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## **Evidence on scleral contact lenses and intraocular pressure**

Running Title: Scleral contact lenses and IOP

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It has been hypothesised that scleral contact lens wear may potentially elevate intraocular pressure (IOP) as a result of post-lens fluid forces exacerbated by eyelid tension, or ocular versions that alter the lens fit and result in corneal bearing or increased conjunctival and scleral tissue compression.<sup>1</sup> A number of studies have investigated the influence of short-term scleral contact lens wear upon IOP, using a variety of experimental paradigms. On average, in young healthy adults wearing various types of modern scleral lenses for relatively short periods (30 minutes to 8 hours), the changes in IOP are typically modest (< 1.5 mmHg).

In 1975, Collewijn et al<sup>2</sup> described an “ocular suction ring” (later known as a scleral annulus or scleral search coil) made from flexible silicon rubber that was used for experimental work investigating eye movements. The annulus was placed on the limbus and pressed upon firmly to eliminate any post lens tear fluid, enhancing suction to the ocular surface. Of the fifty adult subjects examined, the authors reported that one subject experienced an increase in IOP of 8 mmHg after twenty minutes of wear.

More recently, Murphy et al<sup>3</sup> also examined IOP using non-contact tonometry in six healthy young participants prior to, and immediately following 30 minutes of wearing a modern scleral search coil. On average, IOP increased by  $0.4 \pm 1.4$  mmHg (interpreted from Figure 3).<sup>3</sup> Half of the subjects displayed a decrease in IOP following lens wear. In a similar experiment, Irving et al<sup>4</sup> investigated the effect of short-term scleral search coil wear upon IOP in six young healthy subjects (8 eyes). IOP was measured before, during, and after 45 minutes of lens wear in both the lens wearing eye and the fellow non-lens wearing eye using non-contact tonometry. During lens wear, IOP increased in 5 eyes and decreased in 3 eyes. On average, IOP in the lens wearing eye increased by 1.6 mmHg compared to a 0.5 mmHg increase in the fellow control eye (that is, a mean increase of 1.1 mmHg attributed to scleral coil wear).

Few studies however, have examined the impact of scleral lens wear (not scleral search coils) upon IOP measurements. Nau et al<sup>5</sup> recently reported on the effect of two hours of miniscleral lens wear (Jupiter, 15 mm total diameter) on IOP in 29 healthy young adults. A pneumatonometer was used to measure IOP at the central cornea (both pre and post lens wear) and adjacent to the lens edge on the peripheral conjunctiva/sclera (before and during lens wear). Miniscleral lens wear resulted in a mean increase of 0.6 mmHg in IOP during lens wear (peripheral scleral measurement) and a mean increase of 0.5 mmHg immediately following lens removal (central corneal measurement) relative to the non-lens wearing control eye.

In a series of recent publications, we have described the changes in corneal thickness and curvature following short-term miniscleral contact lens wear in healthy young adults with normal corneae.<sup>6-8</sup> In a subset of these participants, we also measured the change in IOP following scleral lens wear and compared this to the natural diurnal fluctuation in IOP on a separate control day with no contact lens wear (these IOP data have not been published previously). In both studies, an ICD 16.5 mm miniscleral contact lens (Paragon Vision Sciences, USA) was worn for either 3 or 8 hours.

In the first experiment,<sup>6</sup> IOP was assessed in seven subjects before and after three hours of lens wear using a corneal compensated IOP measurement from the Ocular Response Analyzer (ORA, Reichert). The mean IOP was  $12.8 \pm 1.5$  mmHg in the morning prior to lens wear and  $11.5 \pm 3.1$  mmHg at midday following lens removal (a mean decrease of  $1.3 \pm 2.0$  mmHg following three hours of lens wear). Data collected on a control day without contact lens wear revealed a similar reduction in IOP between morning and midday time points matched between the measurement days:  $13.5 \pm 2.8$  mmHg in the morning and  $12.2 \pm 3.2$  mmHg at midday (a 1.3 mmHg decrease in IOP).

In a follow-up experiment,<sup>7,8</sup> we also assessed IOP in five subjects before and after 8 hours of scleral lens wear using a non-contact tonometer (TX-20P, Canon). On a control day with no contact lens wear, the mean IOP was  $16.3 \pm 3.6$  mmHg between 8-10 AM and  $15.4 \pm 2.0$  mmHg between 4-6 PM (a mean decrease of  $0.7 \pm 1.9$  mmHg). On the day of miniscleral lens wear, matching the measurement time points to the control day, IOP was  $15.6 \pm 3.5$  mmHg prior to lens wear and  $15.2 \pm 1.2$  mmHg following lens removal (a mean decrease of  $0.4 \pm 2.7$  mmHg).

While our studies were not specifically powered to detect statistically significant changes in IOP, these observed decreases in IOP following lens wear, consistent with a normal diurnal fluctuation in IOP, combined with other previously published studies of minimal (non-statistically significant) increases in IOP following modern scleral lens<sup>5</sup> or scleral coil<sup>3,4</sup> wear suggest that on average, appropriately fitted modern scleral lenses do not substantially elevate IOP in the short-term, despite primarily superficial tissue compression near the scleral spur.<sup>9</sup> Research examining the influence of various scleral lens designs upon IOP, which may compress conjunctival and episcleral tissue to varying extents, may provide additional insights into the role of contact lens related tissue compression and aqueous outflow.

Since some young healthy adults display a small increase in IOP during or following scleral lens wear, all contact lens fittings should be undertaken with caution in patients with ocular hypertension, glaucoma, or filtration devices located near the limbus (that is, a drainage bleb following a trabeculectomy or tube implant).<sup>10</sup> Further well-designed studies are still required to accurately measure IOP changes in elderly patients (with potentially different scleral properties) or following longer term scleral lens wear in eyes

with corneal abnormalities to improve the current understanding of the influence of scleral lens wear upon IOP.

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