# METAMORPHOSIS OF CONTACT LENSES: 1970-1980

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## ABSTRACT

*In 1971, soft contact lenses were a striking addition to the ophthalmic field that related functionally to the existing hard contact lenses by correcting refractive error, but their properties and description were different so as to confound ophthalmic professionals in their introduction. Their inventor Otto Wichterle, a Czechoslovakian chemist and anticommunist dissident, developed the soft lens in the 1950-60s with little knowledge of the hard lens, but its potential was broad enough to break through the communist barriers and to spark international consumer interest and development.*

*Challenges in manufacturing and developing soft contact lenses created a complex discipline around the cornea and lid physiology, and optics. This expanded greatly the scientific knowledge of the eye and adnexa to allow a soft, hydrophilic lens to remain symbiotic with the eye. Challenges were met over the past 50 years with a change in nomenclature and in automated manufacturing closer to hard lenses, optical advancements, new materials and surface treatments, and lens disinfection methods. The science developing from the diminutive soft lens led to the incorporation of related biomedical and polymer science within the broader ophthalmic field that inordinately influenced optical advancements, instrumentation, and ocular pathology.*

## KEYWORDS

*Soft contact lenses, hydrophilic contact lenses, hard contact lenses, Otto Wichterle, Drazolov Lim, National Patent Development Corp., Bausch & Lomb, Silon plastic, contact lens history*

## THE EARLY SOFT CONTACT LENS ERA

In August, 2009, the International Society for Contact Lens Research (ISCLR), met on the Greek island of Crete, and serendipitously six kilometers away, there happened to be a traveling Leonardo Da Vinci Exhibition. Among the treasures was an original Da Vinci optics notebook[1] that included da Vinci's 1506 drawings best described as the first principles of a contact lens.[2] Figure 1 is a photo of the notebook with 2020 ISCLR President-Elect Nathan Efron. This was apropos because it tied together within four miles at a remote location in the world, the well-known genius of Da Vinci and his contact lens concept of 500 years ago, with a research society that, since 1979, has had a profound influence on its development.[3]

The emergence of soft contact lenses in the ophthalmic field during the 1960-70's was an interesting and significant development for a variety of reasons, besides a transformative product for the ophthalmic field by a Czechoslovakian chemist and inventor.[4] A knowledge of the hard lens was not particularly relevant to the initial development of the soft lens material when its creation came from Otto Wichterle in the 1950s and 60s. Otto Wichterle was a prominent polymer chemist, founder, and Director of the Institute for Macromolecular Research in Prague, Czechoslovakia, who conceived of a plastic that was flexible, soft, and hydrophilic. Working with Drazolov Lim, he developed his concept into patents, and in 1960 initially released a widely publicized article in Nature.[5] Wichterle described multiple uses of this material, including a transplantation material, skin covering, and drug release device. However, its use as a soft, hydrophilic contact lens sparked the ophthalmic world and consumers outside of Czechoslovakia. Manufacturing started in the 1960s for the Geltakt and Spofa contact lens in Czechoslovakia, a country that had little prior experience with hard contact lenses.[6]

*Figure 1: Leonardo Da Vinci's Contact Lens from Manuscript D: Codex of the Eye (1508) and Nathan Efron, 2020 President-Elect of the International Society for Contact Lens Research, at the Herkaleon (Crete) Archaeological Museum in 2009 (Image courtesy Dr. Efron).*

The title of this article refers to a metamorphosis of hard to soft contact lenses because there was a transformation in lens appearance, properties, and the emergence of large soft lens corporations versus small hard lens companies that guided the early R&D and distribution of hard lenses. Hard (PMMA) lenses were labor intensive, having unique parameters for the eye contours of each wearer. Enterprising practitioners manufactured them in the US using equipment borrowed from other fields such as jewelry manufacturing, foot care, as well as the optical industry, but they were nevertheless reproducible within fine tolerances.

The circumstances surrounding Wichterle created a colorful introduction. Wichterle was a recognized chemist from the 1930s when he invented Silon, a product similar to nylon which Dupont had developed as a patent slightly earlier. Wichterle was a political dissident throughout his life of the caliber of the Russian physicist Andrei Sakharov, with an on-again, off-again relationship with the Russian-controlled Czech government.[7,8] In the 1980's with the Russians still controlling Czechoslovakia, Wichterle boldly published a short biography in the British Optical Directory, listing his current human rights activities and past political activities including expulsion and imprisonment in a Gestapo prison during the Nazi occupation.[9] He was mostly untouchable, having more than 150 patents, including at least 42 contact lens patents appearing through 1989.[10] Also, as an entrepreneur and inventor, he brought hard currency and investment to Czechoslovakia in addition to his international prominence.

In the 1960s when soft lenses were creating international interest, political conditions resulted in Wichterle leaving temporarily the Directorship of the Institute.[11] Researchers around the world, however, wanted samples of his contact lenses.[12] Wichterle found himself working at home during Christmas, 1961, producing about 5,200 lenses with his physician wife, Linda, over five months. He used a spin casting rotating device constructed from his son's erector (Merkur) set.[13] This consisted of multiple rotating concave molds where liquid co-polymers were added through plastic tubes. By rotating at varying speeds, he would produce lenses of different refractive powers, and the mixing interaction of the liquid yielded a dry, clear co-polymer. The lenses were then removed from the mold and hydrated.

## ADVANCEMENTS THROUGHOUT THE WORLD

A flexible, hydrophilic contact lens actually was accepted very quickly after its initial development, notwithstanding the internal obstacles Wichterle had. Much publicity was given internationally throughout this time and in the US, the FDA became involved because of toxicity, microbiology and the lens absorption potential for bacteria and chemicals. The full benefits from the soft lenses took many months to develop. Spin casting produced a precise lens but with limited optical and physical dimensions, in contrast to the full fitting parameters in the manufacture of hard lenses. Bausch & Lomb found that the hydrophilic material would offer challenges both to the microbiological integrity of the material as well as its optical characteristics. Because of these potential pitfalls, the FDA declared the soft lens a drug, which would differ from any other country except Japan.

After FDA marketing approval, Bausch & Lomb had no competition for cosmetic wear lenses during the first several years in the lucrative US market, and they also marketed lenses throughout the world.[14] Others attempted to develop soft lenses in the US, but the medical protocol was difficult to navigate.

Other countries continued to develop the soft lens without spin casting manufacturing, and the traditional hard lens manufacturers as well as NPDC used machining and molding to produce a mixture of semi-finished blanks and machining. The practitioner had different fitting methods available to them. Initially, manufacturers such as those in Germany and Australia would allow the practitioner to specify almost any base curve and diameter. Their thickness compared with the spin cast lenses was usually greater with reduced flexibility as well as fitting potential.

## LENS MATERIALS

The original soft lens materials from Wichterle consisted of a crosslinked version of the hydroxyethyl methacrylate, a water absorbing polymer. In order to get around Wichterle's patents, companies first tried to manufacture the material by methods not envisioned by Wichterle. However, this was difficult because Wichterle had included molding as well as machining soft lens materials. Then companies attempted to produce co-polymers in combination with hydroxyethyl methacrylate. They included singularly or in other combinations with vinyl pyrrolidine (Barnes Hinds, Sauflon, Scanlens), and methylmethacrylate (Duragel). The materials varied from PolyHEMA in hardness, durability, water content, and oxygen transmissibility. Such properties were determined by percentages of the co-polymers and the chain configuration.

In Europe there was a number of countries that yielded a variety of lens types in the 1970s.[15] The Germans manufactured lenses of great precision with two major companies: Wohlk and Titmus Eurocon, using PolyHEMA. England had wide varieties of lenses thanks to John de Carle who produced the Permalens (Global Vision), the first permanent or continuous wear lens. The Sauflon (Contact Lens Manufacturing Group) for continuous wear developed by Philip Cordrey and David Klulow, followed the Permalens. Japan, like the US, devoted considerable time to the safety and microbiology of lenses. In addition, Japan was preoccupied with alternative care solutions because the early chemical disinfection methods were not satisfactory. Alternatives with thimerosal were unacceptable because it was a mercury compound that Japan avoided because of a national history of mercurial poisoning starting with seafood.

Similarly, Australia's degree of sophistication and offerings having small laboratories, making one-off contact lenses for a sophisticated practitioner and university researcher base produced dynamos among ophthalmic professionals. Australian optometrists and contact lens laboratories supported organized research by Australian educational institutions through the National Research Vision Institute.[16] A certain percentage of the contact lens lab cost went to Australia's educational institutions and the resulting research produced some of the earliest toric, high power, and bifocal contact lenses. Even though it became apparent early on that soft lenses flexed, the usual wide array of parameters for hard lenses were not necessary. However, the availability of all parameters to design soft lenses allowed Australians to produce optimal designs.

## MANUFACTURING SOFT CONTACT LENSES WORLDWIDE

Wichterle first conceived of lenses that were spin cast,[17,18] rather than static molded or surface lathed, which came later. Wichterle and the Czech government first began to negotiate for international rights with Dr. Robert Morrison,[19] a well-known American optometrist. The Czech government soon after began negotiating with Martin Pollak and Jerome Feldman of the National Patent Development Corporation (NPDC)[20], a patent holding company specializing in Eastern European negotiation. NPDC negotiated with Morrison to buy the full worldwide rights for the material and its manufacturing. Wichterle who had earlier attempted to work with other traditional contact lens companies found they had difficulty in grasping the soft lens concept because they varied so much from traditional hard lens fitting and manufacturing. Bausch & Lomb (B&L) at the time was in need of new products, was not a contact lens company, and SOFLENS contact lenses would soon become a lifeline to them. NPDC and B&L negotiated an exclusive, worldwide license for the spin cast technology and lens distribution as well as the non-exclusive use of PolyHEMA by other manufacturing processes. B&L received FDA approval on March 17, 1971, and had exclusivity in the US marketplace until 1974 when Barnes Hinds/Hydrocurve received FDA approval for extended wear soft lenses. In between Bausch & Lomb and Hydrocurve, AO Softcon received approval of a high water content lens for therapeutic contact lens use.

Later, NPDC would commercialize the PolyHEMA lens by licensing lathe and static-molded technology, as well as opening its own separate subsidiaries named "Hydron" in Europe, Australia, and the United States. In addition, other manufacturers previously in the hard lens field would slowly produce soft lenses using either the PolyHEMA sublicensed by NPDC or variations in polymers that would eventually be subject to various legal difficulties with Wichterle patents.[21] The early lenses were similar in manufacturing methods to the hard lens, in that the material could be lathed from a dry, molded button or cut from a rod. Then, the lens would be hydrated to produce its final, flexible shape.

## DISINFECTION AND CLEANING OF THE CONTACT LENS

At the beginning of soft lens development, a complexity was that chemicals and impurities concentrated in the lens, which cast doubt whether the chemicals and especially the disinfectants used for hard lenses would work. In the United States, the FDA further made traditional chemical disinfection harder to consider. Bausch & Lomb introduced heat disinfection using saline made from salt tablets dissolved in distilled water, and heated first in a canister with an electric heater and later with a heater surrounding the lens case. Prior to disinfection, the lenses were to be cleaned by rubbing with saline, and later with a surfactant. Allergan Pharmaceuticals came up with a successful enzymatic cleaner that would treat lenses with a thorough soaking. The problem with the cleaner was that it did not remove much protein, and in fact deposited its own protein through lens absorption.[22] Further research showed that the most detrimental protein was denatured surface protein that could be partly removed by the enzymatic cleaner.

In the 1960s Wichterle portended a solution to the deposition problem that would continue for the next 50 years. In 1980, the International Society for Contact Lens Research held their first conference where a high research priority at the time was lens deposition and lens spoilage. This continued to be a priority until the present where daily disposable contact lenses are supplanting lenses worn for multiple days.

During the 1980 conference Wichterle was asked to comment about solutions and lens spoilage, he said as follows:

*Is it worth investing a great deal of research on this problem? There is one solution that would eliminate all the problems of deposition: Once deposits occur, we could reject the lens and take a new one! I believe we are now very close to the development of technology which will cause a dramatic drop in the selling price of lenses. Once you are able to buy a lens for one dollar or less, lens spoilage won't play a role. If a lens is spoiled, it will be cheaper to buy a new lens than to buy expensive solutions and waste time with cleaning.*

*I remember that 17 years ago, in my first speech about these lenses, I predicted that lenses would soon be sold for less than one dollar. I was wrong, it wasn't that soon.*[23]

Although Wichterle would nurture manufacturing techniques with the potential of producing less expensive lenses, the rigors of research and development would add additional costs in spin casting for Bausch & Lomb. Other manufacturers returned to more expensive lens finishing so as to produce the quality and variety of fitting parameters that were expected.

## DIVERGENCES IN INTERNATIONAL RESEARCH AND DEVELOPMENT

The divergence between manufacturing lenses created a major difference in developments in the US compared with other countries. The Germans continued to produce a hydrophilic contact lens that was created with the precise measurements of a hard lens. The British spent considerable time with a variety of different co-polymers and were active in a variety of related research endeavors. The Australians had the sophistication of designing lenses as well as developing academically-based research institutes. Some of the major contact lens firms were in the United States, and the challenges of the soft lens material required considerable work to satisfy the concerns of professionals throughout the world, and the FDA. Their development and input became increasingly more international.

## NEED FOR INTERNATIONAL APPROACH TO SOFT LENS RESEARCH AND DEVELOPMENT

Research and development of the soft lens proceeded more completely as an international endeavor when regional scientists began to consider and co-mingle the priorities and needs for the future. In the United States, corneal physiology and microbiology were the major additions, whereas in other countries the major clinical additions were to make lenses more comfortable with improved vision. The challenges of soft lenses were formidable, both as a foreign object on the cornea and its physiological effects on the eye. Spin cast lenses of Bausch & Lomb had exclusive world rights which provided maximum fitting capabilities. Certain optical considerations such as the asphericity produced on the concave surface of the spin cast lens induced compromised visual performance; this and other optical challenges were difficult for the FDA to understand in drug terms. FDA regulations were sometimes untenable such as an unlikely restriction that Bausch &

Lomb Soflens Contact Lenses were contraindicated for pregnant women because the necessity for all drugs to be tested in this subgroup. B&L and other early soft lens manufacturers were vulnerable and diverted by FDA in some cases, but meeting the medical and physiological challenges definitely contributed to the safe and effective use of soft contact lenses.

## ADVANCING THE RESEARCH AND KNOWLEDGE OF SOFT CONTACT LENS

The International Society for Contact Lens Research (ISCLR) was cofounded in 1979 with Dr. Otto Wichterle as its Patriarch. ISCLR was instrumental in bringing together principal researchers from throughout the world.[3] Its co-founders were Montague Ruben, MD, from Moorfields Eye Hospital in London, England; Brien Holden, PhD, from the University of New South Wales in Sydney, Australia; and Raymond Myers, OD, from Bausch & Lomb Soflens Division through 1973-1978.[24] The three assembled in London with Dr. Robert Koetting of St. Louis and Dr. Ruben's graduate student, meeting scribe, and future ISCLR President, Michel Guillon. ISCLR would assemble biannually a small group of academic and clinical interprofessional researchers from various countries with unique contributions. The ISCLR under the auspices of its independent Board of Counselors included major contact lens manufacturers as observers, and nurtured a "think tank" environment where they discussed research of highest priority for the particular year, and did this to produce the challenges and directions which eventually would be undertaken by researchers and manufacturers.[3]

Over the many years of contact lens developments, the soft lens started simplistically by Wichterle in Czechoslovakia with a chemist resolving the basic problems and with Czech ophthalmologists fitting commercially the first patients. The challenges which came later throughout the next 50 years occurred from vision, corneal physiology, optics and vision, microbiology, new materials and surfaces, allergies, and contamination. Scientific and biomedical disciplines not having any connection to the ophthalmic field were introduced by scientists at the ISCLR for topics that were important to development at the time, and many of these scientists remained associated with contact lens directed research.

The challenges and opportunities that came from related technologies and sciences to soft lens research have also led to developments and further research in unrelated ophthalmic fields. Early discoveries in corneal physiology redefined the mechanisms of fluid transport and corneal function. The problematic asphericity of Bausch & Lomb spin cast lenses reappeared as opportunities at various times. Aspherical lenses became a positive addition to multifocal contact lenses and also for contact lenses as well as eyeglasses, where the lens peripheral power effect might retard myopic growth in children. The degree to which infections and inflammation by contact lenses were treated required much more understanding of the reactions of the eye, with or without contact lenses.

Brien Holden from Australia was a particularly effective ambassador of contact lens research around the world. Having begun at the University of New South Wales as instructor in 1973 and previously obtaining his PhD from the City University in London, he conveyed the high level of research going on in Australia to other countries, including the US, and a variety of other contact lens manufacturers. Bausch & Lomb needed lens designs including toric lenses to improve the performance of existing lenses. Holden established the Corneal & Contact Lens Research Unit at the University of New South Wales, and also alliances with other researchers in optometry and ophthalmology, as well as disciplines not normally associated with contact lenses.

In summary, the soft contact lens introduction in the 1970s transformed the field in a number of ways. In 1975, there were approximately 2 million soft lens wearers. By 1999,[25] there were 27 million US contact lens wearers, and 75 million in the world; and in 2014, 45 million US wearers.[26] Also, soft lenses had an inordinate influence in bringing about developments that were implemented throughout the ophthalmic field.

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