Ten reasons why rigid contact lenses are obsolete

In the mid-1990s, **Professor Nathan Efron** predicted that rigid lenses would be virtually obsolete by the year 2010. In this article, he offers 10 reasons why he believes his prediction has turned out to be accurate

In 1998, an advertisement appeared in *Optician*[1] featuring my prediction of the demise of rigid contact lenses by the year 2010 (Figure 1). This prediction was ridiculed at the time, and ignited an ongoing debate that has been played out in professional magazines, trade publications and refereed scientific journals.

Now that the 'prediction year' of 2010 has ended, I can reflect upon my prediction in the context of having collected – together with Dr Philip Morgan and an international team of colleagues – 15 years of contact lens prescribing data in the UK and 40 other nations. Figure 2 demonstrates the dramatic decline in rigid lens fitting in the UK from 1965 to the present time. International rigid lens fitting data gathered in 2010 is equally as bleak.[2] In 14 of the 28 countries surveyed, new rigid lens fits amounted to 5 per cent or less of all lens fits.

There are many reasons for the dramatic decline in rigid lens fitting across the world. Here I shall review – in approximate rank order from most to least pertinent – 10 key reasons why I believe that rigid lenses have dropped to such a low level of prescribing.

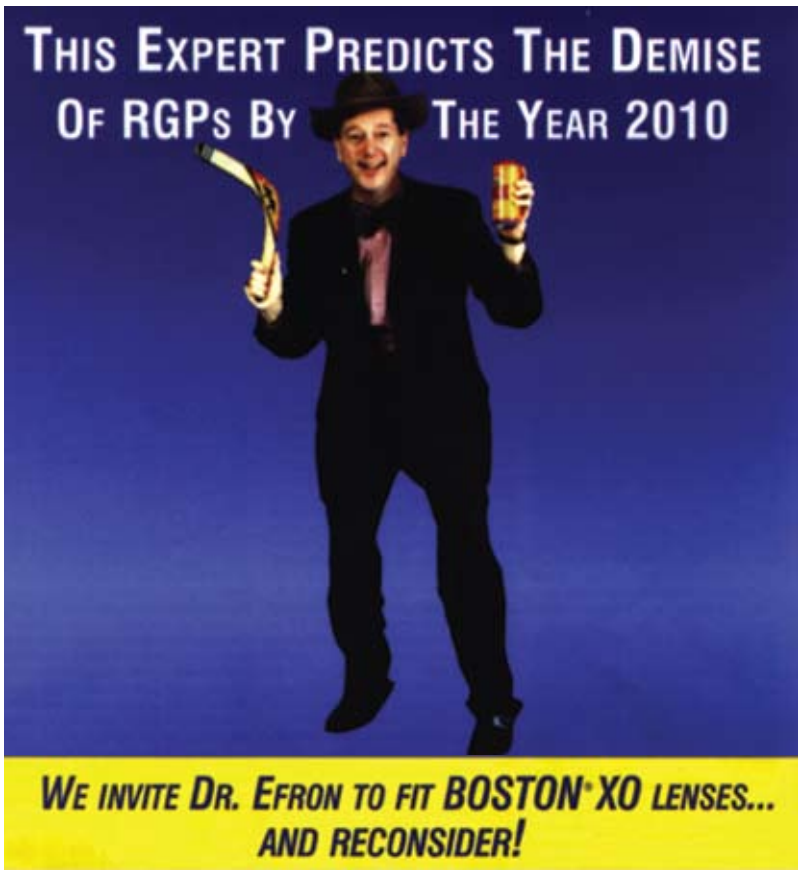

Figure 1 Advertisement from 1998 featuring the author's prediction

1) Initial discomfort with rigid lenses

One of the main reasons that patients seek soft lenses is the common knowledge that, in the first instance, they can hardly be felt in the eye, compared with rigid lenses which are initially uncomfortable.[3,4] Over the years, rigid lens fitters have attempted to employ strategies to overcome the discomfort problem, such as:

- Masking rigid lens comfort using corneal anaesthetic
- Using plasma or hydrophilic surface coatings
- Creating a thinner edge profile
- Changing terminology – such as referring to 'GP' rather than 'rigid' lenses.

These strategies have largely failed. Rigid lenses always have been, and always will be, uncomfortable.

2) Intractable rigid lens-induced corneal and lid pathology

The only severe complication of contact lens wear is microbial keratitis (MK). Although the incidence of MK is numerically lower with rigid versus soft lenses, this small difference pales into insignificance when considered against other life risks.[5] Virtually all soft lens complications are transient and resolve completely upon cessation of lens wear. There are, however, two intractable complications that occur in virtually all rigid lens wearers – blepharoptosis (Figure 3) and 3 & 9 o'clock staining (Figure 4). Successful treatment options for alleviating these conditions remain elusive.[6]

3) Soft lens advertising

The total amount of advertising on soft contact lenses each year to practitioners and the public is estimated to be over £450m. The impact of such advertising is self evident; practitioners are seeking to prescribe, and patients are demanding, comfortable and convenient soft lenses. Rigid lens advertising is only about £6.4m globally and is almost exclusively directed at practitioners rather than the public.

4) Superior soft lens fitting logistics

There are compelling logistical reasons why practitioners generally prefer to fit soft lenses. Modern manufacturing technology and sophisticated lens supply arrangements have resulted in the facility for practitioners to hold a

selection of lenses in a near-complete range of parameters and powers. Consequently, lenses can be fitted quickly and accurately, an initial supply can be given to the patient to take away immediately, and subsequent lens supplies are quick and easy to obtain and dispense.[7] Conversely, rigid lenses take longer to fit and must be ordered from a custom laboratory. The patient cannot be issued with an initial set of lenses and typically must wait many days or weeks for the lenses to be fabricated.

5) Lack of rigid lens clinical training opportunities

The reason why optometrists entering practice have little confidence in rigid lens fitting is because of a lack of experience in the public-access clinics of our optometry schools. These clinics mimic the real world, in which patients are demanding and expecting to be fitted with soft lenses. Although skills can be learned by practising to fit lenses to each other during clinical training sessions, optometry students graduating today from many optometry schools would be fortunate to have fitted one 'real patient' with rigid lenses prior to graduating.

6) Rigid lens 'problem-solver' function redundant

Even by the mid-1980s – 20 years after soft lenses first became available in the UK – mechanical and hypoxic complications were common, and the crude care solutions available at the time frequently resulted in toxic epithelial reactions. In that context, rigid lenses often provided a viable alternate as a 'problem solver'.

However, time has moved on. A majority of soft lenses today are manufactured from silicone hydrogel materials, which typically have Dk/t values in excess of 100,[8] and there are numerous lens designs and material types from which to choose.[9] Contact lens solutions are manufactured from sophisticated chemical formulations that are inert and safe in the eye. The argument that 'a patient is not suited to soft lenses' – which may have been valid up until the mid-1980s – cannot be advanced today.

7) Improved soft toric and bifocal/varifocal lenses

In the early days of soft lenses, when toric designs were crude, spherical rigid lenses offered a viable alternative for the correction of astigmatism by masking corneal toricity. However, current soft toric lenses are easy to fit,

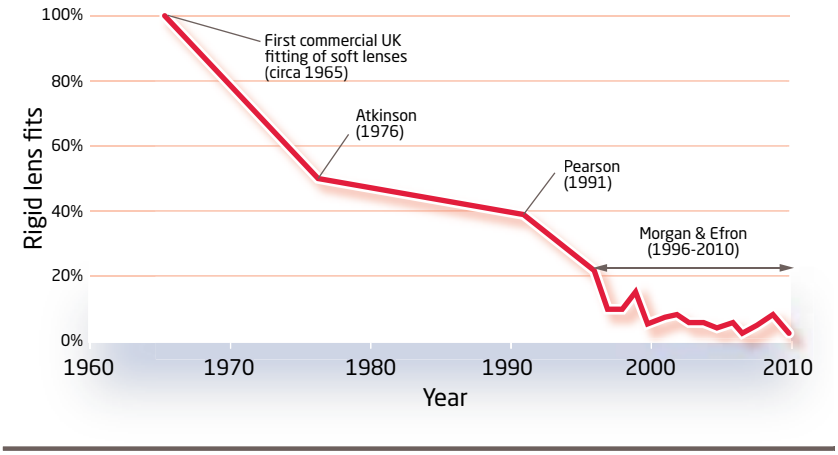

Figure 2 Decline in rigid contact lens fits, as a proportion of all contact lenses fitted, between 1960 and 2010

Figure 3 Ptosis induced by a rigid lens in the right eye (compared with the left eye, which was fitted with a soft lens) (Courtesy of Des Fonn)

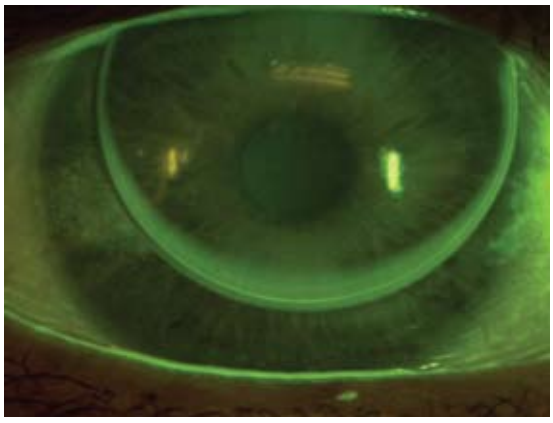

Figure 4 Rigid lens-induced 3 & 9 o'clock staining (Courtesy of Suzanne Efron)

they are available in a wide variety of powers, axes, and stabilisation designs,[9] and the vast majority of astigmatic corrections can be fitted from stock lenses. There have been significant advances in the optical design of soft lens bifocal designs in recent years, such that over the past decade there has been a reversal of the preferred mode of presbyopic soft lens correction from monovision to bifocal lenses.

In view of the significant developments in soft lens toric and bifocal designs for the correction of astigmatism and presbyopia, rigid lenses now only have a very minor role in these domains, except in the most extenuating of circumstances.

8) Limited uptake of orthokeratology

The impetus behind the current interest in orthokeratology among a small number of enthusiasts worldwide appears to be that a 'specialist' niche market can be created based upon often exaggerated claims of temporarily or permanently curing myopia. Another driving force is the natural academic curiosity of researchers. However, overnight orthokeratology is still only capable of reducing myopia by about 2.00D, no matter what approach to fitting is adopted,[10] the magnitude of the effect is unpredictable, and vision regresses during the waking hours.[10]

No orthokeratology lens fits were recorded in 21 of the 28 countries surveyed by Morgan *et al*[2] in 2010 and, of the remaining countries, orthokeratology represented 1 per cent or less of new fits in all but three nations (The Netherlands, New Zealand and Portugal). Clearly, orthokeratology has failed to capture the attention of contact lens fitters around the world, ▶

and those who have claimed that this approach to vision correction could be the saviour of rigid lenses have been proven wrong.

9) Lack of investment in rigid lenses

There have only been minor improvements in rigid lens material developments since silicone acrylates and fluoro-silicone acrylates were introduced over a quarter of a century ago. Although there have been enhancements in mechanical lathing technology in the rigid lens field – primarily as a result of developments in computer-controlled systems – rigid lenses are still manufactured using labour-intensive lathing processes, which is why the lens unit cost remains much higher than for disposable soft lenses. This high unit cost appears to be the primary reason for dispensing rigid lenses on an unplanned replacement basis, despite convincing evidence of the ocular health benefits of regular rigid lens replacement.[11]

10) Emergence of aberration-control soft lenses

A hitherto important application of rigid lenses has been to mask irregular corneal shapes, such as in keratoconus, irregular astigmatism, post-trauma and following refractive surgery and other forms of ocular surgery (eg cataract extraction and penetrating keratoplasty). Over the past decade, important advances in ocular aberrometry have resulted in the development of soft contact lenses capable of significantly reducing the optical aberrations inherent in keratoconus.[12,13] Thus, the role of rigid lenses as the last bastion of optically correcting corneal distortion is about to fall.

Future rigid lens fitting

It is time to bid farewell to rigid lenses as a mainstream form of contact lens correction. Rigid lens fitting has essentially now been elevated to the status of a speciality that is only practised by a small number of clinicians with an interest and requisite skills in this field. We should all mourn the passing of rigid lenses as a once-glorious form of vision correction, which – following the invention in their antecedent, glass scleral lenses, in 1888 – provided the only alternative to spectacles for thousands of visually challenged patients for around 75 years.

Acknowldgement
This article is published with permission of the British Contact Lens Association and Elsevier, as an abbreviated version of a paper by Professor Efron which appeared in *Contact Lens and Anterior Eye*.[14]

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Still blinker

This feature by Nathan Efron, based on a recent article,[1] is yet another attempt to support his one-man theory that rigid contact lenses have become extinct. The content here is essentially the same as in a similar text published in 2001[2] and readers may be forgiven for wondering why there is a need to rehearse the same tired arguments that were rebutted by us at that time.[3] However, we are happy to update the information we provided then which supports our contention that, far from being deceased, the rigid contact industry continues to thrive as a specialist niche market.

When? What, exactly?

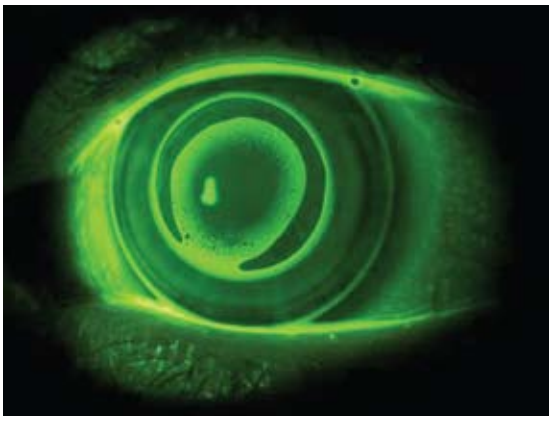
The original prediction by Nathan was that the demise of RGP lenses would occur in 2000. However, when that clearly was not going to be supported by the facts, the goal was changed to 2010. Now he would like to show that his prediction is correct by creating his own definition of 'demise' which conveniently ignores the thriving nature of the industry to which he refers. Indeed he admits that he has 'refined' his prediction to 'virtual' demise so that he could attempt to accommodate the self-evident facts into his arguments.

Simplistic questionnaires do not tell the story

The basis for defining demise appears to be derived from prescribing trend data and share of market. As we argued in 2001, data from an unsolicited questionnaire where responses represent a self-selection sample do not represent a sound scientific basis for making general assertions, especially when the absolute numbers then have to be arbitrarily adjusted to reflect the volume of patients seen by the individual practices or practitioners. Therefore, prescribing trend data are not eligible for supporting the basic contention being proposed by the author. One small example demonstrates the issue here. In the UK in 2000, the number of people who used orthokeratology as a means of vision correction was very small indeed, no more than 500 people, based on data about the supply of lenses by the relatively few custom lens manufacturers who supply the product. As at the end of 2010, based on communications with the manufacturing companies, we estimate that there are at least 5,000 people in

ed, after all these years

Keith Edwards and **Tony Hough** rebut Professor Nathan Efron's argument that it is time to bid farewell to rigid lenses as a mainstream form of contact lens correction



An estimated 5,000 or more people in the UK use ortho-K (courtesy of BCLA Clinical Photography Library)

the UK who use orthokeratology as a means of vision correction.

Now, this is indeed a very small proportion of the contact lens wearing population; less than one-fifth of 1 per cent if we estimate there to be 3 million lens wearers in the UK, but it demonstrates significant growth in this niche over the past decade which is, quite understandably, invisible in the results of the statistical surveys on which Nathan bases his observed extinction. (It is worth noting that in 2000 most orthokeratology lenses supplied in the UK were imported; now the overwhelming majority are manufactured locally).

Sales and investment in manufacturing technology

The real measure of the health of an industry is determined by analysis of its turnover, growth and profitability. In 2001 the primary reason for our response to Nathan's claims was that several custom lens manufacturers were asking if they should continue in business if indeed there would be no demand for their products within a decade. That remains the central question: is the custom lens manufacturing business viable and does it yield a profit for those involved?

Previously, we addressed this issue by reviewing the sales data for RGP lenses collected by the Association of Contact Lens Manufacturers (ACLM). These data were supplemented by the few larger volume companies that were not members of the ACLM. At that time the growth in what we termed factory gate sales between 1997 and 2000 had risen by over 7 per cent. We predicted that by the year 2010, the factory gate sales value would be some £12m. Using the same analysis as we used in the original rebuttal, we conservatively estimate factory gate sales of the custom lens business in the UK 2010 to be at least £13m.

In the same period, custom lens manufacturers have invested significantly in new manufacturing technology; as a proportion of sales this investment is very much greater than the volume contact lens business. As an example of this, consider the case of Cantor+Nissel (C+N), a well known UK custom lens company. By the end of 2010, C+N had moved all of its manufacture to automated high precision lathes; every lens made in this company is now produced on automatic machinery which is no more than three years old.

The reality is completely at odds with Nathan's description of a 'labour intensive lathing process'; the skills base within this and other similar companies has moved to measurement and process management. This clearly shows a business which is currently successful and confident of its future. As we have had cause to mention elsewhere,[4] a 'demise' that is reflected in significant growth in sales accompanied by a solid profit performance is one that most companies would embrace with enthusiasm.

Clearly on the basis of sales, investment and future growth plans in the UK alone, the proposition that the industry is 'virtually' dead is absurd.

The numbers

The reasons that Nathan puts forward to support his flawed contention are similar to those he used in 2001. However, it is perhaps most interesting to note that even the most recent data presented by him show that five of the seven countries he surveyed demonstrated an increase in the proportion of fits in 2008 when compared to the previous year. Are these just the final death throes of a condemned industry? We submit that it is not!

Comfort

The argument used in this case is that RGP lenses are less comfortable than soft lenses on initial insertion. The use of continuous and extended wear to support the lack of comfort and the change in comfort of RGP lenses over time is disingenuous since there are unique issues with overnight wear which can affect comfort. Since daily wear of lenses is the normal modality for RGP lenses, and since Nathan offers no evidence to support the relevance of extended wear data to the daily wear modality, this presents a fairly spurious argument.

Despite the generally held view that rigid lenses are less comfortable, one study that refitted soft lens wearers with rigid lenses found no issues with lens discontinuation due to poor comfort for the majority of wearers.[5]

When any author declares something to be 'self-evident', it is time for the audience to beware and be exceptionally vigilant about the claims that follow. Comfort is one of many factors that influence the patients' choice of lens wearing modality. Principal of these might be the 'self-evident' bias of the prescribing practitioner who has no experience, skill or interest in fitting them. However, vision may be preferred with rigid lenses over soft lenses[6] and a survey at the 1992 Olympics showed that 14 per cent of athletes were wearing rigid lenses (Bausch+Lomb Olympic Centre Data – data on file).

Intractable pathology

To further his position, Nathan puts forward the concept of corneal and lid pathology as a reason not to fit rigid lenses while considering corneal endothelial changes as unworthy of note with soft lens wear. While it can be argued that hypoxia may be eliminated for the average cornea wearing a spherical silicone hydrogel lens for daily wear, this has not been shown to be true in all cases of more complex lenses such as torics and does not account for the innate variability of requirements encountered in the wider population. RGP lenses can produce oxygen levels at least as high as silicone hydrogels and with the benefit of leaving larger areas of cornea with direct access to atmospheric oxygen.

The issue of blepharoptosis has been used before as an argument against RGP lenses. However, the magnitude of this difference was found to be as little as 0.34mm[7] and to affect only 5 per cent of eyes.[8]

In the case of 3 & 9 o'clock staining, ▶

Nathan considers the phenomenon to put the patient at risk of localised infection (which would constitute an infective keratitis) while the figures on incidence of this condition would not support this position, especially if the condition or desiccation staining is as prevalent as he suggests. Is this finding any more or less 'threatening' than the global corneal staining that can be seen with certain hydrogel solution combinations that seems to take up so much space in the learned journals[9-13] and less learned websites (eg www.stainginggrid.com/)?

Torics and multifocals

We would agree with Nathan that soft toric lenses have improved significantly since they were first introduced in the 1970s. In the past decade, the design and clinical performance of soft torics has improved dramatically, perhaps because all of the major manufacturers have developed their individual designs.

However, the generalised statement that RGP toric lenses involve complex fitting and expense says as much about Nathan's lack of experience in this area as it does his bias against any iteration of rigid lenses. Empirical fitting of RGP lenses has been advocated for some time;[14] the 'true bitoric' patient will continue to be best fitted by rigid lenses.

Nathan's claim that 'There have been significant advances in the optical design of soft lens bifocal designs in recent years' is simply a fiction. Bifocal and multifocal soft lens designs have not advanced at all in the past decade. There is a tendency to describe as 'new' lenses which are simply existing designs that have been migrated to silicone hydrogel materials – a characteristic which we predict will continue for at least the next five years as the major manufacturers move the volume lenses to new materials. In design-dependent applications such as presbyopic correction this will not lead to any improvement in vision correction.

Modified monovision ('20/happy') continues to be the *de facto* best outcome for wearers of soft bifocal and multifocal lenses. By contrast, rigid bifocals and multifocals can provide binocular varifocal vision. However, this relies on the practitioner being sufficiently skilled and experienced to deliver the product.

Investment

Nathan confuses lack of investment with developments in manufacturing technology, material formulation and lens design. The recent acquisition of David Thomas Contact Lenses by the Japanese company Menicon and the very substantial investment by most of the leading custom lens manufacturers belies this assertion. Elsewhere, the millions of dollars spent by Paragon in the US getting approval for its Ortho-K lens and the rapid investment-led growth of SynergEyes in the US provide examples which demonstrate a vigorous and viable global business.

Aberration-control lenses

One could be forgiven for thinking that aberration-control soft lenses for the correction of keratoconus is just about to happen, based on Nathan's feature. The issue with post-Lasik cases is less about corneal distortion than it is about failing to get good uncorrected vision. In the presence of corneal astigmatism, soft lenses offer no visual panacea and toric lenses may have fitting issues due to the relatively inflexible nature of the material on the unusual post-Lasik topography. Custom RGP designs have been used for such cases including PRK[15] and applied equally to post-Lasik.

The work to which Nathan refers is based on a small number of cases in which 38 per cent Hema hydrogel material lenses (yes, 38 per cent Hema having a Dk of 8) which have had customised front-surface geometry applied using laser etching. While it is true that the researchers have found that these lenses can correct aberrations in keratoconus, there is no indication of how this technology can be transformed to apply to lenses made in a manufacturing environment at an acceptable cost. The process used could not be applied to any current silicone hydrogel material; the unit cost, and the expensive, time-consuming and technology intensive clinical specification and evaluation, guarantees that the general use of such lenses will not happen within the next decade at least and probably never.

In contrast, RGP lenses for keratoconus continue to be the treatment of choice and are readily available. A more likely development in the next decade is that keratoconus correction by contact lenses will move towards the use of large-diameter rigid lenses.

Conclusion

While Nathan would clearly love to believe that his prophecy regarding the demise of RGP lenses is correct, his position is just as clearly not supported by the facts. Once he accepts this we suspect that we can look forward to a revised estimation of 2015 or 2020 as the due date and be forced to see the same arguments regurgitated yet again to support his clearly untenable position.

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