

Introduction

Keratoconus (KCN) is a bilateral, progressive, but self-limiting corneal disorder characterized by the protrusion, distortion, thinning, and sometimes scarring of the cornea, which reduces optical clarity.¹⁻⁴ Its prevalence has been reported to be 50-265 per 100,000 with an annual incidence of 2-13.3 per 100,000.⁴⁻⁶ Early management of KCN includes spectacles and soft contact lenses. As the condition progresses, gas permeable (GP) lenses, such as corneal GP, intralimbal GP, piggyback lenses, hybrid lenses, and scleral GP lenses are used.

KCN is the leading indication for scleral lens fitting and composes of the majority of the scleral lens patient population. The SCOPE study found 97% of the respondents identifying KCN as an indication for scleral lenses.⁷ According to a study at the University of California Davis, out of 107 eyes, 63% were fit in scleral lenses to manage KCN.⁸ However, scleral lens wear is not without its complications. Commonly reported complications include:^{5,8-15}

- Mechanical irritation (10%-12.6%)
- Infection (0.68%)
- Midday fogging (20-33%)
- Protein deposits (3.5%)
- Inflammation
- Solution toxicity
- Poor lens fit due to disease progression

Scleral lens safety is vital to preserving the vision of these patients who are heavily dependent on contact lenses for their visual needs. Previous scleral lens safety studies were published when PMMA lens materials were common and often included a variety of other anterior segment conditions, making generalization difficult for modern scleral lens wearers with keratoconus.^{8-10,16-19}

Methods

A retrospective records review was performed on subjects examined at Southern College of Optometry between January 1, 2013, and December 31, 2018.

- Inclusion Criteria: Successful scleral lens wear > 1 year since fitting, regardless of age, sex, pre-existing morbidity, or scleral lens design.
 - Exclusion criteria: Previous corneal surgery, dystrophy, degeneration, and corneal trauma.
- Statistical analysis was performed using Microsoft Excel 2016 (ver. 16.0.4266.1001, Santa Rosa, CA) and Analyse-it for Microsoft Excel (ver. 4.90, build 6422.19585, Leeds, UK) with a significance level of p<0.05 and confidence interval of 95%.

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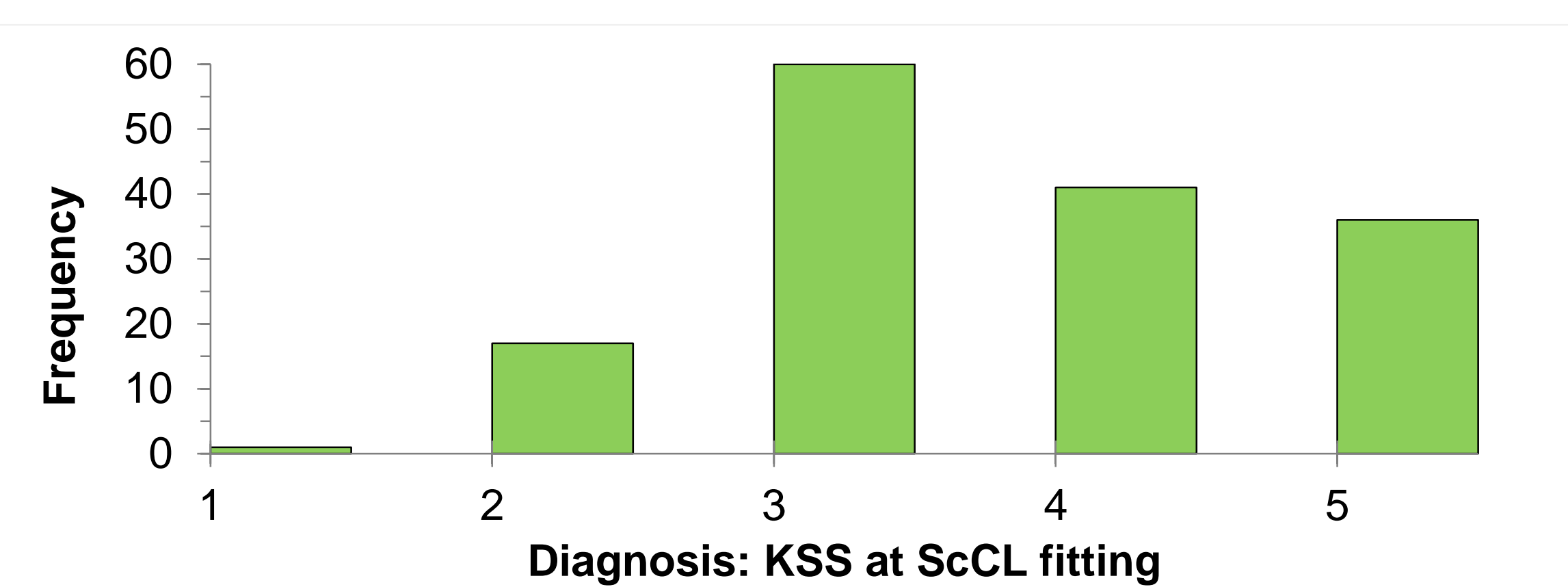
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Results

Demographics

- Total screened: N=385 subjects with the diagnosis of keratoconus, examined between January 1, 2013, and December 31, 2018.
- Qualified: 157 eyes of 86 subjects (15 unilateral, 71 bilateral scleral lens wearer).
- Primary reason for exclusion: less than one year since fitting, wearing contact lens modality other than a scleral lens, and prior corneal surgeries. These accounted for 284 (95%) of the 299 subjects excluded from the study.
- Gender: 39:51 (male/female).
- Age: 34.8 ± 11.7 (14 to 64 years).
- Kmax: 61.4D ± 10.9D (31.0D to 89.9D).
- Best manifest refraction: Mean spherical equivalence -5.36D ± 5.84D (-26.00D to +12.50D), mean cylindrical correction of -3.79D ± 2.43D (-0.25D to -12.00D).
- KSS score at time of fitting: See **Figure 1**.

Figure 1: KCN stage of subjects at time of scleral lens fitting by the KSS ranking scheme.



Efficacy

Scleral lenses significantly improved best-corrected visual acuity from mean LogMAR 0.41 in spectacles to mean LogMAR 0.08. Seven scleral lens designs from six companies were used to fit our subjects (Table 1). The lenses were all lathe-cut, non-fenestrated scleral contact lenses with an overall diameter between 14.3 and 17.0 with a mean of 15.8mm ± 0.6 (Figure 2). The lenses were all made of gas permeable materials (Figure 3). Seventy percent of the lenses had toric scleral periphery and 17% had front surface toric optics.

Table 1: Percentile distribution of scleral lens brands and designs included.

Laboratory	Design
Alden Optical (14.6%)	Zenlens (14.6%)
Art Optical (3.2%)	AmpleEye (1.9%)
Blanchard Lab (9.6%)	MSD (4.5%)
	OneFit (5.1%)
Essilor (5.1%)	Jupiter (5.1%)
Valley Contax (65.6%)	CustomStables (65.6%)
X-Cel Specialty Lens (1.9%)	Atlantis (1.9%)

Figure 3: Relative frequency of lens materials.

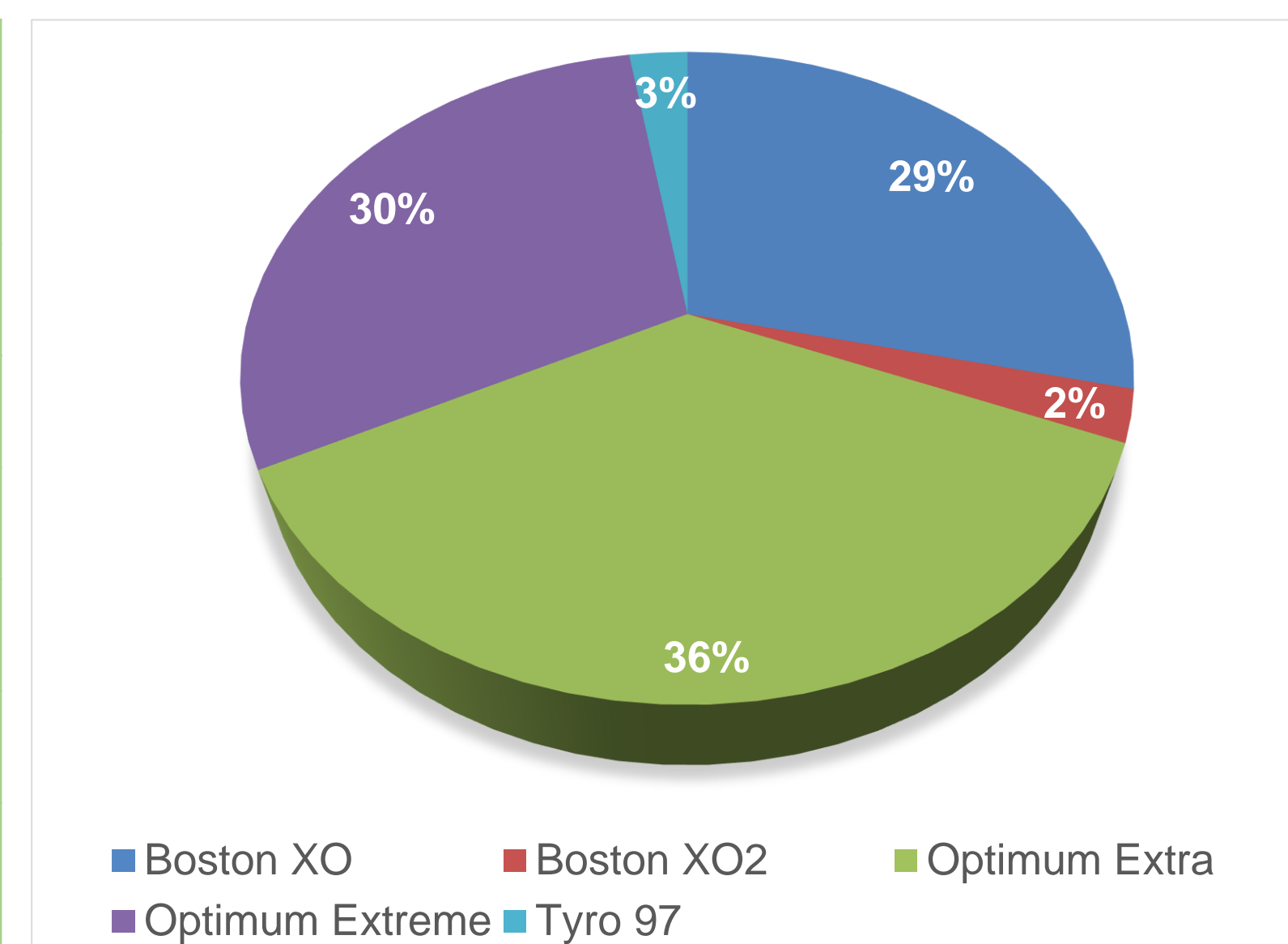
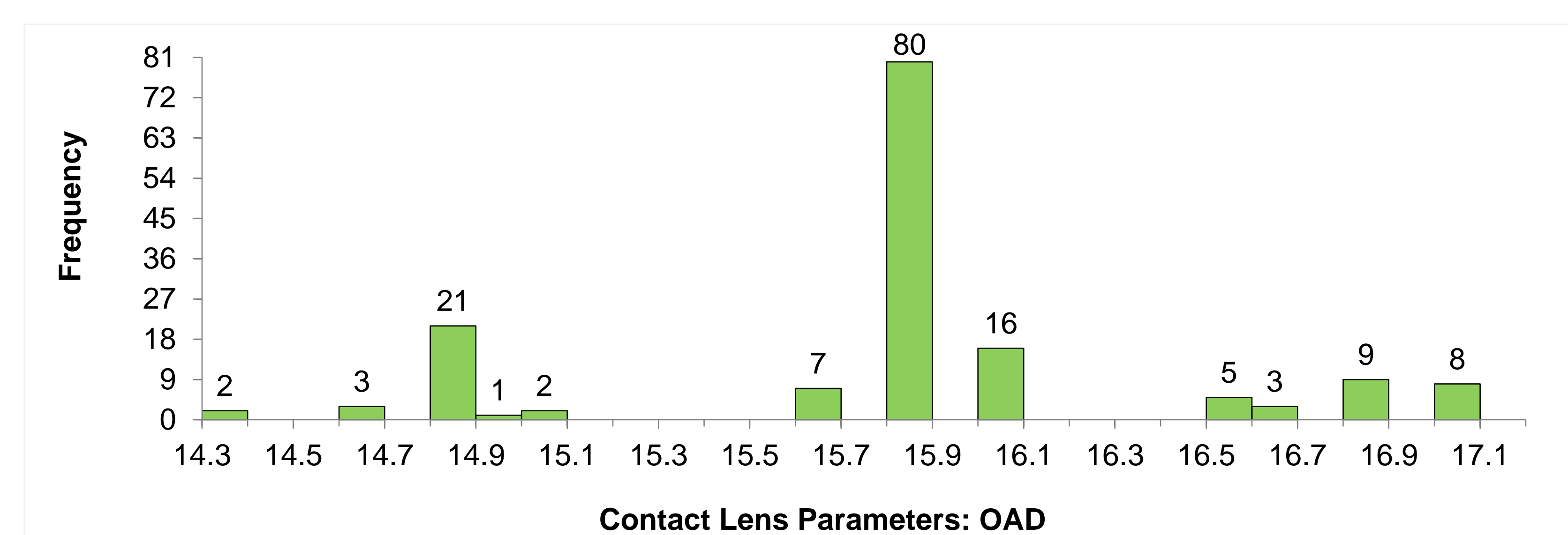


Figure 2: Distribution of scleral lens diameters.



Adverse Events & Outcome

A total of 86 subjects presented for 493 office visits after initial contact lens fitting. The mean follow-ups for each patient was 5.7 ± 4.8 visits (1 to 34 visits). Twenty six of the 86 subjects missed their annual exam and were seen after 13.3 ± 9.0 months (2 to 48 months). Of these, seven subjects were lost to follow up. The most common reasons for follow up and for missing a prescribed recall is shown in **Figure 4 and 5**.

Figure 4: Reason patients provided for follow up visit.

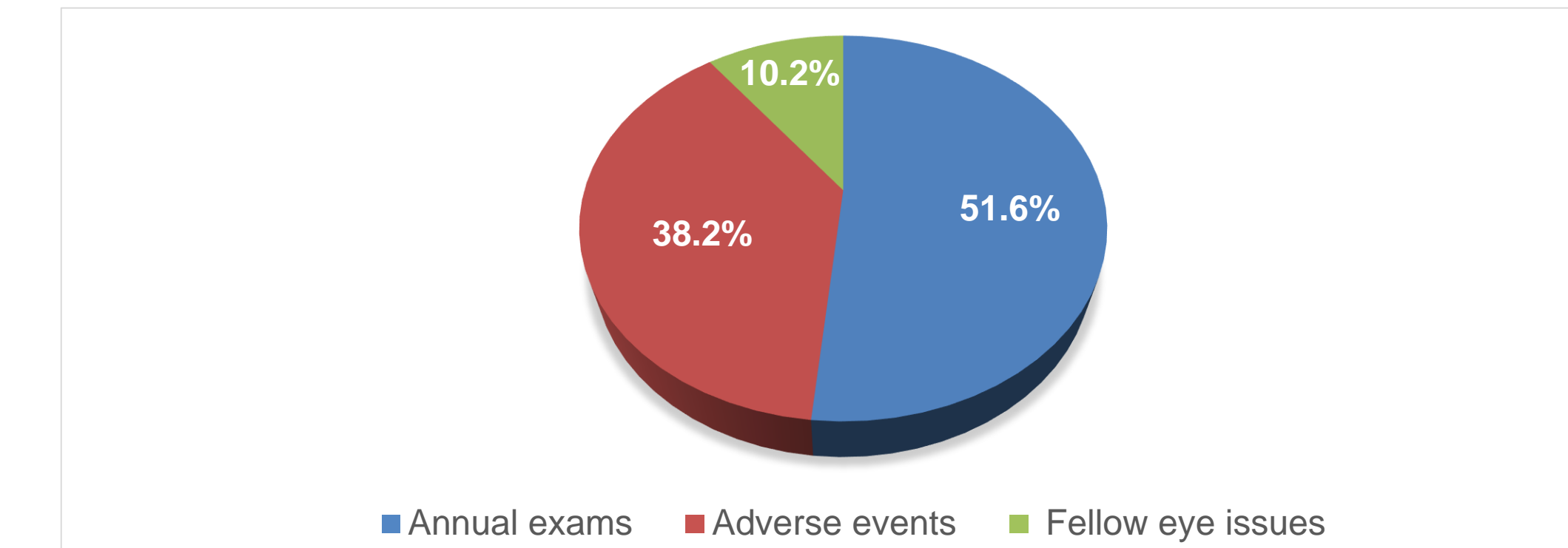
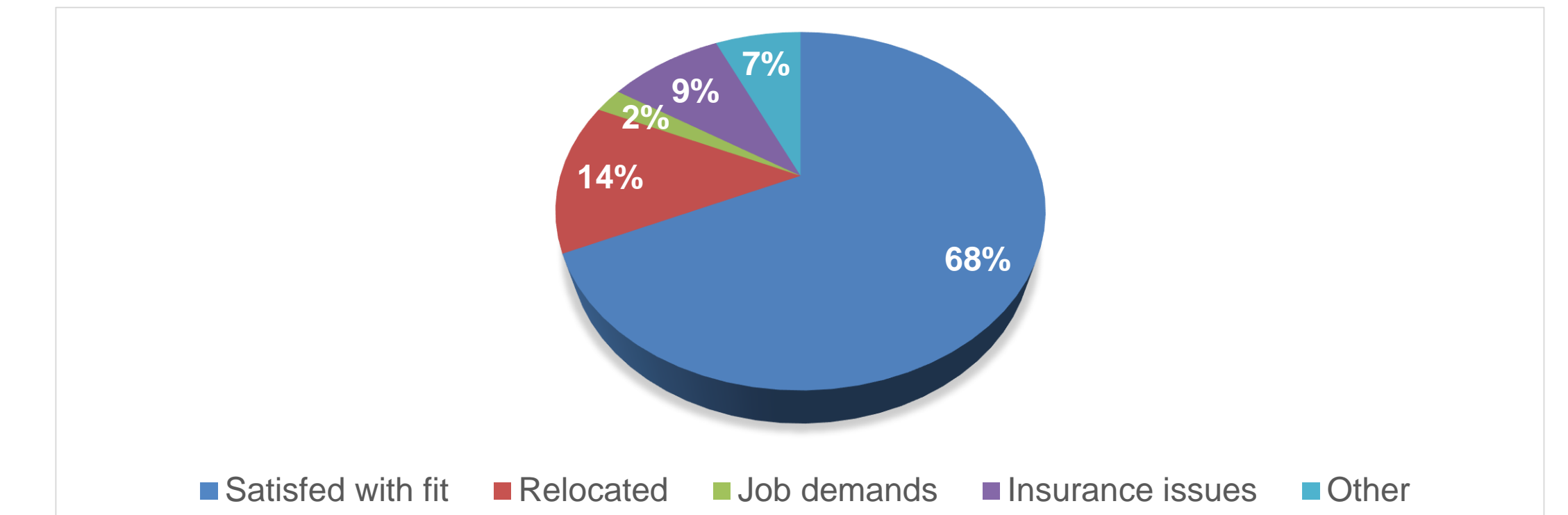
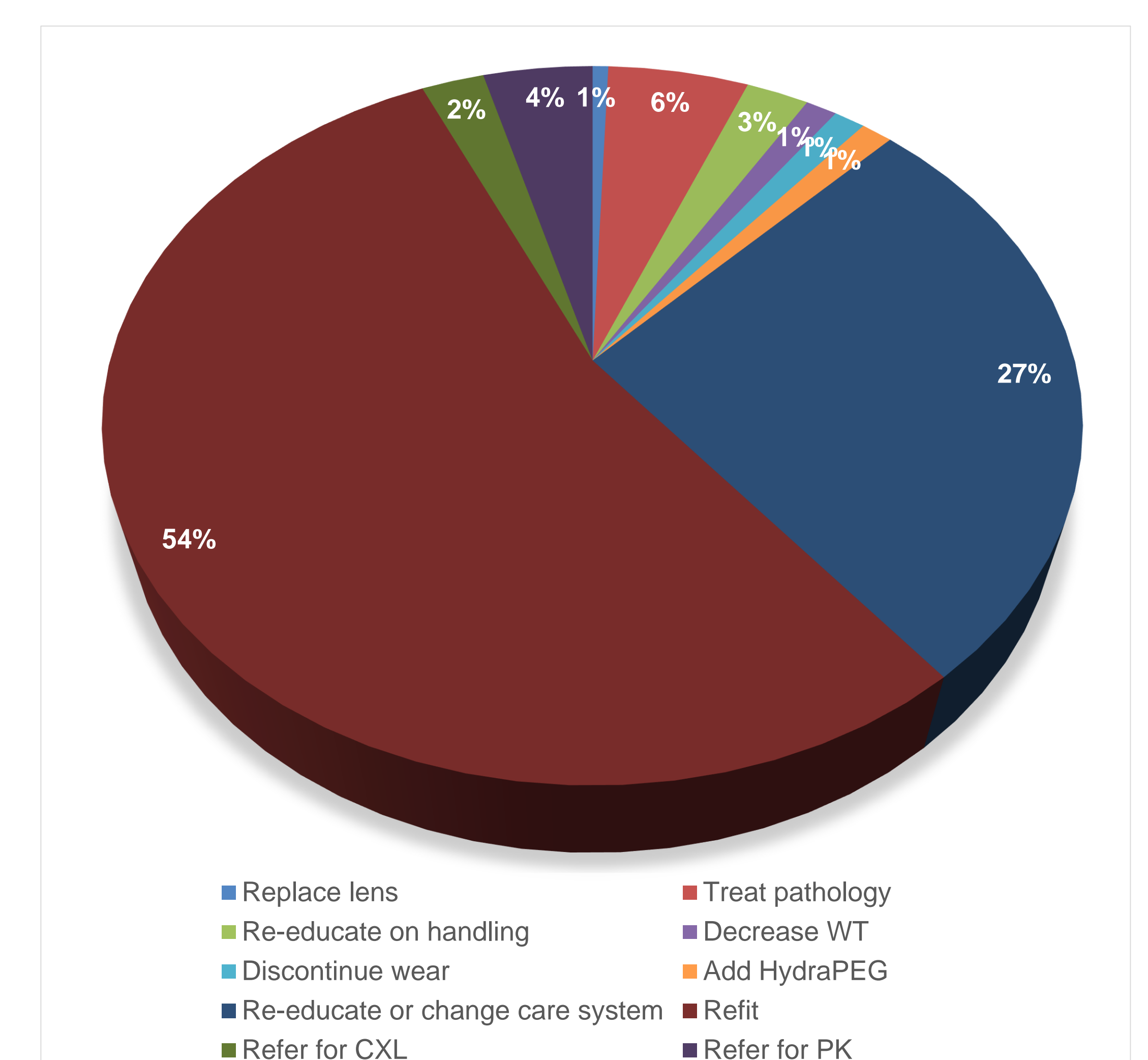
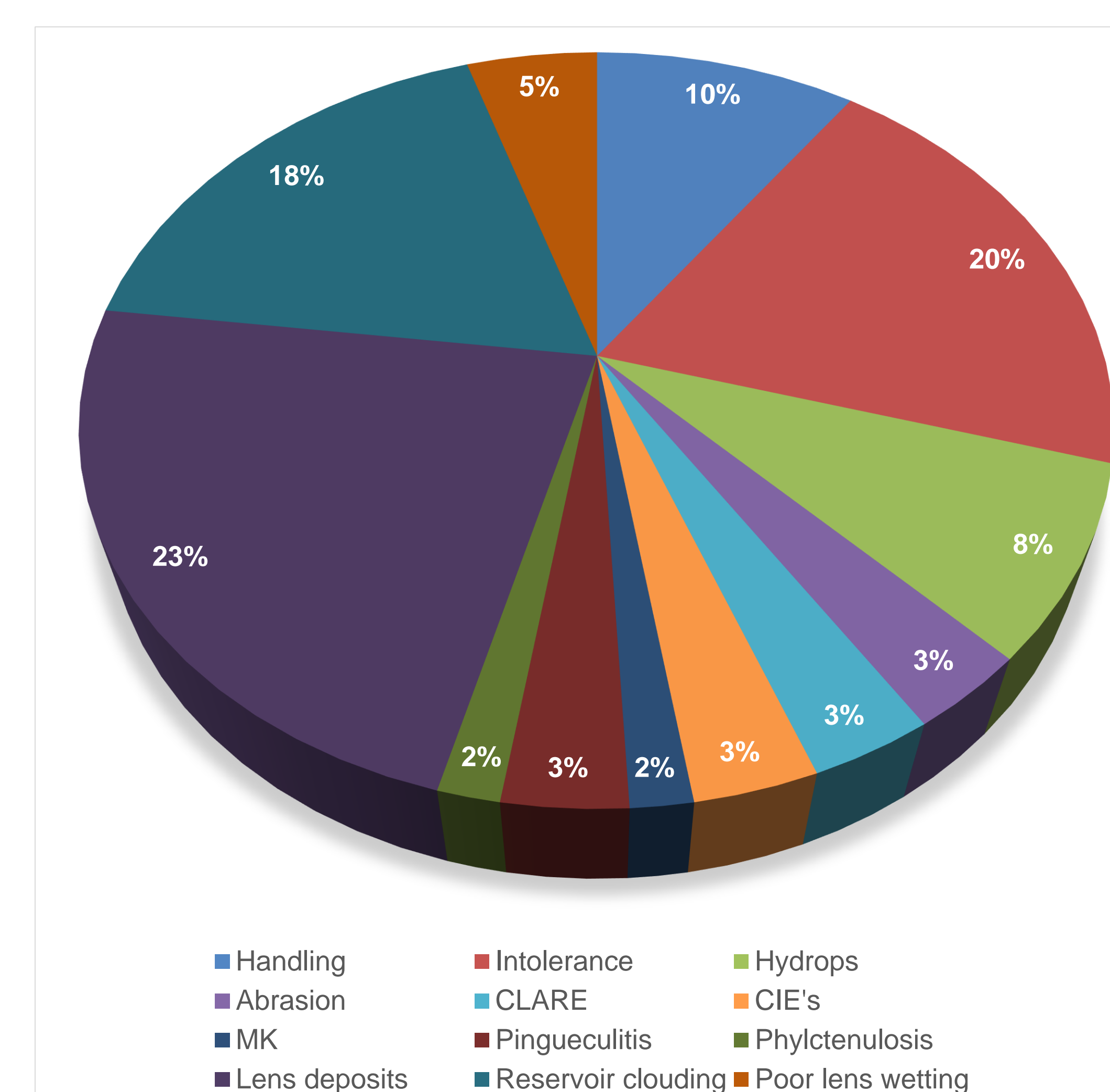


Figure 5: Reasons for missing prescribed recall.



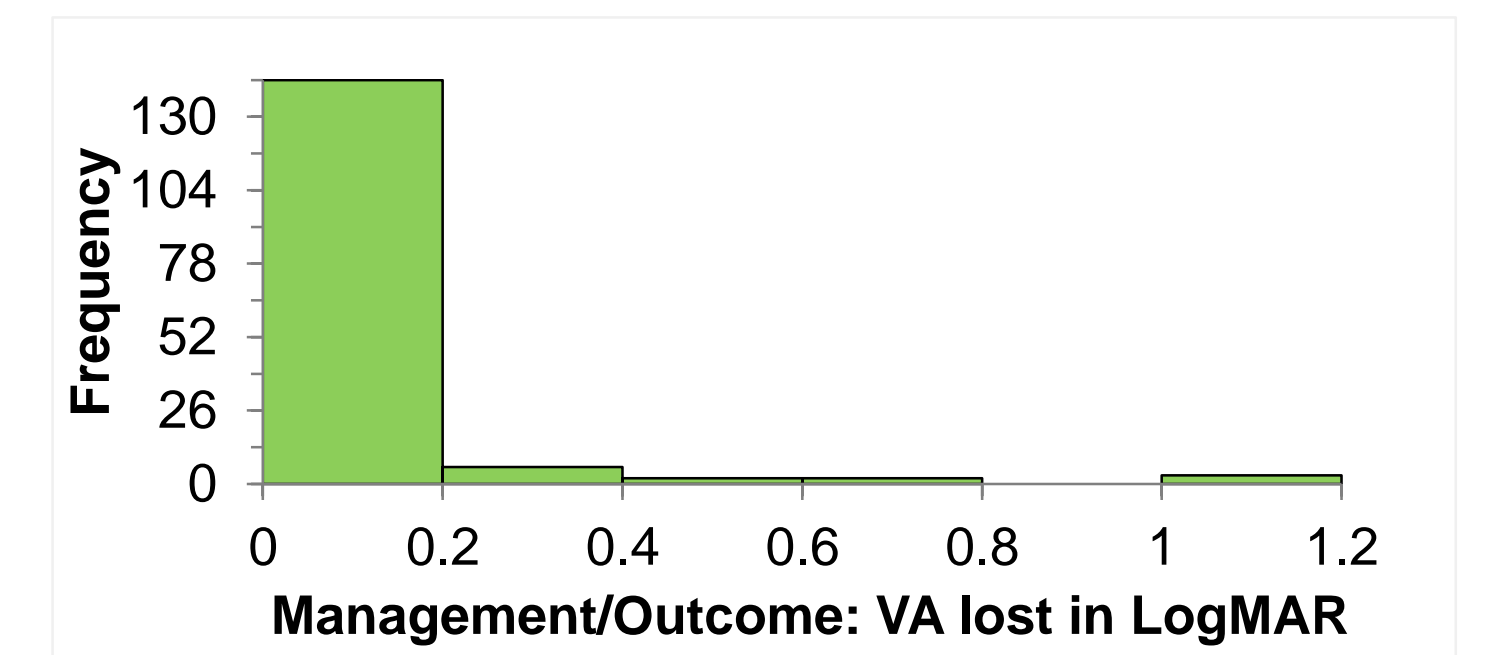
The distribution of adverse events related to scleral lens wear is summarized in **Figure 6**. A total of 5 (3.2%) cases of adverse events unrelated to the scleral lens wear were documented, including two eyes of 1 patient with viral conjunctivitis, one eye with severe seasonal allergic conjunctivitis, one microbial keratitis secondary to foreign body injury, and one corneal abrasion secondary to trauma.

Figure 6: Distribution of adverse events related to scleral lenses. **Figure 7:** Management strategies of adverse events.



All adverse events were managed with minimal subsequent complications (**Figure 7**). In total, 13 (8.3%) eyes experienced reduced BCVA, demonstrating a decrease in average LogMAR from 0.079 to 1.176 (**Figure 8**). Of the 13 eyes, 11 (84.6%) developed reduced BCVA due to the progression of KCN. Two eyes of 1 patient experiences reduced vision by one line of Snellen in each eye related to scleral lens-induced anterior segment complications. The patient had developed corneal infiltrate OU secondary to noncompliance, which led to mild corneal scarring.

Figure 8: Decrease in BCVA in LogMAR



Discussion

- Vision improvement was the primary indication for scleral lens fitting, with GP intolerance as a secondary indication.
- Subjects experienced significant improvement in best-corrected vision in scleral lenses compared to spectacles.
- Our study is the first retrospective gas permeable scleral lens study in which patients with keratoconus have worn scleral lenses successfully for > 1 year. Compared to other scleral lens safety studies with PMMA lens material:¹¹
 - Gas permeable material reduced the risk for severe corneal neovascularization, edema, and contact lens papillary conjunctivitis.
 - Gas permeable lens material increased the risk for lens breakage and lens deposits.
- Limitations: Short study period, retrospective study in an academic institution with multiple clinicians, leading to high inter-clinician variability in lens fitting philosophies, documentation habits, and adverse events management.
- Consistent with the findings of other groups, our study demonstrates the efficacy of scleral lenses in visual rehabilitation and safety after prolonged wear in subjects with keratoconus.^{8,15,17,19-22}