

## OPPORTUNITIES FOR IMPROVING THE LONG-TERM MANAGEMENT OF KERATOCONUS PATIENTS

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### ABSTRACT

**Background and Objective:** This study determined whether practitioners specializing in keratoconus (KC) adhere to published guidelines for disease management and to what extent comorbid conditions of dry eye, contact lens tolerance, and psychological consequences of KC are formally assessed as part of long-term management.

**Materials and Methods:** This cross-sectional study used an IRB-approved, Internet-based, REDCap platform. Descriptive statistics are presented.

**Results:** A total of 222 participants qualified for participation. Most 134 (60%) followed young and unstable patients every 6 months and less frequent follow-up examinations for patients with stable findings, with 142 (64%) recommending annual examinations. Scleral lenses were the preferred optical correction method (36%), followed by corneal gas-permeable lenses (21%). A total of 118 (55%, n=216) participants recommend crosslinking to any patient with documented disease progression regardless of age. Fewer than 25% of patients were referred for surgical correction of KC. Half of respondents, 114 (51%), reported testing for tear film dysfunction, while 108 (49%) never tested. No participants used a depression screening instrument.

**Conclusion:** Practitioners managing patients with KC largely adhere to current consensus recommendations. This survey identified several potentially high-impact, low-cost improvements to current practice patterns, including screening for dry eye and depression.

**Keywords:** keratoconus, dry eye, depression, practice patterns

## INTRODUCTION

Keratoconus (KC) is a disease characterized by progressive steepening and thinning of the central or paracentral cornea, which causes irregular astigmatism and varying degrees of visual disability.<sup>1</sup> KC is often diagnosed in the second or third decade of life and waxes and wanes until stabilizing in the fourth decade.<sup>2</sup> Contact lens wear remains the mainstay of achieving useful vision for this condition. Because of its progressive nature, patients with this condition often develop long-term relationships with their eye care providers for ongoing evaluation of corneal stability and vision management,<sup>3</sup> control of atopy,<sup>4</sup> scarring,<sup>5</sup> and refractive shifts during periods of instability.

The complete dependence of many KC patients on contact lenses for useful vision can be emotionally and physically problematic over time. According to a recent review, contact lens dropout is frequent among normal populations, with a mean of 21.7%, and meibomian gland dysfunction appears to be a primary driver of attrition.<sup>6</sup> While there is no evidence that KC itself causes dry eye,<sup>7</sup> recent studies suggest that patients with KC may have concurrent dry eye disease<sup>8,9,10</sup> and that this condition may interfere with their ability to wear contact lenses upon which they depend on function comfortably.<sup>11,12</sup> The near ubiquity of electronic media consumption is a primary driver for evaporative dry eye,<sup>13</sup> compounding the risk for contact lens problems. Scleral lenses can solve some of the comfort issues related to eye dryness. Still, a recent survey of keratoconus patients showed that 67% of respondents reported discomfort issues even with scleral lenses.<sup>12</sup> For patients with KC, the inability to successfully use contact lenses (defined as 12 hours of comfortable daily wear)<sup>14</sup> can negatively impact the ability to drive, work, study, and perform other activities of daily living. Practitioners who care for patients with KC are aware of the profound disruptions that cessation of lens use for even a few days can provoke. Chronic medical conditions, including visual disability, are well known to be associated

with depression;<sup>15</sup> therefore, it is unsurprising that depression and poorer quality of life occur in patients with KC.<sup>16,17</sup> The patient's age may also influence the extent to which depression occurs, employment, ability to afford treatment, and lifestyle choices. In the past, when a KC patient could no longer be fit with, tolerate, or achieve functional vision with contact lens correction, full-thickness penetrating keratoplasty was the only available surgical choice. Options for surgical intervention have greatly expanded to include corneal crosslinking, intracorneal stromal ring segments, phototherapeutic keratectomy, photorefractive keratectomy, deep anterior lamellar keratoplasty (DALK), phakic intraocular lenses, and more recently, laser-based smoothing of the cornea<sup>7,18-21</sup> Although surgical advances can improve best-corrected acuity, post-operative medical contact lens use remains necessary for many patients.

This study aimed to determine whether practitioners specializing in KC adhere to published guidelines for disease management and to what extent dry eye, contact lens tolerance, and psychological consequences of KC are formally assessed as part of long-term management.

## METHODS

This cross-sectional study used an IRB-approved, internet-based, REDCap platform<sup>22</sup> hosted at the Mayo Clinic, Rochester MN. Research described herein followed the tenets of the Declaration of Helsinki, and participant consent was obtained before participation. The survey was conducted from July 22, 2019, to June 30, 2020. It was distributed to the attendees of the International Congress of Scleral Contacts (Fort Lauderdale FL, July 2019) and to participants in previous research conducted by the authors, who agreed to be contacted for additional studies. It was also posted electronically on both the Scleral Lens Practitioners and the International Keratoconus Foundation Facebook group pages.

To qualify for participation, potential respondents were required to verify that, on average, they cared for at least one patient with KC per week. Demographic data collected from eligible participants included years of practice, profession, and primary practice modality. The participants were also asked to estimate the average number of patients with KC they evaluated per month. Participants' clinical practice patterns (frequency of examinations, frequency of corneal imaging, preferred optical treatments, preferred surgical treatments, criteria for surgical or optometric referral, prevalence of dry eye evaluations, prevalence of mental health screenings, and self-assessment of care quality) were ascertained. The full survey is available in Supplemental Appendix 1. Descriptive statistics are reported.

## RESULTS

Of the 245 respondents, 222 with an average of 22.8 + 12 years in practice (range 3–47 years; males = 136, females = 85, undisclosed = 10) met the entry criteria of caring for at least one patient with KC per week. An average of 27.2 + 35.2 (range

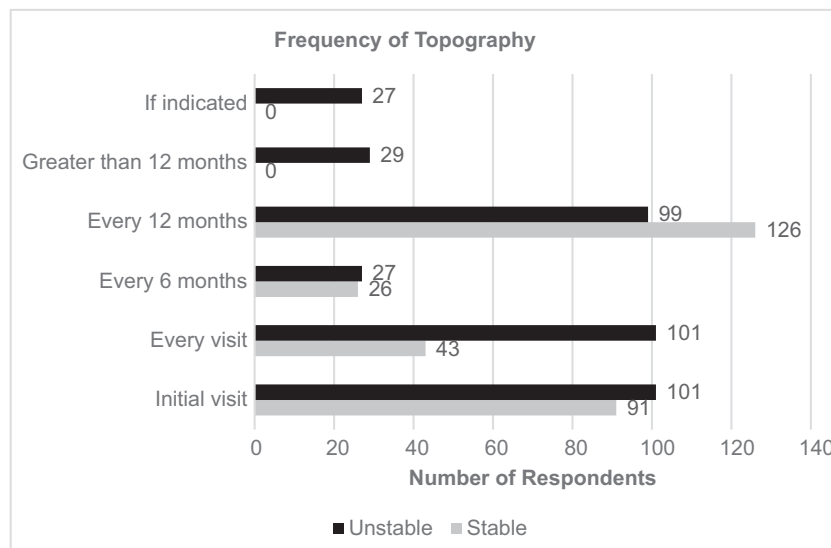
4–300) patients with KC were evaluated monthly by survey participants (n=222). Supplemental Appendix 2, Table 2 details the additional demographic characteristics of survey respondents.

### Frequency of Examination

A total of 222 participants indicated the recommended examination frequency. The current guidelines suggest that younger and less stable patients should be examined more frequently.<sup>7</sup> Most participants 134 (60%) followed young or unstable patients every 6 months, with 78 (35%) following these patients every 3 months and 10 (5%) following them annually. Participants reported less frequent follow-up examinations for patients with stable corneal findings, with 142 (64%) recommending annual examinations, 76 (34%) recommending biannual examinations, three (1%) following these patients less frequently than every 12 months, and one (0.04%) after every 3 months.

### Frequency of Corneal Imaging

All participants reported regularly obtaining topographic or tomographic corneal analyses in patients with KC. Figure 1 shows the frequency



**FIGURE 1.** Data detailing participants response to queries about the frequency of topography scans for both stable and unstable keratoconus patients.

with which the participants obtained corneal images for each group of patients.

**Optical Correction Methods**

Of the 222 participants, 205 actively fit contact lenses. Those who fit lenses were queried regarding their first-choice preference for lens modality. The estimated percentage of patients using various correction modalities is presented in Table 1.

**Surgical Treatment**

The participants also indicated that they recommended corneal crosslinking for patients. A total of 118 (55%, n=216) participants indicated that they recommend crosslinking to any patient with documented disease progression regardless of age. An additional 75 (35%) considered crosslinking primarily for patients under the age of 40 with disease progression. Sixteen patients (7%) indicated that they would recommend crosslinking for all patients with KC. The remaining participants detailed their criteria for recommending crosslinking using free-text responses, which are available as supplemental material in Appendix 3. Participants then estimated the percentage of patients with KC who had undergone either corneal crosslinking or keratoplasty (Figure 2).

**Referral Patterns**

Out of 190 responses from optometrists, 21 (11%) participants considered referral to an ophthalmologist upon diagnosis, 47 (25%) referred to the first sign of progressive disease, and 122 (64%) referred only if surgical intervention was required. Referrals from optometrists to other optometrists were placed when their clinic schedule did not allow them to care for the patient for 34 (18%) or if a satisfactory contact lens fit could not be achieved for 92 (48%). Only 64 (34%) never needed to refer to another optometrist. Of the 22 participants who were ophthalmologists, 14 (64%) would refer to an optometrist if satisfactory vision required the expertise of a contact lens specialist, 4 (18%) would refer upon diagnosis, and 4 (18%) never referred to an optometrist.

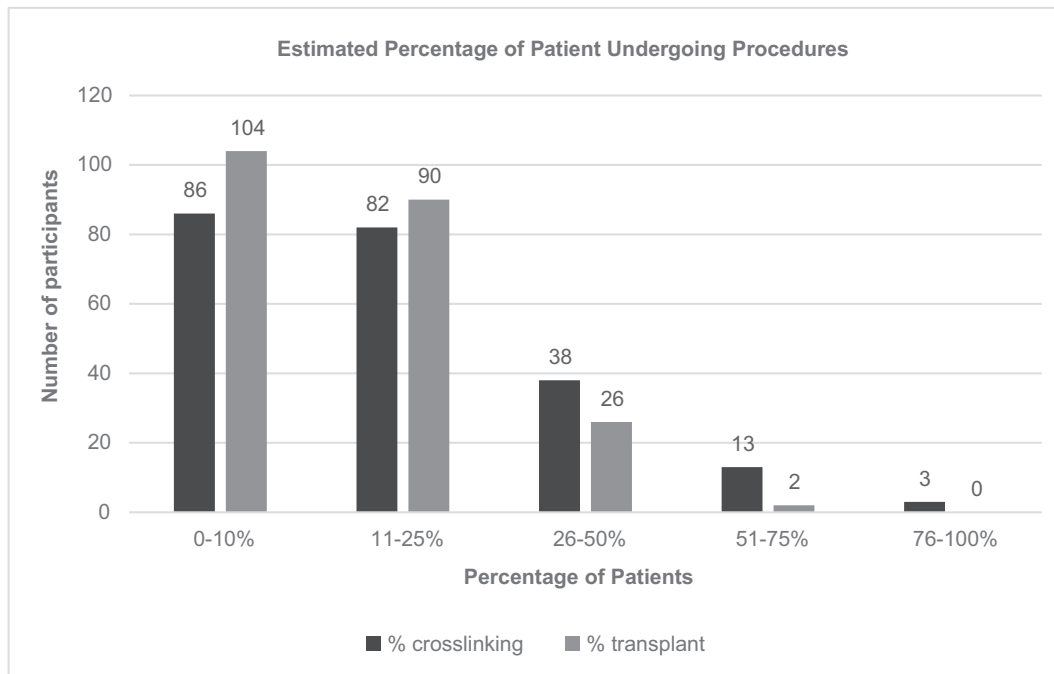
**TABLE 1** Participants Responded to Which Type of Contact Lens Modality Was Their General Preference for First-Line Choice for Fitting KC Patients.

Correction Modality	% (Mean [SD]) of patients
Scleral lenses	36.4 [23.6]
Corneal gas-permeable lenses	21.0 [16.7]
Glasses	15.9 [16.4]
Standard hydrogel/silicone hydrogel lenses	10.5 [11.8]
Custom hydrogel/silicone hydrogel lenses	5.1 [5.9]
Hybrid lenses	4.3 [6.0]
No correction	4.1 [5.0]
Piggyback lens systems	2.8 [3.6]

**Dry Eye Testing**

The survey investigated which tests or procedures were used to evaluate dry eye disease patients with KC. About half, 114 (51%) reported that they ever tested for tear film dysfunction, while 108 (49%) never tested. Of those who test for dry eye in their KC patients, tear break-up time is assessed by 108 respondents (49%) and vital dye staining of the cornea is assessed by 78 (35%). Other reported methods of dry eye evaluation included meibography by 38 (17%), lipid layer testing by 33 (15%), Schirmer’s test by 32 (14%), tear osmolarity by 23 (10%), “other” unspecified dry eye testing was used by 19 (6%), MMP-9 analysis by 17 (8%), and Korb-Blackie test by 4 (2%).

Only 42 (19%) of participants ever administered validated questionnaires to assess dry eye or contact lens comfort symptoms. Of those, 28 (56%) employ them at the initial visit only, 18 (36%) use them at every follow-up, and 15 (8%) do so on an annual basis. The most used questionnaires were the Ocular Surface Disease Index<sup>23</sup> (n=21) and the Standard Patient Evaluation of Eye Dryness (SPEED)<sup>24</sup> (n=20). Only 4 participants utilize the Contact Lens Dry Eye Questionnaire (CLDEQ).<sup>25</sup> Six participants responded using one of the following: McMonnies



**FIGURE 2.** Participants were asked to estimate the percentage of patients who had undergone either corneal crosslinking or unspecified corneal transplantation. Results show that for most respondents, fewer than 25% of patients were referred for surgical correction of keratoconus.

Dry Eye Questionnaire<sup>26</sup> (n=1), an unspecified National Eye Institute Questionnaire (n=1), Ocular Pain Assessment Score<sup>27</sup> (n=2) and self-created (n=1). However, almost all, 216 (98%) indicate they routinely ask their patients about their comfort level with contact lenses.

**Mental Health Screening**

No participants use a depression screening instrument.

**Self-assessment of Care Quality**

Most participants 176 (80%) are confident that their KC patients are very satisfied with the level of care that they provide, with an additional 42 (19%) believing that their patients are somewhat satisfied, and 1 (1%) responded that patients are likely neutral about their care. Almost all participants 206 (93%) believe that their patients honestly discuss any issues or concerns related to KC with them.

**DISCUSSION**

This study aimed to determine whether practitioners who regularly care for patients with KC adhere to the most recent practice recommendations and whether commonly associated comorbidities such as dry eye and depression are being assessed. This is the first survey among eye care providers to examine ancillary aspects of long-term KC management. The results of this study show that most, but not all, respondents follow the global consensus panel<sup>7</sup> guidelines regarding the frequency of follow-up and corneal imaging. Ninety-five percent (n=212) of participants followed patients with stable KC every 6–12 months, and younger or less stable patients at 3-to-6-month intervals. Among the participants, Corneal imaging (either topography or tomography) is routinely performed for all patients with KC. Because the criteria for inclusion in this survey were the management of at least one patient

with KC per week, responses are likely skewed in favor of individuals likely to have resources to monitor patients with KC. This may not be generalizable globally; a study of optometrists in the United Kingdom and Spain showed that only 38.1% of UK practitioners had access to a topographer.<sup>3</sup> It is reasonable to expect that access to advanced imaging, contact lens and surgical technologies will greatly influence practice patterns. One strength of this study is that 78% of participants worked in private practice settings. Information regarding practice patterns in this cohort is often difficult to obtain. Such facilities do not have the same resources as academic or hospital-based institutions and often do not actively participate in research.

Corneal gas-permeable lenses have been the mainstay of visual rehabilitation in patients with KC for decades. In recent years, the use of scleral lenses has disrupted this practice. The participants in this study mostly used scleral lenses as first-line therapy for visual rehabilitation. This result is consistent with several other studies that point to an increasing reliance on scleral lenses to correct irregular astigmatism.<sup>28,29</sup>

Most respondents advocated corneal crosslinking for any patient with evidence of disease progression, regardless of age, which also conforms to the general recommendations of the 2015 Delphi panel.<sup>7</sup> However, only 25% of the patients reported that more than half of their patients had undergone the crosslinking procedure. This could be attributed to several factors during the referral process: patients are not progressing and are therefore not referred, patients referred for CXL may ultimately elect not to undergo surgery due to personal or financial reasons, or finally, that referred patients were not deemed to qualify for surgery. Another possible explanation is that patients were referred for other interventions such as corneal transplantation; a weakness of this survey is that we did not query less commonly performed surgical procedures. According to the data, referral to specialists hinges on outsourcing complex contact lens fitting or when

surgical intervention is anticipated. Additional participation from the ophthalmology community would have improved the generalizability of the data and should be pursued in another study.

The increasing prevalence of dry eye,<sup>30</sup> the association between the use of contact lenses and dry eye,<sup>31</sup> and the association between contact lens intolerance and dry eye<sup>32</sup> should compel practitioners to screen for this condition in a largely contact lens-dependent population. Based on the available literature, dry eye is emerging as a problem for patients with KC.<sup>11,33</sup> However, very few participants are actively testing for this condition, which can negatively affect contact lens tolerance and overall quality of life. The Dry Eye Workshop II (DEWSII) recommends tear film testing and management,<sup>34</sup> but no established guidelines exist for dry eye management in patients with KC.

It is well understood that patients with KC, like patients with other chronic medical conditions, may be predisposed to depression.<sup>15</sup> Moschos et al. demonstrated the usefulness of the PHQ-9 and Zung SDS questionnaires as screening tools for depression in patients with KC.<sup>16</sup> However, Kandel et al.<sup>17</sup> concluded in a 2020 literature review that The Keratoconus Outcomes Research Questionnaire,<sup>35</sup> the only validated keratoconus-specific questionnaire, had the most superior psychometric properties, but that a need exists for comprehensive and high-quality patient-reported outcome measures in KC. It was disconcerting that despite the recognition that KC is associated with depression, participants seldom administered symptom questionnaires, inquiries about quality of life and depression, or referrals to mental health professionals.

## CONCLUSIONS

The results of this study show that practitioners managing patients with KC largely adhere to the consensus recommendations. Current algorithms for KC management do not contain guidelines about screening for related ocular morbidities or

holistic aspects management.<sup>7,36</sup> This survey identified several potentially high-impact and low-cost improvements to current practice patterns, including screening for dry eye and depression.

#### **Prior Presentations of this Information**

Nau A, Nau C, Shorter E, Schornack M, Fogt J, Harthan J. Holistic Management Practices for Keratoconus. ARVO e-abstract 353757, May 2021.

#### **CONFLICTS OF INTEREST AND SOURCES OF FUNDING**

**Schornack M:** None

**Nau A:** Sight Sciences (Paid Consultant), Vital Tears (advisory board), Optometry Times (speaker)

**Harthan J:** Paid consultant for the following: Allergan, Essilor, Euclid, International Keratoconus Academy, Johnson & Johnson Vision, Metro Optics, Visioneering Technologies, Inc. Research for Bausch + Lomb, Kala Pharmaceuticals, Ocular Therapeutix, Metro Optics

**Fogt JS:** Nevakar (research grant), Bausch & Lomb (research grant), Eyenovia (research grant), Alcon (research grant), Cooper Vision (research grant), Interojo (research grant), Envision Biomedical (paid consultant), Tear Optix (Paid consultant)

**Nau, C:** none

**Shorter, E:** Johnson & Johnson (research grant), Synergeyes (research grant), Art Optical (research grant), Boston Sight (paid lecturer), Oculus (paid lecturer)

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#### **DATA ACCESS STATEMENT**

Research data supporting this publication are available from the corresponding author by written request.

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**SUPPLEMENTARY**

**TABLE A1.** Demographic characteristics of qualified survey respondents.

<b>Category</b>	<b>Number of Qualified Respondents</b>
<b>Years in Practice (n=220)</b>	
1–5 years	8
6–10 years	40
11–15 years	33
16–20 years	34
21–25 years	27
26–30 years	18
31–35 years	30
36–40 years	29
≥ 41 years	19
<b>Profession (n=221)</b>	
Optometrist	191
Ophthalmologist	22
Contact Lens Technician	6
Other	2
<b>Primary Practice Modality (n=220)</b>	
OD only practice (private or group)	85
MD/OD practice (private or group)	54
Academic medical center	35
Retail/commercial practice	15
Optometry school	15
VA clinic or hospital	9
MD only practice (private or group)	7