

Experimental Investigation on Corneal Astigmatism Fitted With Disposable Soft Toric Contact Lenses

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Abstract

In two publications that examined the myths and realities of CL fitting and wear, Ephron and colleagues talked about how practitioner and customer attitudes change more slowly than technology and knowledge, which move very quickly. In the study, 30 patients with soft toric lenses had a corneal astigmatism greater than 1.25 D or between 0.75 and 1.25 D (22 eyes; Group B), and 30 patients with soft spheric lenses had a corneal astigmatism between 0.75 and 1.25 D or less than 0.75 D (23 eyes; Group D). For all patients, corneal topography, autorefractometry, biomicroscopic characteristics, corrected and uncorrected monocular visual acuity measurement with log MAR, and both were done before and at least 20 minutes after contact lens application. Three criteria were used to measure the effectiveness of contact lens fittings: astigmatic neutralization, visual success, and retinal deviation. differences between spherical and toric contacts. The 60 subjects had a mean age (6SD) of 27.565.0 years, a spherical refractive error of 23.6862.01 D, and a cylinder refractive error of 21.2860.36 D. In terms of high- and low-contrast visual acuities, toric lenses performed better than spherical lenses both during the fitting process (toric high-contrast: 20.06560.078 and low-contrast: 0.13360.103 vs. spherical high-contrast: 0.00160.104 and low-contrast: 0.22460.107; and follow-up; toric high-contrast: 20.08360.0. When toric contact lenses were fitted, electromyography-measured eyestrain was less with them than with spherical lenses, but not at the follow-up.

Keywords: *Astigmatism, Soft Toric Lenses, Soft Spheric Lenses, Spherical Equivalent Refraction, Surface Topography.*

1. INTRODUCTION

It has been reported that it takes an average of 17 years for clinical research to become clinical practice in the broader field of general healthcare. Many steps, including basic and human research, the development of guidelines, and adoption in practice, are acknowledged as being involved in this process. 1 It has been estimated that between 30 and 40% of patients do not receive care in accordance with the best available scientific evidence because behavior change in normal medical care is notoriously difficult to achieve. 2 With this understanding in mind, focusing on soft contact lens (CL) practice raises concerns about widely held attitudes among eye care professionals and the adoption of current evidence-based clinical practice. Given the rapid advancement of CL material and care system technology and our growing understanding of how these factors affect ocular physiology, it's probable that old ideas still persist that, in light of recent research, are no longer valid.

In two papers that looked at the myths and realities of CL fitting and wear, Ephron and colleagues^{3,4} addressed the relatively fast pace of change in technology and knowledge compared to slower-changing practitioner and consumer attitudes. It makes sense to look at some current prevalent misconceptions about soft CL fitting after three decades have passed since those reports were published. This analysis reviews the facts to support or refute ten widely held assumptions. The review is divided into three major topic categories linked to the CL and care system, patient-related problems, and business-focused hurdles. It may come as a surprise given the 30-year gap since Ephron and colleagues^{3,4} originally addressed this subject since six of the topics discussed in this review were also addressed in those initial studies. While it's undeniable that technology and clinical knowledge have advanced over time, there still seems to be some reluctance to let go of archaic, but now outmoded, perceptions of CL success, appropriateness, and profitability.

2. CONTACT LENS AND CARE SYSTEM

Increasing oxygen transmissibility improves lens comfort

Although it wasn't expressly addressed in the early "myths" publications by Efron and colleagues practitioners and manufacturers have shared a long-standing interest in approaches to improve on-eye comfort of lenses.

The idea of increasing comfort through more oxygen was first proposed in the late 1970s with the introduction of rigid gas-permeable corneal lenses, which offered greater comfort than the PMMA lenses then in use.

5 Rapid acceptance of soft lenses was sparked by the development of soft lenses and the faster rate of patient adaptation and comfort compared to rigid lenses. The second time this idea that more oxygen results in more comfort became popular was in the late 1990s, with the introduction of silicone hydrogel (SiHy) materials. Many of the earlier hypoxic issues associated with hydrogel lenses were definitely resolved with the development of SiHy lenses, especially in patients with thick lens designs where oxygen transmissibility was significantly decreased or when lenses were worn overnight.

Hydrogels should no longer be fitted

Around the world, silicone hydrogel materials account for 80% of reusable lenses and 63% of daily disposable lenses, or nearly three-quarters (73%) of all soft lens fittings. 30 SiHy materials have been commercially accessible for more than 20 years, and it seems feasible that the increased oxygen they provide to the cornea should have made them the primary choice of lens for all patients. This is why it's interesting. Why then do hydrogel lenses still make up nearly 25% of all new fits after 20 years? Hydrogel lenses, which are frequently comprised of materials created in the 1980s or even earlier, are still being prescribed by some doctors, new hydrogel lenses are still being introduced to the market, and users of existing hydrogel lenses are still wearing them effectively.

3. LITERATURE REVIEW

Carole Maldonado-Codina (2021) In order to determine whether there was a correlation between subjective comfort and both subjective and measurable eyesight when using current daily disposable soft toric contact lenses, this study set out to look at the issue. In a prospective, crossover, randomized, single-masked research, 38 regular users of soft contact lenses wore one of three daily disposable toric lenses for one week. At the dispensing and follow-up visits, the following clinical measurements were noted: biomicroscope results, lens fitting (including rotation and rotational stability), high and low contrast visual acuity, subjective vision quality, and subjective comfort of the ocular surface. Numerical grading systems of 0 to 10 were used to obtain subjective scores. Age, sex, visit, phase of crossover ('phase'), lens type, rotation, rotational stability, visual acuity, cylinder power, and subjective vision quality were all taken into account when analyzing comfort scores using a linear regression model. The results were then further refined using backward stepwise regression. 36 participants (31.1 13.5 years) finished the research. Comfort ratings were discovered to be related to subjective visual quality, phase, and lens type ($F = 4.9$; $p = 0.009$). Greater subjective visual quality scores were correlated with higher comfort scores. The model did not show statistical significance for visual acuity. According to this research, symptoms of ocular discomfort may be more severe if daily disposable soft toric lenses are believed to cause visual compromise. Comparatively to comfort and measured visual acuity, there was a stronger positive association between comfort and subjective vision quality.

Craig A Woods (2016) Despite novel techniques and materials, contact lens pain is still cited as the main cause of soft lens dropout. The goal of this study of comfort-related data from a number of clinical investigations was to see whether there was a difference in the comfort responses of habitual lens wearers with symptoms and those without symptoms throughout the course of the day. Data were combined and analyzed from five separate non-dispensing clinical investigations. Depending on whether they were identified as symptomatic or asymptomatic contact lens wearers using a modified Subjective Evaluation of Symptoms of Dryness (SESOD) questionnaire, participants in these studies were divided into one of two groups. The ocular comfort of masked individuals wearing either a hydrogel or a silicone hydrogel contacts lens was assessed on a visual analogue scale at insertion and every two hours for the course of a single lens-wearing day. The SESOD questionnaire identified 45 persons as asymptomatic and 58 as symptomatic among the 103 participants whose data were used. The comfort factor was unaffected by lens material ($p = 0.43$). There was a substantial connection between time and symptoms, though. Each time point had a significant difference in the mean level of comfort between the sick and asymptomatic group ($p 0.05$). However, for the asymptomatic group, comfort did not change significantly

throughout the day ($p = 0.87$), whereas for the symptomatic group, mean comfort ratings dramatically decreased from 84.6 13.2 (S.D.) at insertion to 73.0 18.5 at 8 hours ($p = 0.001$). In our study, a day's worth of changes in contact lens comfort were unrelated to lens material, but symptoms were. Conversely, asymptomatic lens wearers did not report a steady decline in comfort. Therefore, in clinical research, it is not recommended to utilize asymptomatic wearers to gauge contact lens comfort. The sensitivity of comfort ratings as a measurement in contact lens studies would probably rise if asymptomatic lens wearers were excluded.

Michael L Read (2020) a wrist-mounted electronic "lens awareness logger" will be used to evaluate ocular pain caused by contact lens usage (LAL). For three days, 30 symptomatic contact lens wearers wore the research lenses. Two lens types known to vary in end-of-day comfort (lens A: senofilcon A and lens B: balafilcon A) were worn as a matching pair for the first two days of the experiment (randomised order). A pair of lens B was worn on day three. The participant applied an LAL each day. The subject used the LAL on days one and two, pressing a button anytime they became aware of their lenses due to pain. The subject reported their discomfort on day three by using a multiple click approach (1 = mild awareness to 3 = severe awareness). LAL activities on days one and two were comparable (17.3 vs. 15.8 events per day). Compared to lens A (11.6 events per day), lens B had considerably higher LAL events (21.6 events per day) ($p = 0.006$). Peaks in awareness that occurred after lens application and near the conclusion of the wearing cycle were highlighted by the LAL event profile. Comparing the LAL event profiles for the two types of lenses revealed notable variations in lens awareness, especially during the initial phase of the wearing cycle. On day 3, LAL events revealed a consistent pattern of single and double clicks throughout the day, but a distinct peak in triple clicks in the final two hours of lens usage. The study lenses' LAL event profiles differed, and the LAL was able to distinguish between them. Towards the conclusion of the wearing cycle, lens awareness linked with discomfort seemed to occur more frequently and with greater intensity. The LAL's capacity to monitor lens awareness suggests that it will probably prove to be a helpful tool in advancing our understanding of ocular discomfort.

Sulley, Anna (2018) To calculate the retention rate (RR) for newly fitted patients with contact lenses (CLs) and to detect dropout and retention-related factors. At this multisite, sponsor-masked registry study, the 1-year status of new CL wearers who were fitted in a cross-section of UK clinics was assessed. 26 UK experimental locations in total accepted up to 89 prospective patients each. At one month (about one week after the fitting), three months (about two weeks), and twelve months (about three weeks), participants were asked to complete surveys online or over the phone. Participants were contacted by email (or phone) and asked to respond to a series of questions about their experience wearing CL in an online survey. 65.3% (347/531) of the 531 individuals that were recruited responded to at least one follow-up survey, while 42.3% (225/531) of the participants answered to all three questions. By 12 months, one in four patients had stopped wearing their CL. The RR was 77.6% based on individuals who were evaluable at 12 months (194/250, 95% confidence interval: 72.0-82.3). Vision issues (41%) were the most frequent cause of cessation, followed by discomfort (36%) and handling issues (25%). First-year RRs are influenced by sex, spherical refraction, the use of lenses (whether full- or part-time), and the supply technique (collected or posted). The first-year RR for novice CL wearers in this prospective research was 77.6%. This matched the 74.0% figure found in a retrospective investigation. Similar to the prior study, visual issues were frequently stated as the cause of discontinuation.

Cox, Stephanie (2018) To determine whether the clinical time required to fit soft tori contact lenses (TCLs) is longer than the time required to fit soft spherical contact lenses (SCLs) and whether patient-reported outcomes are improved with TCLs. A TCL or SCL was fitted binocularly into habitual contact lens wearers with vortexed spherical refraction of +4.00 to +0.25 D or 0.50 to 9.00 D and cylinder of 0.75 to 1.75 DC, who were also masked to the treatment assignment. Time taken to complete the fit was noted. The modified Convergence Insufficiency Symptom Survey (CISS) and the National Eye Institute Refractive Error Quality of Life Instrument (NEI-RQL-42) were completed after 5 days. Subjects were inserted into the alternative lens design after washing (TCL or SCL). Results were assessed using generalized linear models for the successful fit, linear mixed models for the time to fit and CISS score, and Wilcoxon tests for the NEI-RQL-42. The study was completed by 60 participants (71.7% women, mean age [SD] = 27.55.0 years). The TCL's mean fitting time was 10.2 4.3 min, whereas the SCL's was 9.0 6.5 min (least square [LS] mean difference (TCL-SCL)=1.2, $P=0.22$). Tori contact lenses outperformed SCL in terms of overall NEI-RQL-42 score ($P=0.006$), subscales measuring visual clarity and satisfaction with correction ($P=0.006$). A 15% reduction in symptoms was seen with CISS (LS mean difference [TCL-SCL]=2.20, $P=0.02$). Given the subjective improvements in results, TCLs are a suitable alternative when attempting to correct the eyesight of individuals with low-to-moderate astigmatism.

4. METHODS

In the study, 30 patients with soft tori lenses had a corneal astigmatism greater than 1.25 D (25 eyes; Group A) or between 0.75 and 1.25 D (22 eyes; Group B), and 30 patients with soft spheric lenses had a corneal astigmatism between 0.75 and 1.25 D (28 eyes; Group C) or less than 0.75 D (23 eyes; Group D). Table 1 provides a summary of the tori and spherical contact lenses' specifications. Patients who were open to wearing contact lenses were chosen, while those with ocular surface conditions or tear film dysfunction were excluded. Patients gave their written, informed permission. All patients underwent measurements of their corrected and uncorrected monocular visual acuity, biomicroscopic characteristics, autorefractometry, and corneal topography using a Placido disk-based corneal mapping system and transferring the results to color mapping software (Topcon KR 7000P, Topcon Corporation, Tokyo, Japan) before and at least 20 minutes after applying contact lenses. According to Young¹¹, utilizing spherical lenses matched to the mean spherical equivalent prescription allowed for the best corneal coverage, horizontal and vertical centration, and movement. Following lens settling, the scribe marks on the tori soft lenses were situated 0 to 10 degrees apart from the location of the lens marking. Centralization, axial rotation, and deposits on the contact lenses were seen during the biomicroscopic analysis. With the help of a slit lamp, the lens' orientation was determined, and rotations were noted in relation to laser markings.

Success of contact lens fitting was evaluated by three parameters:

- i. **Astigmatic neutralization:** The residual astigmatism after contact lens application was divided by the initial or total corneal astigmatism determined before contact lens application, and expressed as a percentage using the following formula: residual/total cylinder%. This allowed researchers to compare the effectiveness of different diopters of corneal astigmatism.
- ii. **Visual success:** In log MAR, corrected visual acuity with glasses and contact lenses was compared. Applications that had a difference in visual acuity of less than 2.0 lines were considered successful, and the success rate was calculated based on a subjective formula.
- iii. **Mean retinal deviation (absolute spherical equivalent fraction):** The residual refractive errors of the patients based on autorefractometry were developed as stated by Payor et al. to simplify the combined effect of spheric and cylindrical power. 12 By averaging the absolute values of the main meridian lines in diopters, deviation was computed. There was no regard for axial rotation. Mean retinal deviation values, referred to as "total" and "residual" retinal deviations, were calculated for each of the groups before and after contact lens administration. Success was defined by residual retinal deviation readings below 0.50 D. By calculating the (individual) residual/total retinal deviation value ratio for each case, success rates for each group were assessed.

Table 1 Specifications of tori and spherical contact lenses

| Group As-B | No. | Central thick (mm) | Groups C-D | No. | Central thick (mm) |
|--|-----|--------------------|------------------------------|-----|--------------------|
| Focus [®] toric (Ciba) | 13 | 0.14 | Focus visitint (Ciba) | 13 | 0.1 |
| Freshlook [®] toric (Wesley jessen) | 19 | 0.11 | Freshlook LT (Wesley jessen) | 19 | 0.08 |
| SL-66 toric (Bausch and Lomb) | 15 | 0.19 | SL-66 (Bausch and Lomb) | 20 | 0.1 |

5. DATA ANALYSIS

Eight different data points collected from each electromyography recording were used to model the electromyography data. Each window of the 40-sec recording was 100 ms long and covered the window before it by 50 ms. Using the formula root mean squared, the root mean squared value of the electromyography data (in volts) was determined for each window. $\frac{1}{4} = \sqrt{[(1/n)(x_1^2 + x_2^2 + \dots + x_n^2)]}$.

A median root mean squared value was created by taking the median of each of the five-second blocks made up of about 100 windowed root mean squared values. Prior to the linear mixed model analysis, a log transformation was applied to the median root mean squared values to establish data normality. High-contrast visual acuity, low-contrast visual acuity, and electromyography data were compared between the toric and spherical contact lenses using linear mixed models. The lens order, lens wear time, lens, event, and lens by event interaction were all adjusted for in the high-contrast visual acuity and low-contrast visual acuity models. The electromyography model took into account the eight data points per electromyography recording (lens order, lens wear time, lens, event, and time interval), as well as all two- and three-way interactions for lens, event, and time interval.

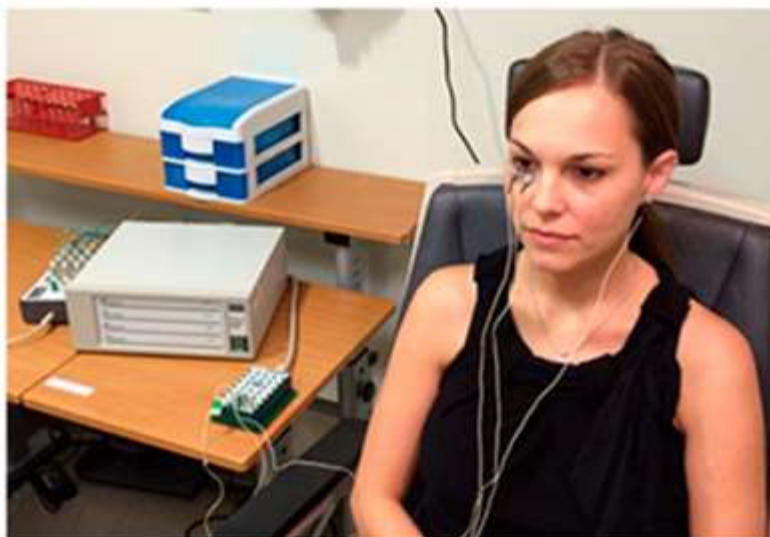


Figure. 1. The experimental setup for the electromyography showing the placement of electrodes

6. CONCLUSIONS

With the use of Toric and spheric contact lenses, visual acuity and residual spherical equivalent refraction stayed within acceptable ranges. While toric lenses generated central neutralization and a decrease in the corneal cylinder in low and moderately astigmatic eyes, spherical lenses failed to disguise corneal toricity during topography.

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