Intraocular Pressure in Ocular Hypertensives With Scleral Lens Wear

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Introduction

Retrospective studies have defined fitting characteristics and indications for the use of rigid gas permeable scleral lenses over the past three decades[1-6]. These lenses have traditionally been used for visual rehabilitation in cases of corneal surface irregularity and in the management of severe ocular surface disease. Long-term use of topical medication in the management of glaucoma can cause chronic epithelial irregularity or even frank epithelial defects. Thus, patients who must use these medications to lower intraocular pressure may experience discomfort due to these symptoms. Scleral lenses can protect the ocular surface, and may allow the epithelium to heal. Although patients with glaucoma or ocular hypertension have undoubtedly been fit with scleral lenses, the effect of scleral lens wear on intraocular pressure in patients with glaucoma have not been specifically reported.

The defining fitting characteristic of scleral lenses is that they land upon the conjunctival tissue that overlies the sclera, and completely vault the cornea and limbus. The haptic, or landing zone, of a scleral lens may exert posteriorly-directed pressure on the sclera overlying the trabecular meshwork and vascular structures associated with aqueous humor drainage. The amount and location of this posteriorly-directed pressure depends upon lens diameter. Smaller-diameter lenses feature relatively narrow landing zones which impact tissue relatively close to the limbus, less landing zone contact area could lead to greater pressure per unit area. Indeed, smaller lenses appear to settle more than larger lenses during wear[7], which could potentially lead to more distortion of structures within the angle. Large-diameter lenses have relatively wide landing zones that tend to be farther from the limbus. This characteristic may make distortion of angle structures less likely with large-diameter lenses. However, the wide haptics that characterize large-diameter lenses may inhibit aqueous outflow through the episcleral venous system. Some have speculated that scleral lens wear could potentially affect intraocular pressure[8].

Background and significance:

We previously studied the use of small diameter lenses and found no change in IOP with two hours of continuous lens wear[9]. In this study, IOP was measured by pneumatonometry peripherally (on the sclera, 2mm temporal to the limbus) in the study eye with a scleral lens on, and compared to the peripheral IOP of the contralateral eye, with no scleral lens wear, at the same times. There were no differences in IOP between peripheral IOP measurements between the eye wearing the lens or the control eye without the lens. Central and peripheral IOP in these eyes were not different before or after 2 hours of lens wear. Peripheral IOP, measured higher in both eye, similar to other studies[10]. However, the study population was relatively young, and had no history of eye disease. The development of

scleral changes in some elderly individuals suggests that scleral rigidity may change over time[11]. This could change the dynamics of scleral influence on aqueous humor outflow and be of concern particularly in individuals with ocular hypertension.

Ocular surface rigidity can be measured using the ocular response analyzer and ultrasound surface wave elastograph. Ocular surface rigidity could affect the settling of scleral lenses, and could thus influence the amount of settling, and amount of potential pressure the scleral lens may place on the aqueous drainage structures of the eye. Settling of scleral lenses can be measured through scheimpflug images obtained by pentacam. The pentacam program has a caliper tool that may be used to measure the distance between the back surface of the scleral lens and the front surface of the eye[12]. This process has been used to measure settling of scleral lenses in previous studies.

A recent study measuring IOP during scleral lens wear, using a diaton to measure IOP found an increase in IOP with short-term scleral lens wear[13].

One other study has explored ramifications of scleral lens wear in patients with glaucoma[14], but concentrated on preferred shunt placement in scleral lens patients who required glaucoma filtering surgery.

We hypothesize that scleral lens wear will not exert enough pressure onto the scleral and ocular structures of the eye to raise IOP in patients with ocular hypertension over 2 hours of scleral lens wear.

Specific Aims:

Specific Aim 1:

> To determine if 4 hours of small diameter scleral lens wear will not create enough pressure to underlying trabecular meashwork and/or episcleral veins structures to create a statistically significant increase in intraocular pressure in patients with ocular hypertension.

Study Design and Methods:

Inclusion:

1. Diagnosis of ocular hypertension (IOP >22 in each eye during at least two visits over the previous 3 years)
2. May have had cataract extraction and IOL
3. Not on topical medication for glaucoma
4. No History of ALT/SLT
5. Any Age, 18 years or older
6. History of contact lens wear (except scleral lenses), as long as they are willing to not wear their lenses the day of the study

Exclusion:

1. On topical medication for glaucoma
2. Eye disease
3. Inability to wear scleral lenses
4. Any intraocular surgery other than uncomplicated cataract extraction.
5. Known allergy to proparacaine eye drops.

Variables collected:

- Corneal thickness
- IOP prior to and during scleral lens wear; with Pneumatonometer and Diaton
- Pentacam images
- Ocular Response Analyzer (ORA)
- Ocular tissue elasticity by Ultrasound Surface Wave Elastography

Procedure:

1. During initial evaluation, patient will be fit with a 15.0 mm diagnostic scleral lens which provides 300-400 microns of clearance immediately after lens application. (We expect lens to settle, which would leave 200-300 microns of clearance). The lens will be fit to one eye, randomly selected. No modifications will be made to lenses of the fitting set, so vision will not be corrected with the lens. The peripheral fit of the lens will be recorded.
2. At study visit:
    a. A series of three measurements of corneal hysteresis with (ORA)
    b. A series of three measurements of corneal elasticity with ultrasound surface wave electrography prototype
    c. IOP will be measured centrally and peripherally by pneumotonometry, in each eye before lens wear. The control eye will be measured centrally and temporally every half hour for 4 hours.
    d. IOP will also be measured through the eyelid with a diatom on each eye. The non-lens wearing eye will serve as a control for the eye wearing the scleral lens.
    e. Lens will be applied to the study eye.
    f. IOP will be measured in the temporal quadrant just beyond the edge of the scleral lens by pneumotonometry immediately after lens application, and every 30 minutes for 4 hours of lens wear. Central and peripheral IOP will be measured in the study eye immediately after lens removal.
    g. IOP will also be measured through the eye lid after lens application, every half hour for four hours after lens wear, and again after lens removal.
    h. Pentacam images will be obtained prior to lens application, immediately after lens application and every half hour after lens application; immediately before lens removal, and after lens removal.

Participant reimbursement: Participants will receive $100 for completing the study visit, along with reimbursement for parking expenses during study visits.

Risks:

There are no more risks to this study then there are for any general eye exam. Proparacaine drops will be used for the IOP measurements, these drops are often used in general eye exams. There is a small risk of allergic reaction to the drops, but it is rare. Likewise, the IOP measurements or scleral lens placement or removal could induce a corneal abrasion. IOP measurements are measured frequently with rare abrasions. Scleral lenses are often fit on fragile eyes, with rare complication.

Data analysis:

All analysis will be completed using paired t-test IOP prior to lens wear will be compared to IOP during lens wear and following lens removal.

Power Statement:
To detect a 2 mmHg elevation of IOP with scleral lens wear a sample size of 21 subjects would be needed. This is assuming and a mean daytime IOP of 13.8 ± 2.8, an α error of 5% and a β error of 10%.

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