Replacing Gas Permeable Lenses: The Benefit of a Professional in Office Dispense

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Introduction

Complications of contact lens wear have received considerable academic attention over the last several decades.[1] Several studies and case reports document many instances where patients suffered ocular complications secondary to wearing a contact lens acquired without a doctor's supervision or written prescription.[2,3] Such documented complications confirm the necessity of maintaining the need for a doctor's written contact lens prescription with an expiration date. An area that may need further investigation is what issues subjectively successful patients could encounter if they acquire new replacement contact lenses from a third party even with a valid prescription.

In response to patients' desire to purchase contact lenses at competitive prices from sellers other than their eye care practitioner, the US Congress passed the *Fairness to Contact Lens Consumers Act* (FCLA) in December of 2003 to provide "consumers with the greater ability to fill their contact lens prescriptions from sellers other than their prescribing eye care practitioner".[4] This law came into effect in February of 2004. Since then, all eye care practitioners in the United States have been required by law to release contact lens prescriptions to all patients once the fitting is completed. Exclusions are allowed as follows: 1) if contact lens wear is damaging to the patient's ocular health; 2) if the patient has a documented medical condition that requires closer professional supervision; and, 3) if the patient has not fulfilled their financial obligation with the practitioner on current services and materials. Released contact lens prescriptions are valid for 1 year following the examination date, and patients thereby have the option to liberally acquire replacement lenses directly from non-professional providers without professional in-office evaluations.

In a clinical setting, however, practitioners may note unanticipated complications during the dispensing of contact lenses. Such complications include (but are not limited to): lab errors, patient ocular change, dry eyes, poor lens wetting, as well as contact lens related complications such as giant papillary conjunctivitis, solution hypersensitivity and corneal neovascularization. During these office visits, moreover, doctors have the opportunity to diagnose both asymptomatic disease (ocular and systemic) as well as address any concerns the patient may express.

The purpose of our study is to examine complications that are encountered when replacement custom made lenses are dispensed in office. These complications might otherwise be unseen by the eye care practitioner if the contact lens had been provided to asymptomatic patients without professional dispensing. This study focuses on rigid contact lenses that are custom made for the patient (scleral or corneal lenses). Both custom and mass-produced soft (hydrogel, silicone hydrogel, and hybrid) contact lenses were not evaluated in this study.

Methods

A prospective cross-sectional study was performed to evaluate situations in which a custom-made replacement GP contact lens was ordered using a current prescription and dispensed to the patient in office. The data was collected at the Jules Stein Eye Institute of the David Geffen School of Medicine in the Contact Lens Service. This is a specialty lens service where the majority of the patients wear custom lenses. This practice is comprised of approximately 80% patients with irregular corneas, 15% normal refractive error, and 5% are aphakic. The patient base consists of patients referred to the Contact Lens Service from ophthalmologists and optometrists both within and outside of UCLA as well as student athletes.

UCLA IRB approval for this study was obtained. Patients were identified when a replacement GP lens was ordered and the patient, although asymptomatic, requested an in office dispense. Patients who wear mass-produced (e.g. soft) contact lenses, patients under the age of 18 years, and patients who declined to participate, were all excluded from the study. These lenses were all verified by a trained contact lens technician prior to the dispensing date. Stage One was

GP lens verification to determine if each ordered lens met ANSI standards (Figure 1). Once an ordered GP lens passed verification, Stage Two was dispensing the GP lens to the patient in office. A total of 3 different labs were used to order the lenses depending of type of lens. Keratoconic and post graft lenses were ordered from lab A, standard RGPs were ordered from lab B and sclerals were ordered from lab C.

Some lenses were rejected by the verifying technician before the dispensing appointment. The specific reason for the rejection was noted and then the "defective" lens was returned to the manufacturer and another lens ordered for the patient. A professional exam/visit was scheduled to dispense contact lenses that passed Stage One. At this dispensing visit, the ordered lens could also be found to be problematic by the patient or the dispensing optometrist even though it had previously passed the verification stage. The cause of lens rejections in office were determined through examination: a thorough patient history, including visual acuities and over-refractions, evaluation of both anterior and posterior segments, and evaluation of the contact lens mechanical fit and physiologic adaption.

A trained ophthalmic technician collected all data from lens verification. The data from the exam was collected by a licensed optometrist. If patients requested a spare set of CLs, only one lens of the pair was considered for each patient, the lens to be studied determined by random coin flip.

Results

Seventy patients who ordered custom GP lenses were enrolled in our study. The demographics of our cohort of patients consisted of: 25 females and 50 males between the ages of 18-95 years. The diagnoses of these 70 patients were distributed: 45(64.3%) had keratoconus; 9 (12.8%) were post-penetrating keratoplasty; 8 (11.4%) were myopic; 4 (5.7%) were aphakic; 2 (2.8%) each were diagnosed as corneal irregularity (both of these patients were post LASIK ectasia) and hyperopia.

Of the 70 lenses evaluated in this study, 8 failed verification by ANSI standards (11.4%) prior to the dispensing visit and were reordered (See Tables 1 and 2). Inaccurate contact lens optical power was the most common reason for such rejection (3/8 rejections). The other causes of rejection were: 1 instance of incorrect lens overall diameter, improper peripheral curve system as noted on invoice, a chip noted on edge of 1 lens, the incorrect material was used for the lens by the fabricating laboratory, or the optics were found to be quantitatively correct but qualitatively poor. Seven of these contact lenses were corneal rigid GP lenses, and 1 was a scleral gas permeable lens.

Figure 1. ANSI Standards: RGP Contact Lens Tolerances.[6]

Parameter	Tolerance
Diameter	+/-0.05mm
Optical zone diameters	+/-0.1mm
Base Curve Radius	+/-0.05mm
Power	
0 to +/-5.00D	+/-0.1mm
5.12 to +/-10.00D	+/-0.12D
10.12 to +/-15.00D	+/-0.18D
15.12 to +/-20.00D	+/-0.25D
>20D	+/-0.37D
Prism Power	
0-10 s	+/-0.50D
>10 s	+/-0.25D
Cylinder Power	
<2.00D	+/-.25D
2.00-4.00	+/-.37D
>4.00D	+/-.50D
Cylinder axis	
0-1.50DC	+/-5x
>1.50DC	+/-3x
Toric Base Curve Radii	
Back surface cylinder	
0-0.20mm	+/-.05mm
0.21-0.40mm	+/-.06mm
0.41-0.60mm	+/-.07mm
>0.06mm	+/-.09mm
Bifocal Add Power	+/-.25mm
Center Thickness	+/-.02mm

Table 1. Lens Rejections.

Lenses that failed verification inspection	8/70 (11.4%)
Lenses that were rejected during in office examination	14/70 (20.0%)

Table 2. Reasons for rejection during verification.

Wrong power	3
Wrong diameter	1
Edge Imperfection	1
Wrong peripheral curves	1
Wrong material	1
Poor optics	1

Table 3. Reasons for rejection during in office examination.

Power change	8
Base curve change	2
Non-wetting	1
Lens irritation	2

Of the 62 rigid GP contact lenses that passed verification, 14 later were deemed inappropriate for the patient not by fault of the manufacturing, rejected by either the patient or the practitioner. Change in patient's optical prescription was the most common reason for clinical rejection (8/14). Two lenses were reordered because the dispensing clinician found that a change in base curvature of the lens was needed to provide proper fit (keratoconus patients). Another 2 lenses failed because each of these lenses was deemed uncomfortable by the patient. An additional lens failed in office dispensing because the lens surface was found by the clinician to show poor wetting on the patient's eye (Table 3).

It should be noted that, of these 14 patients: 8 had keratoconus; 3 eyes were post penetrating keratoplasty; and 1 each were myopic, post-lasik ectasia, and graft vs. host disease (Table 4). Thirteen lenses were rigid GP corneal contact lenses while 1 was a scleral GP lens.

Of the 8 lenses that were rejected at the verification level, 5 lenses were ordered from lab A and 3 lenses were ordered from lab B. The labs were not randomized and the sample size was too small to prove clinical significance of which labs were used.

Discussion

Our study reports a rejection rate of 31.4% for custom rigid GP corneal and scleral contact lenses made to valid prescriptions. Most of these rejections (20%) occurred with the patient in the chair. These lenses therefore could have been worn by the patient for some time without detection of any problems. While some might deem this acceptable; it is, in our opinion, not ideal patient care. Some lens problems (e.g. damaged edge) might have resulted in a corneal abrasion or asthenopia (e.g. optical power errors). We believe it is important for eye care practitioners to educate their patients on potential problems that they may encounter if they purchase a custom made contact lens unsupervised by an eye care provider. On the same note, if contact lenses are directly shipped to the patient without verification, regardless of the source, the patient should be encouraged and alerted to be wary for potential problems that could occur (e.g. damaged edge, fit doesn't feel right, improper optical prescription).

Twenty percent (14/70) of our lens rejections occurred at the verifying technician level. In theory, all of these errors should have been detected by the manufacturing laboratory prior to the lens being sent to our practice, but they were not. Some of these might have been determined by an alternate non-professional provider if it is standard practice for such providers to verify lenses. The high lens rejection rate documented in this study, however, suggests to us that in-office lens verification is a valuable safety process during patient care.

This research cannot be easily extended to non-custom lenses, such as mass-manufactured soft lenses, but complications of such lenses have indeed been reported when patients decline to present for professional care at reasonable intervals.[1,4]

Our study is possibly biased because our clinic serves a large number of patients who have special needs, and complex contact lens prescriptions, and it would be reasonable that we might detect more complications. It would be interesting to see the results of this study performed over a more diverse and larger population with less complex lens prescriptions, but the authors, from our clinical experiences, doubt this rate would approach zero.

In conclusion, we believe it would be reasonable for clinicians to advise in-office dispensing for all patients who wear GP custom contact lenses, and perhaps for all custom made contact lenses of every type. At the very least, we believe that all contact lens wearing patients should be educated on the signs and symptoms of problems that can occur upon wearing any contact lens unsupervised by an eye care professional.

References

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