

The burden of proof

An area that should seriously concern all of us has been opened for debate/consultation following release on the January 23 of the GOC's call for 'stakeholders and partners to comment on the standard of proof that should be used to judge the truth of facts presented in its professional hearings'. The consultation process will end on the March 31.



It may not at first glance seem as heavy as some of the other recent 'intrusions' into practice life. However, one's continued (and hopefully blemish-free) registration is pivotally crucial to one's professional life and career. I have been fortunate thus far in not having been subjected to a GOC investigation. I do, however, know one or two who have, and irrespective of the outcome (in their situation the cases were dismissed), it was totally disruptive to their well-being at that time. The mere fear of being 'up in front of the GOC', should ensure this is one experience that we can all go happily to our graves without.

Currently, along with the vast majority of all the other major professions, the GOC's required standard of proof is the 'criminal' standard. The prosecution would have to show that the defendant was guilty 'beyond all reasonable doubt'. This is quite different to what is termed the 'civil' level of proof which is somewhat lower, requiring that a defendant be shown to be guilty 'on the balance of probabilities'. In percentage terms, this means that a defendant is about 33 per cent more likely to have a guilty verdict reached against them under a civil level of proof, as opposed to a criminal level.

If this is yet another example of the post-Shipman fallout having a potentially disproportionately impact on professions other than medicine, then we need to ensure our concerns are heard before yet another 'diktat' is unnecessarily imposed.

I am sure the GOC (among others) is under some pressure to reduce the burden of proof from the 'criminal' to the 'civil' level, and more readily and less expensively reach a positive outcome against alleged transgressors of its rules. I hear on the grapevine that the dentists have just moved from the criminal to the civil level of proof. A similar reduction in the required standard of proof may help the GOC more positively consider action where currently it languishes in inaction. However, the downside is that appeals in these dormant cases would most likely also be judged at the lower level of proof, thus encouraging more appeals that 'on the balance of probabilities' are more likely to succeed.

The risks of physical harm within a typical optometric *modus operandi* are significantly lower than medicine, pharmacy and dentistry. This is reflected in both our professional indemnity premiums and the number of registered complaints. The public should have significantly less concern for their well-being in our hands than with others. The guidance issued by our professional bodies, elements such as our need for maintenance of competency as a requirement of continued registration and the increasing vigilance within the GOS context is sufficient enough argument to leave the standard as it is. Those who truly transgress should quite easily be dealt with under the current standards. I would much rather the recently introduced fitness to practise panels be allowed to operate under the current, criminal level of proof for a period of time sufficient for the process to be judged on merit.

I am all for public protection (although the GOC's Section 60 and recent contact lens legislation would seem at odds with this). Clearly, a lower standard of proof may be argued to err on the public's side. However, what is more important is the quality of evidence and magnitude of the crime, not the ease with which any complaint may be upheld. If we sit back and do not submit our concerns to be added to the consultation process, we will only have ourselves to blame. There but for the grace of god...

Two recent studies focused on the status of soft toric contact lenses. Sheila Hickson-Curran and Louis Dias explain

SOFT TORIC CONTACT lenses have become an increasingly viable and popular fitting option thanks to improvements in lens designs and manufacturing as well as the introduction of frequent replacement and planned replacement lenses. But despite this modality's improving status, contact lens practitioners still widely view soft torics as complex, time-consuming and expensive. Additionally, the proportion of soft toric lenses fitted fails to reflect the incidence of astigmatism among contact lens wearers.

To make the fitting process simpler, faster and more cost-effective, it's important to understand current habits and practices in soft toric fitting. And to understand what astigmatic patients really want from their contact lens correction, we need to evaluate patient satisfaction with currently available lenses. We conducted two studies to investigate the current status of soft toric lenses and to try to determine the reasons why these lenses have yet to meet their full potential. This article will review the results of those studies.

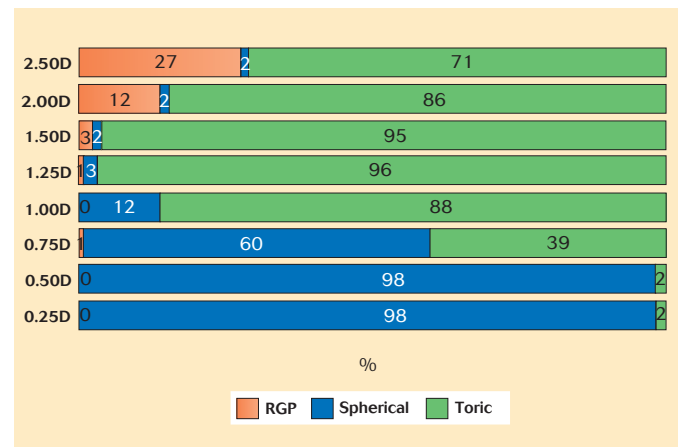
STUDY 1

Fitting habits and practices

We conducted online interviews with 153 eye care professionals (qualified optometrists and ophthalmologists who prescribe soft toric lenses) across the US to gain a better understanding of their practices, expectations and requirements with respect to fitting soft toric lenses.

Our survey found that contact lens practitioners most commonly prescribe soft toric lenses at 1.00DC of astigmatism and above (Figure 1). Eye care practitioners use spherical lenses mostly for

FIGURE 1. Most often prescribed lens type by level of astigmatism



Toric soft contact lenses where are we now?

cylinder powers of 0.25DC and 0.50DC. They don't widely use GP lenses, with only one in four eye care practitioners prescribing this modality.

Fitting considerations

Many studies have found that practitioner recommendation is a key factor in the uptake of contact lenses. In this study we found that only half of eye care practitioners proactively recommend soft toric lenses to their astigmatic patients for previously uncorrected astigmatism even though the majority do present soft torics as an option.

Eye care practitioners most commonly use soft torics because they feel that they provide the best vision and optical quality, are more comfortable for patients and are easier to fit with available diagnostics. Among the most important secondary considerations when choosing to fit soft torics are the replacement schedule and the patient's specific visual demands.

Soft toric success factors

The number of trial fitting and follow-up visits has important implications for appointment scheduling and pricing and may play a role in practitioners' perceptions of soft torics and their willingness to fit them. A lens that fits rapidly and works almost every time would permit shorter fitting appointments and less follow-up visits. In such a situation, practitioners may become confident enough with the lens performance to fit and order lenses without asking subjects to return to the clinic after a trial-wearing period.

Ultimately, more successful, simpler toric lenses would reduce fitting time for both patients and practitioners and may eventually bring toric fitting fees in line with those of spherical soft lenses. Practitioners report that one to two trial visits and the same number of follow-up visits are needed to successfully fit a soft toric.

Lens rotation is a key measure of successful soft toric fitting. Lens rotation of 10° or less is generally considered the maximum for acceptable fit. According to the results of our online interviews, at 1.75DC, fewer than half of eye care practitioners are satisfied with lens rotation greater than 5°. Eye care practitioners successfully fit only eight out of 10 patients using their lens of choice.

Making your first lens choice

When selecting a lens brand of first choice, the ability to fit patients successfully is the primary factor eye care practitioners consider, followed by comfort, vision and ease of handling. On average, they would try a new brand on 10 patients before deciding to fit that lens regularly, although around one in three would base their decision on five or fewer patients. The minimum success rate eye care practitioners would consider before a new brand becomes their lens of choice is about 66 per cent.

One to two-week disposable lenses for daily wear and monthly replacement for daily wear are the most preferred and regularly fitted soft toric lens modalities, according to our interview results.

The findings of this first study confirm the wide range of approaches that eye care practitioners currently take to fit soft toric lenses and we can use these approaches to develop and improve fitting processes and

management strategies.

Through our interviews, we've found that eye care practitioners believe that soft toric contact lenses are the best option for meeting the needs of their astigmatic patients, but fitting soft toric lenses still remains challenging. There is an opportunity to increase eye care practitioner satisfaction in fitting soft toric lenses with a faster fitting, more stable lens.

STUDY 2

Patient satisfaction

To understand what astigmatic patients really want from their contact lens correction, we conducted a second study in which we surveyed 335 astigmats at 19 sites across the US about their attitudes toward their current lenses and toward contact lenses in general. Patients were existing daily wear soft lens users (85 per cent currently wearing a soft toric) with 0.75 to 2.50DC of astigmatism and

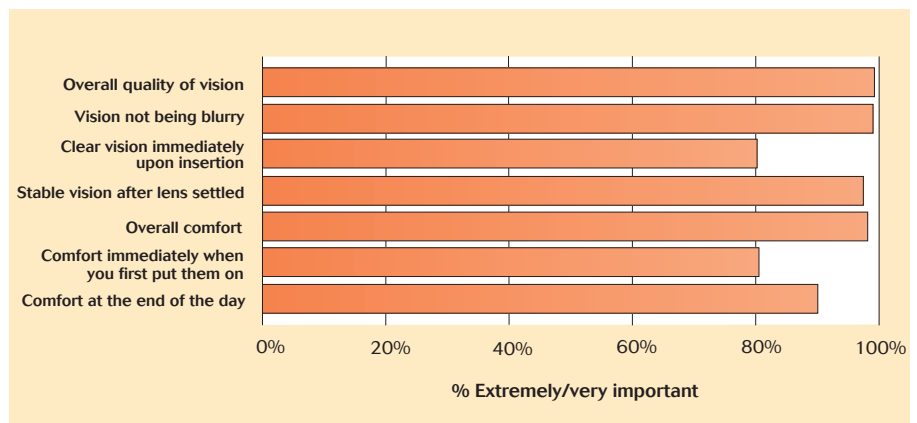


FIGURE 2. Patient opinions of importance of lens attributes to performance (n=335)

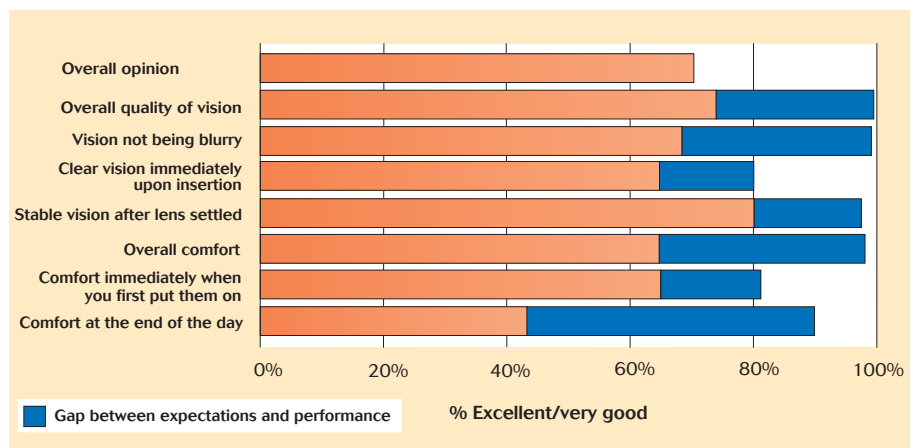


FIGURE 3. Patient opinions of performance of their habitual contact lenses (n=335)

were chosen to represent a cross-section of the population with respect to age, previous lens use and current lens brand. The study consisted of an initial baseline visit, fitting visit, two-week wearing trial and follow-up visit.

At the initial visit to the study site, patients completed a questionnaire regarding the factors important to them in the performance of contact lenses and their opinions of their current lenses. To optimise clinical performance, they were then fitted with one of four soft toric contact lens brands: Acuvue Toric (Johnson & Johnson Vision Care) [n = 86], SofLens 66 Toric (Bausch & Lomb) [n = 86], Biomedics Toric (OSI) [n = 77] and CV Encore Toric (Cooper Vision) [n = 86], under study conditions.

We asked those patients who were dispensed lenses to return after two weeks to complete a questionnaire assessing their satisfaction with the study lenses.

Expectations and opinions

Figure 2 illustrates the patient opinions regarding the importance of lens attributes with relation to toric contact lens performance. Patients cited vision and comfort-related factors as having the highest importance.

The subjects' habitual contact lenses were broadly representative of the US market and were rated consistently lower than their expectations of contact lenses (Figure 3). Only 70 per cent of the patients surveyed described their overall opinion of their lenses as 'excellent' or 'very good' and ratings for aspects of vision and comfort, the factors they considered most important to contact lens performance, also fell short of expectations. Only 74 per cent rated overall quality of vision and 65 per cent described overall comfort with their current contact lens as 'excellent' or 'very good'. Among the symptoms reported, 86 per cent said they experienced blurred vision with their current lenses and 57 per cent reported fluctuating vision.

Gauging satisfaction

Satisfaction ratings at two weeks (when subjects returned wearing the toric lenses prescribed to them in the study) were consistently lower than patients' expectations of contact lenses (Figure 4). Only 58 per cent rated overall satisfaction as 'excellent' or 'very good' and ratings for aspects of vision and comfort again revealed gaps in performance.

Mean visual acuity was nearly one line (0.07 logMAR) poorer than spectacle visual acuity and only 70 per cent of patients rated overall quality of vision as 'excellent' or 'very good'. Only 54 per cent said that the statement "They were comfortable to wear all day long"

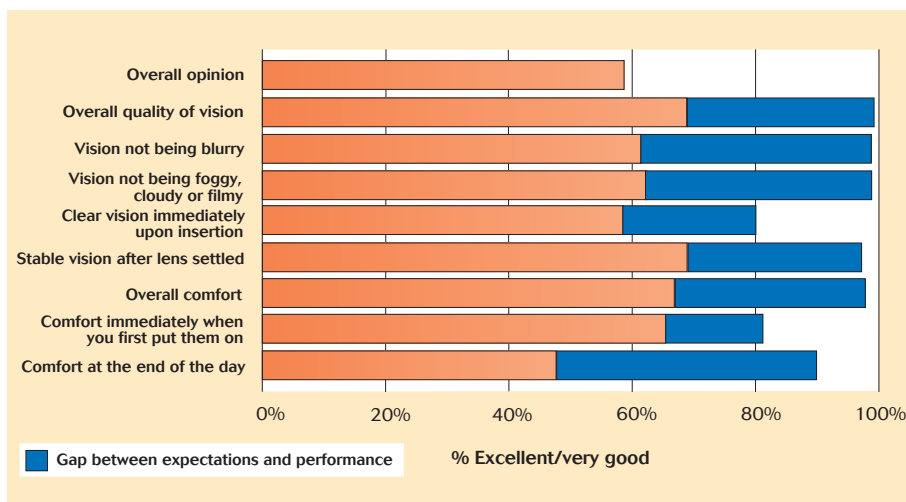


FIGURE 4. Patient satisfaction with study lenses (n=318)

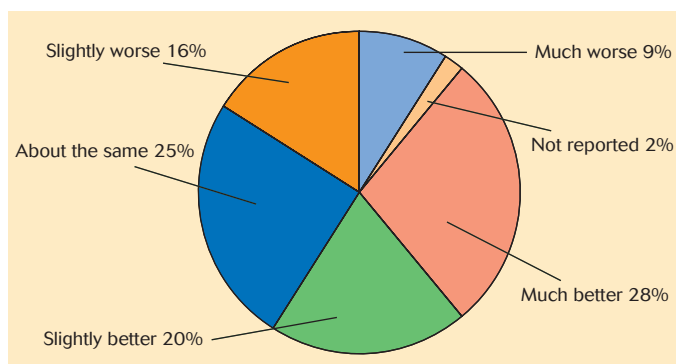


FIGURE 5. Extent to which study lens met patient expectations (n=318)

described the lenses 'completely' or 'very well' and only 68 per cent of patients rated overall comfort as 'excellent' or 'very good'.

Asked how well the study contact lenses met expectations, patients' opinions were divided (Figure 5). Less than half (48 per cent) of the respondents said that the contact lenses were 'much better' or 'slightly better' than expected and in 25 per cent of cases, the contact lenses failed to meet expectations ('much worse' or 'slightly worse').

Lessons learned

This study has confirmed that astigmatic patients have high expectations of their contact lenses, particularly with regard to vision and comfort. Patients' satisfaction with their current lenses was consistently rated low in comparison with their rating of the importance of various attributes to contact lens performance and the characteristics they considered important when deciding which brand of soft toric lenses to buy.

Comparing these findings with those of our previous study, we found that good vision and comfort, the features that astigmatic patients consider most important to contact lens performance, are also the principal reasons why practitioners prescribe soft toric contact lenses and are among the deciding factors when selecting a lens brand of first choice.

WHERE DO WE GO FROM HERE?

The number of patients who could benefit from soft toric contact lenses is still vastly greater than those who are prescribed and who successfully wear currently available products, and the unmet eye care practitioner and patient needs that these two surveys highlight suggest reasons for this fact.

If manufacturers provide a contact lens that better meets the needs of eye care practitioners and satisfies patients' expectations, then everyone will benefit. A faster fitting, more stable lens that delivers expectations of excellent comfort and vision will close the gap between these expectations and the soft toric contact lenses that are currently available.

We should judge new soft toric contact lenses that enter the market on their ability to address the need for improved vision, comfort and ease of fit in the category.

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