1975–1990

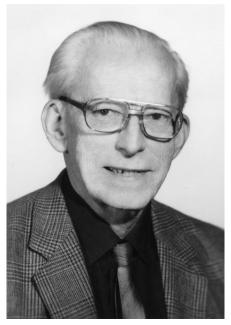
Contact Lenses for Vision Correction: A Journey from Rare to Commonplace

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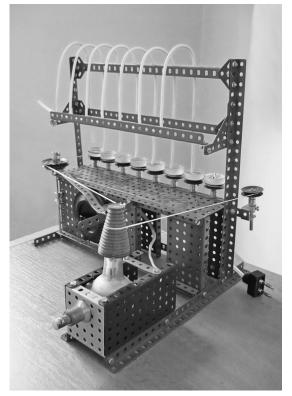
Ithough the first practical contact lens was described in 1888 [1], glass-blown shells formed individually to rest on the sclera and vault across the cornea were the norm until the 1930s. The advent of polymethyl methacrylate (PMMA) made it possible, in a method pioneered by William Feinbloom [2], to process an all-plastic lens that could be fitted by custom molding or trial fitting from a range of premade lenses. This reduced the weight and cost of lenses while improving comfort and wearing times. It was not until 1948 that Kevin Tuohy, an optician, made the first corneal contact lens [3]. Accidentally cutting through a scleral shell at the edge of the optic zone, Tuohy tried the small-diameter lens that was left on his own eye and quickly realized that a lens fitted within the cornea could be more comfortable and provide longer wearing times than a scleral shell. The realization by Smelser and Ozanics that oxygen for corneal metabolism came directly from the atmosphere led to a major shift to corneal contact lenses because the fit could be adjusted to replenish the oxygenated tear film with every blink, thus extending comfortable wearing times from just a few hours. The contact lens market expanded with commercially available corneal contact lens designs enabling the correction of myopia, hyperopia, astigmatism, and even novel bifocal designs for presbyopia correction.

Otto Wichterle (Fig. 1) was a brilliant Czech polymer chemist who made the world's first "soft" contact lenses from his newly invented HEMA hydrogel material [4]. This 38% water content material was highly flexible, oxygen permeable, and significantly more comfortable than the rigid PMMA corneal contact lenses that were available. Although working behind the "Iron Curtain," an American patent company acquired the intellectual property rights from Wichterle and licensed them to Bausch & Lomb (B&L). The company licensed both the material and the novel "spincasting" manufacturing technique that Wichterle had developed in his own kitchen. The prototype for this production method was built from an erector set, powered by the electric motor from his phonograph (Fig. 2). Henry Knoll, a physicist working at B&L and one of a team assigned to developing the Wichterle prototypes, pointed out the difficulty in working with this hydrogel material. "The first lens we released commercially was called the C series lens, we built the A series and the B series but neither would stay on the eye after a few blinks. Management said if the third design didn't work we would give up on the project." The C-series contact lens design (Fig. 3) fitted the eye, and although the optics were compromised by the wildy aspheric posterior lens surface produced by the "spincasting" manufacturing process, the lens was a commercial success when launched in 1971 following FDA approval. The dramatically improved comfort changed the contact lens industry in the U.S., and ultimately the world, with rigid corneal contact lenses today accounting for less than 10% of the lenses fitted worldwide. Otto Wichterle was recognized for his great contributions to the world of optics when he was awarded the R. W. Wood Medal by The Optical Society (OSA) in 1984.

Initially available only in spherical powers to correct myopia and later hyperopia, soft lenses to correct astigmatism were first introduced in the U.S. in the early 1980s. Unlike rigid lenses which "mask" the astigmatic component of the cornea, soft lenses conform to the



▲ Fig. 1. Otto Wichterle, Czech polymer chemist, inventor of the first hydrogel material to be used in making soft contact lenses. Wichterle was responsible for making the first usable soft contact lenses in his lab behind the "Iron Curtain." (AIP Emilio Serge Visual Archives, Physics Today Collection.)



▲ Fig. 2. A model of the first spin-casting machine that Otto Wichterle used to make the first soft contact lenses in his kitchen.

underlying corneal shape, requiring a method of stabilization and orientation to be built into the physical shape of the lens. The most successful designs used an increasing thickness profile in the vertical meridian of the lens, allowing the squeeze force of the upper eyelid to stabilize the lens on the eye between blinks. Multifocal soft lenses designed to correct presbyopia were introduced by B&L and CIBA VISION in 1982. B&L used its early experience with significant spherical aberration in its first lenses for myopia to help manufacture a lens with sufficient spherical aberration to expand the depth of field of the wearer. Ironically, after spending years trying to eliminate spherical aberration inherent in the "spincast" lens product, B&L was purposely designing it in the lens with the PA1 bifocal.

A major issue with soft contact lenses over the 1970s and 1980s was combating adverse ocular responses related to deposition of protein and lipid on lens surfaces from the tear film. This required daily cleaning and disinfection routines and impacted the longevity of the lenses, prescribed as a single pair to be worn daily for as long as they lasted, typically a year or more. A second issue was transmitting sufficient oxygen from the atmosphere through lenses to ensure an adequate physiological environment for the cornea. Many patients had their lens wear curtailed from insufficient oxygen being available to the eyes during wearing. This was also the time of "continuous wear," a modality where patients wore their contact lenses constantly, with removal as needed for cleaning (typically every 30 days in the early 1980s) [5]. Although convenient, continuous wear only exacerbated the issues of deposition, reduced lens life, and caused a significant increase in ocular adverse responses due to reduced oxygen availability to the cornea. In 1982, a small company in Denmark started cast molding hydrogel contact lenses and packaging them in small plastic blisters with foil covers. All other companies delivered their lenses individually, stored in a small glass serum vial, packaging that dated back to the original B&L lens. Danalens was the first "disposable" contact lens and lit the fuse on a major upheaval in the contact lens industry (Fig. 4). Johnson and Johnson, sensing an opportunity to enter the lucrative contact lens

market in the U.S., acquired the Danalens production process and a small contact lens company called Vistakon whose hydrogel lens material was already approved by the FDA. Within five years Vistakon launched the first disposable lens in the United States (1987). Launched as a continuouswear lens to be replaced weekly, the marketplace eventually dictated its use as a daily wear only (no overnight wear) lens with a biweekly replacement schedule. Although the oxygen permeability of these new lenses was no better, the fact that patients could buy them for only a few dollars each (previously patients would typically pay hundreds of dollars for a pair of lenses) and replace them frequently made them a rapid success. Toric and multifocal options soon followed as companies invested in the manufacturing capacity necessary to process these complex designs for a low cost. As manufacturing technology improved and cost of goods decreased, the option of a truly disposable lens, one that was worn once and then discarded, became a reality. Vistakon again led the industry by launching the first daily disposable contact lens in 1994. Although the cost of each lens was less than one dollar to the patient, the high annual cost prohibited rapid adoption of daily disposables, and it was another decade before this modality made any significant inroads into the marketplace.

In the intervening years, others were still chasing the ultimate in convenience, a lens that was so physiologically compatible with the eye that it could be worn continuously for 30 days



▲ Fig. 3. The first commercially available soft lens in the U.S., the Bausch & Lomb "C" Series. (Courtesy of Andrew Gasson.)

without the risk of adverse ocular responses. The massive oxygen permeability of silicone elastomer led researchers to develop lenses made from this material in the late 1970s, with Dow Corning being the most well-known manufacturer to try this alternative material. Although physiologically successful, silicone elastomer lenses had one undesirable and potentially dangerous flaw: their rubber-like nature generated negative pressure under the lens during wear and resulted in the lens sticking to the eye. The only path forward was a hybrid material, a silicone hydrogel. Although seemingly simple, material scientists were essentially trying to mix "oil and water" and maintain a transparent material. B&L, the first company to bring soft hydrogel contact lenses to the market in 1972, were also the first to develop a commercially viable silicone hydrogel lens. This lens provided four times the oxygen transmission of hydrogel lenses, and it was approved for up to 30 days of continuous wear in 1999. Clinicians immediately noted that highly oxygen transmissive lenses eradicated significant adverse responses related to oxygen deprivation at the cornea, but they were slow to adopt silicone hydrogel lenses due to the up to 30 days continuous-wear indication awarded by the FDA. Experience over the years had shown that corneal ulcers, or microbial keratitis, was the single most significant adverse response associated with continuous wear, with the FDA limiting approval of all hydrogel lenses to six nights maximum in 1989 over their concern with incidence levels. Clinicians and companies now recommend silicone hydrogel lenses for daily wear or extended wear with monthly or more-frequent replacement, but the largest area of growth within the contact lens industry is the daily wear modality.

Currently available soft lens materials provide excellent physiological compatibility with the eye, and the cornea specifically, when worn in a daily wear modality, and so the focus of the industry has



▲ Fig. 4. Examples of the first disposable soft contact lens. Although the Danalens lens design and material were not unique, the packaging and delivery concept were innovative and ultimately changed the way contact lenses were sold the world over. (Courtesy of Andrew Gasson.)

moved to improving end-of-day comfort through design and material formulation, as well as improved optical performance. This last development has been driven by the development of clinically applicable Hartmann-Schack wavefront sensors. Porter et al. [5] measured the wavefront error of the eye of a large contact-lens-wearing population, identifying that the Strehl ratio of the eye can be significantly improved by correcting at least the major higher-order wavefront aberrations. This technique proved to be an ideal method to evaluate the optical performance of contact lenses on and off the eye, and OSA members led the development of standards for reporting the optical aberrations of eves. Ideally, individual prescription contact lenses should be made for each eye based on wavefront measurements performed in a clinical setting, enabling correction of all higher-order aberrations for improved low-light vision. Although the feasibility of this concept has been demonstrated by Marsack, the challenge for industry is to deliver these customoptics contact lenses in the same low-cost, disposable paradigm that patients and clinicians are currently using. In the meantime, at least one manufacturer (B&L) is altering the inherent spherical aberration of their spherical and toric contact lens

products using aspheric optical surfaces to minimize the spherical aberration magnitude of the eye with the lens in place and improve the quality of vision under low-illumination conditions.

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