



Reimagining approaches to solving common contact lens conundrums

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Reimagining approaches to solving common contact lens conundrums

INTRODUCTION

For those of us who have been in the contact lens field for some time, there are several research themes that have persisted over many years. We want our patients to have contact lenses that are comfortable to wear, fit well and allow them to see optimally throughout life and are safe with minimal impact on normal ocular surface physiology and a low rate of complications. It is a short list, but these clinical themes drive research and, ultimately, translational advances in the field. This contact lens special edition of *Ophthalmic and Physiological Optics* reimagines these themes, examining the impact of contemporary and emerging lens technology using modelling, imaging, bioinformatics and artificial intelligence (AI) to address these persistent questions.

The themes for this edition include mitigating contact lens discomfort in wearers who had discontinued contact lens wear due to poor comfort; lens fitting and patient characteristics to optimise both comfort and contact lens performance and the role of vision in contact lens discomfort, which segues into emerging vision correction approaches, including those incorporating wavefront-guided designs and new technologies in their evaluation. The final section revisits the oxygen performance of contact lenses, including a review of the seminal contributions of George K. Smelzer to our fundamental understanding of the phenomenon and modelling of the oxygen performance of contemporary scleral contact lenses, noting the resurgence in their use and opportunities for advanced optics and therapeutic applications.

EXPLORING CONTACT LENS DISCOMFORT

It has been well established for many years that discomfort plays a key role in contact lens dropout: both in established and new wearers. Recently, it has been estimated that as many people are ceasing lens wear as are being fitted per year in the UK.¹ In fact, one in four new wearers will discontinue lens wear within the first year.^{2,3} If this figure could be reduced, it would provide a much-needed boost to the global contact lens market and have all-round benefits; our patients would be happier, practices would be more successful and the increased revenue for contact lens

manufacturers would in turn lead to more investment into new materials, designs and technologies.

The paper by Lievens et al.⁴ highlights the importance of giving those who have previously dropped out of contact lens wear the opportunity to try a different lens because they are very likely to be successful. Unfortunately, the reality is that the majority of these patients are not offered an alternative lens or management strategy.³ Lievens et al. re-fitted 60 pre-presbyopic subjects who had discontinued soft lens wear within the previous 2 years due to discomfort (or dryness) and followed them for 6 months. They were all re-fitted with the same contemporary soft daily disposable silicone hydrogel contact lens, and only a single subject had discontinued lens wear by the final 6-month time point. They measured comfort using a ± 50 visual analogue scale and reported excellent comfort after 1 month (median score of 44). A series of Likert questions showed very high levels of satisfaction, which did not show signs of decline between 1 and 6 months. This study corroborates previous work, which has found that three in four people can be successfully re-fitted when given the chance.^{5,6} Eye care practitioners should be vigilant for growing dissatisfaction and intervene as early as possible. In doing so, we open up all the lifestyle benefits that contact lenses have to offer.

Of course, discomfort is not the only reason for contact lens discontinuation. Poor vision is often cited as the top reason for dropping out of lenses in those who are new to contact lens wear^{2,3} and in those wearing multifocal lens designs.^{2,6} Richards et al.⁷ conducted an investigation utilising robust regression modelling to analyse participant-reported ratings of comfort, dryness and vision. Their analyses were based on a comprehensive dataset aggregated from 31 studies employing numerical scales ranging from 0 to 100. They confirmed strong positive pairwise associations between the ratings, the most pronounced being between comfort and dryness, as well as between ratings collected at the same time of day. The way in which various participant and lens factors could affect these ratings was also explored. Their modelling showed that the average decrease in comfort, dryness and vision over 8 h would be 8.2, 15.4 and 3.6 units, respectively. By the end of a typical lens wearing day, it is not difficult to see that an average lens wearer will easily surpass the threshold for what is considered to be a clinically significant change for comfort.⁸ Age was not predictive for any of the ratings, but

comfort and dryness were lower in females than in males, which is consistent with previous work.^{9,10} Lens factors such as modulus, material and replacement frequency did not impact comfort but did affect the other ratings. The paper shows that even if a lens design were optimised for one attribute, for example, vision, it could negatively impact another factor.

Maldonado-Codina et al.¹¹ undertook a prospective study to identify participants who were either very comfortable (asymptomatic) or very uncomfortable (symptomatic) when fitted with a single daily disposable lens type and investigated differences in five clinical parameters over the course of a 14-h wearing day. There are very few published investigations that provide clinical data over a true, typical lens-wearing period like this. In order to separate the symptomatology of the two groups as much as possible, they used a Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score of ≤ 7 and ≥ 20 for the asymptomatic and symptomatic subjects, respectively. Upper eyelid margin staining and lower tear meniscus height were found to be significantly different between the two groups after 14 h. Symptomatic subjects demonstrated greater upper eyelid margin staining and decreased lower eyelid tear meniscus height compared with asymptomatic subjects. Upper eyelid margin staining was the parameter with the strongest relationship to comfort; higher scores were associated with lower levels of lissamine green staining. These findings support the hypotheses that contact lens surface lubrication and the resulting frictional forces involving the upper eyelid margin may play an important role in the complex mechanisms involved in contact lens discomfort.

The paper by Vaughan et al.¹² reminds us that a contact lens disrupts the delicate structure of the tear film and, in doing so, could lead to discomfort and reduced visual quality. 'Lubrication' is once again indirectly an important theme here. Their work involving 14 habitual soft lens wearers investigated how environmental stress (low humidity) affected blink rate, ocular scatter and ocular surface cooling in spectacles versus contact lenses. Contact lens wear showed increased blink rate and ocular scatter compared to spectacles in a comfortable humidity environment, but the cooling rate of the ocular surface did not differ significantly between the two. It is possible that this increased blinking may contribute to discomfort since the eyelids, especially the upper eyelid, are in effect forced to travel even further over the lens surface. Exposure to low humidity led to a significant increase in blink rate with both refractive corrections, but ocular scatter and cooling rate did not change significantly. The authors hypothesise that the increased blink rate in contact lens wearers is a compensatory mechanism designed to prevent degradation of the tear film, which in turn helps to maintain optical quality and ocular surface cooling. Their work re-reinforces the importance of the blink in managing tear film instability, and perhaps explains why simplistic measures such as non-invasive tear break-up time may not be ideal for investigating the tear film.

The study by Garaszczuk et al.¹³ focuses on another aspect of the tear film—osmolarity—which when elevated has been associated with dry eye disease and contact lens discomfort. They make the very good point that although osmolarity is a valuable clinical metric, measurement in everyday clinical practice is not commonplace, most likely because of the expense. Their work investigates whether the use of machine learning techniques can predict osmolarity from other routine clinical parameters, thereby potentially negating the need to measure it directly. The study found that simple linear regression did not provide an accurate prediction. Advanced regression models as well as techniques for categorising individuals into groups (e.g., low, medium and high osmolarity) were explored and showed that machine learning could significantly aid in predicting tear osmolarity with about 80% accuracy in some cases. The key predictor variables included non-invasive break-up time, tear meniscus height, ocular redness, meibomian gland coverage and the Dry Eye Questionnaire-5 (DEQ-5). The potential for AI and machine learning solutions in this area is huge, and it may not be too long before we see the evolution from research to clinical tool.

EVERYTHING OLD IS NEW AGAIN— EVEN IN CONTACT LENS FITTING CHARACTERISTICS

We are occasionally reminded that 'everything old is new again'. This quote has been attributed to Jonathan Swift (1667–1745), known for his satirical writing on the social issues of his time. This phrase has worked its way into the contemporary lexicon to describe many things, including science and medicine. Indeed, a search of this phrase in PubMed® (pubmed.ncbi.nlm.nih.gov) yielded 153 citations.

In this issue, two studies exploring contact lens fitting characteristics are presented. Both investigations build upon a longstanding, fundamental metric of contact lens fitting: lens centration. While Walther et al.¹⁴ present a new perspective on measuring lens centration, Applegate et al.¹⁵ explore the exacting requirements of lens centration for a specific clinical application. The contributions of these works suggest that in science, as in society, one can revisit and reinterpret the old to create something new.

In the first of these two studies, Walther et al. explored the on-eye centration of modern spherical soft contact lenses (SCLs) and examined centration relative to the pupil. This is significant because lens centration is a parameter that has traditionally been measured in the clinical setting by evaluating the position of the contact lens edge relative to the limbus or corneal centre.¹⁶

To measure lens centration relative to the pupil, Walther et al. acquired 60 images of 101 eyes and used custom image analysis to identify the boundaries of the contact lens, pupil and corneal limbus. Using these boundaries, Walther et al. then calculated the horizontal and vertical positions of the contact lens relative to the pupil and

corneal limbus. The mean [95% confidence interval] decentration, relative to the pupil centre, observed for SCLs was -0.23 mm temporal [-0.26 , -0.20] and -0.08 mm inferior [-0.12 , -0.04], but the lenses were well-centred relative to the corneal limbus. They concluded that modern SCLs decentre in the same direction but with lesser magnitude than older lens modalities.¹⁷ The authors suggest that because the pupil is typically positioned nasally and superior, defining lens centration relative to the pupil rather than the corneal centre may optimise image quality and visual performance.

In addition to measuring lens centration relative to the pupil, Walther et al. also explored the impact of lens thickness (as a proxy for lens power) and material on how lenses decentred. The authors reported, contrary to previous accounts, that centration did not vary with sphere power or lens material. They suggest that ocular anatomy rather than lens characteristics may be the primary determinant of lens position on the eye.

The second study featured in this issue explores a specific application of lens centration relative to the pupil centre, with rigid lens correction for keratoconus. Specifically, Applegate et al. used SyntEyes^{18,19} data—that is, a dataset of synthetic (not clinically measured) but representative data—to gauge the acceptable alignment error of wavefront-guided (WFG) rigid contact lens corrections in normal and keratoconic eyes as measured by the visual Strehl ratio (VSX) for 20 normal and 20 keratoconic SyntEyes. Using a novel approach, the authors used the visual image quality (measured by VSX) of normal eyes to serve as a reference for acceptable image quality in keratoconic eyes and ultimately to determine the acceptable alignment error in WFG lenses for keratoconus.

The authors found acceptable tolerances for correction misalignment of keratoconic image quality, corrected to that of average normal eyes, varied between 0.29 and 0.63 mm for translation and $\pm 6.5^\circ$ for rotation. Notably, the tolerable misalignment decreased with the increasing disease severity in keratoconus, as defined by the anterior curvature (K_{max}). They concluded, in agreement with the literature, that scleral lenses provide the optimal platform, given the stability of the lenses on the eye relative to the pupil centre, as compared with corneal rigid gas-permeable lenses.²⁰

Discussing the implications of their findings, Applegate et al. highlight the potential for WFG corrections to provide 'near-perfect' visual image quality, as measured by the VSX. However, the authors temper this bold statement by outlining the (still distant) technological advancements that would be required to translate this work from research to clinical practice effectively. The required innovations include the fabrication of clinically efficient aberrometers, continued improvements in scleral WFG lens designs and the development of precise lathing techniques essential to the manufacture of WFG lens designs. They acknowledge that there is still much work to be done.

Both Walther et al. and Applegate et al. make important contributions to current clinical care. For example, Walther et al. cite specific contemporary examples for which lens centration of SCLs is crucial, including multifocal and dual-focus lens designs commonly utilised for the management of presbyopia or myopia control. Similarly, Applegate et al. describe how WFG lenses can potentially correct both the lower-order aberrations of sphere and cylinder and higher-order aberrations to optimise rigid gas-permeable scleral contact lens correction. Moreover, the work of Applegate et al. reminds us that WFG contact lenses potentially provide a custom, rather than population-based, vision correction, paralleling other healthcare trends towards personalised care.²⁰ While not specifically stated, the authors' comments on lens centration relative to the pupil could also be applied to orthokeratology fitting, where lens centration is also critical.

Both works advance current knowledge by presenting a strong argument for assessing the contact lens centration relative to the pupil rather than the traditional manner of lens assessment. Additionally, returning to the older concept of lens centration helps us appreciate the progress in the contact lens industry: innovations in lens design, the resurgence and enhancement of scleral lens modality, new methods to construct datasets such as SyntEyes and the potential of WFG lenses to correct refractive error and mitigate the visual impact of keratoconic eye disease. In other words, these works illustrate that there is still much to 'make new' when studying concepts as fundamental and seemingly straightforward as lens centration.

EMERGING VISION CORRECTION AND TECHNIQUES—ESTABLISHED LENS DESIGNS ANALYSED USING NOVEL TECHNIQUES

Three papers focus on novel assessment of emerging lens designs. These designs are in no way novel: scleral lenses were the original lens design invented by Leonardo DaVinci in the early 16th century and were first manufactured in Europe in the late 1800s; in the 1960s, George Jessen (co-founder of Wesley-Jessen Corporation) and the grandfather of orthokeratology (orthoK) first described 'orthofocus' with polymethyl methacrylate (PMMA) lenses; and improving vision and preventing dropout of multifocal soft contact lens wearers has been the bane of contact lens practitioners and researchers worldwide.²¹ However, the applications of these lens designs have been reimaged in different populations: scleral lenses are part of the Tear Film and Ocular Surface Society (TFOS) DEWS 11 step-based management protocol for dry eyes²²; orthoK are among the most effective refractive myopia control method for children²³ while multifocal contact lenses, still chasing the increasing presbyopic market, are also used in myopia control.²⁴ Along with these different populations, we are also seeing the benefits of an ophthalmic imaging

revolution. Spurred on by posterior ocular imaging, anterior eye imaging techniques are on the rise. These not only include new instrumentation but also algorithms to analyse big datasets and AI.

These imaging advances are well demonstrated by Martinez-Plaza et al.,²⁵ who investigated peripheral and scleral shape changes using the Eye Surface Profiler (ESP, eagle t-eye.com) in myopic orthoK wearers. By analysing ESP standard scans and using an algorithm based on raw data from the ESP, they showed changes in the central and mid-peripheral cornea over 3 months of orthoK wear, but no changes in the sclera or peripheral cornea. As the authors rightly pointed out, this was only over a 3-month test period, and longer term changes should be assessed. It is also important to note that this study was conducted on adults ≥ 18 years of age, and longer-term assessment of children < 18 years of age, that is, the population most frequently being prescribed these lenses and whose cornea and sclera are likely to be less rigid,²⁶ should be assessed.

This study is noteworthy for another reason, namely that it is in alignment with the expansion of open source bioinformatic techniques and an increase in the publication of protocols that is set to accelerate discovery and reproducibility, which will be important in the age of AI. The authors point out the application of their methods for other optical interventions, and of course scleral lenses come to mind, which unlike orthoK lenses do indeed bear on the sclera.

In Fogg et al.,²⁷ the age-old question of scleral lens fogging is investigated. With the increase in scleral lens prescribing in recent years,²⁸ a prospective observational multisite study with sufficient power to analyse the contributing factors was performed. Confirming the multifactorial nature of this phenomenon, the authors attribute 27% of the variance to lens and solution factors but could not isolate any one factor in particular. They also administered the Ocular Surface Disease Index (OSDI) survey to participants, finding that those with midday fogging had a mean score of 44 (classified as severe dry eye) compared to 10 (normal) in those without fogging. As they rightly mention, the greater fitting of scleral lenses for dry eye might have played into this finding, highlighting the difficulty of teasing out cause and effect. This study demonstrates nicely the interactions between the device (scleral lens), the environment (ocular surface) and person factors (symptoms).

While the OSDI is a well-utilised and useful instrument, other techniques of patient-related outcomes could also be used such as item banking.²⁹ In this process, data were collected via focus groups and then distilled into a bank of questions tested with a larger cohort. The increase in scleral lens wearers opens up these other avenues of reporting outcomes.

Carrying on the theme of person-based effects, Smith et al.³⁰ consider the individual gaze preferences of presbyopic lens wearers. They tested a range of refractive options, including spherical distance, intermediate and near contact lenses, multifocal contact lenses and multifocal spectacles, with a novel panel of tasks, including hazard perception.

The testing kit included a head-mounted video eye tracker (Pupil Core, pupil-labs.com) to record eye movements during reading, visual search and hazard perception. The forward-facing camera on the device was also used to quantify head movement. Smith et al. found that the type of refractive option affected reading speed, although reading accuracy and visual search time were not affected. As well as investigating person behaviours, they state that peripheral optical designs for myopia management might also benefit by gaze behaviour metrics.

These latter three papers demonstrate a myriad of advances in novel investigation techniques, theory, analysis and application of contact lens corrections. Thinking back to the 1960s, the contact lens field has expanded exponentially in scope. These advances will hopefully result in an increased uptake of contact lenses as both a refractive solution and a therapeutic device.

OXYGEN PERFORMANCE

In this special issue, Vincent and George³¹ detail the meticulous experiments that Professor George Smelser (1908–1973) directed to elucidate the atmospheric oxygen requirements of the cornea through the use of scleral lenses. So relevant today to our understanding of atmospheric oxygen and corneal homeostasis, Smelser, an anatomist, used human and animal studies to explore this hypothesis. It underlies the importance of interdisciplinary research, clinicians broadening their scope and engaging with other scientists to test their hypotheses.

While many authors³² have furthered our understanding of oxygen to epithelial cell homeostasis in patient and animal studies, and Papas³³ eloquently showed the oxygen requirements for limbal hyperaemia, there has been conjecture as to the minimum oxygen transmissibility of modern soft contact lenses to limit corneal swelling. Of note, Thomson et al.³⁴ modelled the person and environment variability that should be taken into account. This indicates that the minimum oxygen transmissibility might vary depending on the situation.

In the 2000s, there was great hope that eliminating atmospheric oxygen impedance might remove the increased risk of microbial keratitis associated with extended (overnight) contact lens wear. This was disproved by large-scale epidemiology studies by Stapleton et al.³⁵ However, there is a tendency for less severe keratitis in high oxygen transmissibility compared with low transmissibility extended wear lenses.³⁶ Other theories from Smelser's era, which include stagnation of fluid reservoir and build-up of metabolites, are being investigated today, thus emphasising the ongoing lessons that the forebearers pay forward. Added to the patterns of collaboration, we have much to thank them for.

In the second paper, Iqbal et al.³⁷ showcase the capability of both modern-day instrumentation and theoretical modelling to analyse the profile of corneal oedema with scleral

lenses. This is the first study to compare central and peripheral (adjacent to the limbus) corneal oedema with short-term scleral lens wear and to a theoretical model. In the study of participants with healthy eyes, they varied the central fluid reservoir thicknesses by manipulating the sagittal heights.

Iqbal et al.³⁷ found that the peripheral and central corneal oedema induced by short-term scleral lens wear was greater for higher central fluid reservoir thicknesses than for lower thicknesses. This is in agreement with previous observations³⁸ that central corneal responses affect the peripheral cornea. Although not statistically significant, Iqbal et al.³⁷ reported an increase in peripheral swelling compared to central changes. Interestingly, when they modelled the response based on the theory of Kim et al.,³⁹ they found the response correlated with a model that did not include peripheral limbal metabolic support.

There have been reports of limbal stem cell deficiency in contact lens wearers,⁴⁰ whose mechanisms are unclear. Using these techniques may help us understand whether peripheral corneal oedema can contribute to such adverse events, as well as other changes that can be mitigated by lens and material design. Not only are we now collaborating with laboratory-based scientists, we also have data scientists as part of research teams to tackle these questions.

In summary, we are truly 'back to the future' with examining persistent themes in the contact lens arena, but this special edition illustrates how new technologies, approaches and designs to optimise vision and optical performance, comfort and ocular physiology have moved us forward. This helps reflect on the progress within the industry and reimagine how we can use innovative tools to continue advancing the field, translate the technical advantages to wearers and move towards personalisation or customisation of fitting approaches, lens designs and individual solutions for our contact lens patients.

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Carole Maldonado-Codina: Conceptualization (equal). **Nicole Carnt:** Conceptualization (equal). **Heidi Wagner:** Conceptualization (equal). **Fiona Stapleton:** Conceptualization (equal).

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Nicole Carnt is a scientia associate professor at The School of Optometry and Vision Science, UNSW, Sydney, Australia. She graduated from optometry at the University of New South Wales (UNSW) in 1989 and worked in private practice for 10 years in Australia and the UK before taking a position with the Brien Holden Vision Institute at UNSW in 1999. She completed a PhD on Genetics and Epidemiology of Contact Lens-Related Infection and Inflammation in 2008–2012 and has been the recipient of many research awards, including two American Academy of Optometry Ezell Fellowships. She was awarded a prestigious Australian Government NHMRC Research Fellowship in 2012 and spent the first 2.5 years at Moorfields Eye Hospital, London. Currently, she leads a multi-disciplined team investigating genomic, environmental and behavioural risk factors for keratitis. She is chair of the Australian Standards Committee on Contact Lenses and an ISO Contact Lens Working Group panellist. Nicole also holds honorary research positions at University College London (UCL) and The Westmead Institute for Medical Research, University of Sydney, and teaches ocular disease in the UNSW Clinical Optometry Masters course. Nicole is passionate about patient engagement in research, healthy contact lens wear, women in STEMM and mentoring in research and optometry.



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