, Kennedy et al, and Lass et al found no association between age and risk of keratoplasty; however, these studies are somewhat outdated, with year of publication ranging from 1981 to 1990.[22–24]

Finally, we found that individuals residing in a neighborhood with more socioeconomic deprivation were at higher risk of keratoplasty, even after controlling for insurance status. It may be that a person's zip code serves as a gross measure of income and resources, with downwind effects on ease of access to optometric specialists, affordability of CLs, and decision to proceed with keratoplasty. Similarly, Sarezky et al showed that patients with a household net worth of $150,000-249,000 and >$500,000 were significantly less likely to undergo PK than those with household net worth <$25,000.[25]

Limitations to the methods exist. The KCN population in an academic tertiary care academic centers may not be representative of all cornea practices. Our available data from 2012 (with the adoption the EPIC EHR) does not represent patients who may have a risk of keratoplasty

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greater than eight years. The impact of collagen cross-linking procedures on rates of keratoplasty could not be assessed due to the recent implementation of crosslinking after approval in April 2016 by the Food and Drug Administration (FDA). MaxK values used for analysis were not always acquired from the same topographic or tomographic source. Lastly, with our dataset and methods we were unable to comment on prior CL use and the reasons why patients choose to wear, switch between, or discontinue wearing various CL designs. It is unknown which of those patients who underwent keratoplasty but could have potentially achieved good outcomes with a SCL.

This study supports clinical evidence from cornea experts that patients' access to SCLs reduces the risk of keratoplasty for patients with KCN. Further research is needed on the impact of patient ethnicity and age, the effect of SCLs on the time latency to surgery for those that underwent keratoplasty, and the reasons why patients may have success with some CL designs but not others. Our hope is to improve familiarity with these underutilized CLs and to encourage clinicians to explore this option with their patients prior to proceeding with keratoplasty.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Mannis MJ. Keratoconus: why and when do we turn to surgical therapy? Am J Ophthalmol 2006;142:1044–45 [PubMed: 17157588]
2. Rabinowitz YS. Keratoconus. Surv Ophthalmol 1998;42:297–319 [PubMed: 9493273]
3. 2017 Eye Banking Statistical Report. Eye Bank Association of America. www.restoresight.org. Accessed Dec 1, 2019
4. Gordon MO, Steger-May K, Szczotka-Flynn L, et al. Baseline factors predictive of incident penetrating keratoplasty in keratoconus. Am J Ophthalmol 2006;142:923–930 [PubMed: 17157577]
5. Jhanji V, Sharma N, Vajpayee RB. Management of keratoconus: current scenario. Br J Ophthalmol 2011;95:1044–1050 [PubMed: 20693553]
6. Lim N and Vogt U. Characteristics and functional outcomes of 130 patients with keratoconus attending a specialist contact lens clinic. Eye 2002;16:54–59 [PubMed: 11913889]
7. Rathi VM, Mandathara PS, Dumpati S. Contact lens in keratoconus. Indian J Ophthalmol 2013;61:410–415 [PubMed: 23925325]
8. Barnett M, Mannis MJ. Contact lenses in the management of keratoconus. Cornea 2011;30:1510–6 [PubMed: 21993461]
9. Deloss KS, Fatteh NH, Hood CT. Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) scleral device compared to keratoplasty for the treatment of corneal ectasia. Am J Ophthalmol 2014;158:974–982 [PubMed: 25058902]

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10. Knighton AJ, Savitz L, Belnap T, et al. Introduction of an Area Deprivation Index measuring patient socioeconomic status in an integrated health system: implication for population health. EGEMS 2016;4:1238 [PubMed: 27683670]
11. Ortenberg I, Behrman S, Geraisy W, et al. Wearing time as a measure of success of scleral lenses for patients with irregular astigmatism. Eye Contact Lens 2013;39:381–4 [PubMed: 24145901]
12. Pecego M, Barnett M, Mannis MJ, et al. Jupiter scleral lenses: the UC Davis Eye Center experience. Eye Contact Lens 2012;38:179–82 [PubMed: 22543730]
13. Koppen C, Kreps EO, Anthonissen L, et al. Scleral lenses reduce the need for corneal transplants in severe keratoconus. Am J Ophthalmol 2018;185:43–47 [PubMed: 29103959]
14. Woodward MA, Blachley TS, Stein JD. The association between sociodemographic factors, common systemic diseases, and keratoconus: An analysis of a nationwide health care claims database. Ophthalmol 2016;123:457–465.e2
15. Tuft SJ, Moodaley LC, Gregory WM, et al. Prognostic factors for the progression of keratoconus. Ophthalmol 1994;101:438–447
16. Gordon-Shaag A, Millodot M, Shneor E, et al. The genetic and environmental factors for keratoconus. BioMed Res Int, vol. 2015, Article ID 795738
17. Pearson AR, Soneji B, Sarvananthan, et al. Does ethnic origin influence the incidence or severity of keratoconus? Eye 2000;14:625–628 [PubMed: 11040911]
18. Sugar J, Macsai M. What causes keratoconus? Cornea 2012;31:716–719 [PubMed: 22406940]
19. Wang Y, Rabinowitz YS, Rotter JI, et al. Genetic epidemiological study of keratoconus: Evidence for major gene determination. Am J Med Genet 2000;93:403–409 [PubMed: 10951465]
20. Ferdi AC, Nguyen V, Gore DM, et al. Keratoconus natural progression: A systematic review and meta-analysis of 11,529 eyes. Ophthalmol 2019;126:935–945
21. Reeves SW, Stinnett S, Adelman RA, et al. Risk factors for progression to penetrating keratoplasty in patients with keratoconus. Am J Ophthalmol 2005;140:607.e1–607.e6 [PubMed: 16226512]
22. Pouliquen Y, Forman MR, Giraud JP. Vitesse d'evolution du keratocone: etude des relations entre l'age de decourverte et l'age auquel il est opere. J Fr Ophthalmol 1981;4:219–221
23. Kennedy RH, Bourne WM, Dyer JA. A 48-year clinical and epidemiologic study of keratoconus. Am J Ophthalmol 1986;101:267–273 [PubMed: 3513592]
24. Lass JH, Lembach RG, Park SB, et al. Clinical management of keratoconus: a multicenter analysis. Ophthalmol 1990;97:433–445
25. Sarezky D, Orlin S, Pan W, et al. Trends in corneal transplantation in keratoconus. Cornea 2017;36:131–137. [PubMed: 28060057]

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Table 1.

Characteristics of study sample

	All eyes (n = 2806)	**No keratoplasty (n = 2716)**	**Keratoplasty (n = 90)**	***p*-value**
Age (years)	45.1 (16.0)	45.2 (16.1)	39.8 (12.3)	0.001
Male	1717 (61.2%)	1662 (61.2%)	53 (58.9%)	0.65
Race White Black Other	 1897 (67.6%) 567 (20.2%) 342 (12.2%)	 1852 (68.2%) 530 (19.5%) 334 (12.3%)	 45 (50.0%) 36 (40.0%) 9 (10.0%)	<0.001
Health insurance status Insured Uninsured Unknown	 1801 (64.2%) 146 (5.2%) 859 (30.6%)	 1760 (64.8%) 141 (5.2%) 815 (30.0%)	 42 (46.7%) 6 (6.7%) 42 (46.7%)	0.002
ADI score	49.3 (27.3)	48.9 (27.2)	62.6 (27.4)	<0.001
Max K (diopters)	54.8 (11.4)	54.7 (11.4)	58.1 (12.6)	0.008
Current CL use None Soft RGP Scleral	 1016 (36.2%) 202 (7.2%) 951 (33.9%) 637 (22.7%)	 951 (35.0%) 204 (7.5%) 934 (34.4%) 627 (23.1%)	 64 (71.1%) 0 (0%) 18 (20.0%) 8 (8.9%)	<0.0001

ADI: Area Deprivation Index, Max K: maximum keratometry, CL: contact lens, RGP: rigid gas permeable

Data are displayed as mean (standard deviation) or number (percentage)

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Table 2.

Multivariable Cox regression model showing risk factors associated with receiving keratoplasty for keratoconus (n=2075)

	Hazard ratio	95% CI	*p*-value
Scleral CL vs. No CL use RGP CL vs. No CL use	0.19 0.30	0.09-0.39 0.17-0.52	<0.0001 <0.0001
Insured vs. uninsured Unknown vs. uninsured	0.50 0.95	0.21-1.20 0.40-2.29	0.12 0.91
Age (per 5 years)	0.92	0.86-0.99	0.03
ADI score (per 5 point)	1.08	1.03-1.13	0.0008
Max K (per 5 diopters)	1.05	0.97-1.13	0.21
Male (vs. female)	1.11	0.71-1.74	0.64
Black race vs. White Other race vs White	1.87 0.91	1.10-3.16 0.42-1.97	0.02 0.81

CI: confidence interval, CL: contact lens, RGP: rigid gas permeable, ADI: Area Deprivation Index, Max K: maximum keratometry

Statistically significant p-values are bolded