

# HINDSIGHT

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**SPECIAL ISSUE:  
FOCUS ON SOFT CONTACT LENSES**

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**optometric**  
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## ON THE COVER



*Photo and bust of Otto Wichterle, discoverer of the material used in the first soft contact lens (images courtesy the Wichterle family), and the Czech Republic stamp issued in 2013 to commemorate the 100th anniversary of Wichterle's birth (image courtesy the Contact Lens Museum).*

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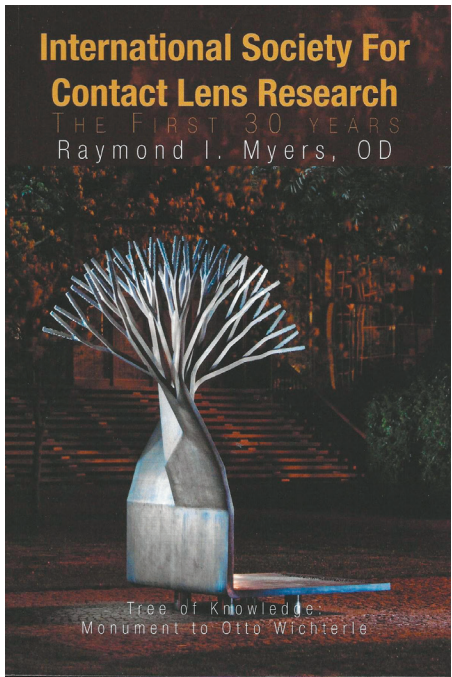
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In 1959 Dr. Maximillian Dreifus of the Second Ophthalmological Clinic in Prague fit some of the first soft lenses in practice. (Image courtesy the Wichterle family)



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# HINDSIGHT

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## OHS HOSTS “BLAST FROM THE PAST” LECTURE AT OPTOMETRY’S MEETING



*W. Howard McAlister, O.D. and Jeffrey L. Weaver, O.D. presenting during the "Blast from the Past" lecture at Optometry's Meeting 2021.*

On June 25, 2021, the yearly Blast from the Past lecture was presented by W. Howard McAlister OD and Jeffrey L Weaver OD. Their lecture entitled “Military Optometry from World War I to Present” was well attended by history buffs, AFOS members and active military Optometrists. Drs. Weaver and McAlister cited the significant contributions made by military ODs and their impact on contemporary optometry.

## FIVE LUMINARIES INDUCTED INTO THE NATIONAL OPTOMETRY HALL OF FAME



*Marlene Poston-Bell accepting the award on behalf of her late father, Marvin R. Poston, O.D.*



*Tony Q. Chan, O.D. accepting his award.*

The American Optometric Association and Optometry Cares – The AOA Foundation were pleased to induct the following doctors of optometry into the National Optometry Hall of Fame during Optometry’s Meeting® on June 25, 2021:

- Tony Q. Chan, O.D. (2020)
- Robert A. Koetting, O.D. (2020)\*
- Michael H. Mittelman, O.D. (2019)
- Marvin R. Poston, O.D. (2021)\*
- Satya B. Verma, O.D. (2020)

Pictured is Marlene Poston Bell, who accepted the award on behalf of her late father, Marvin Poston, O.D.

Since 1998, the National Optometry Hall of Fame has recognized and honored optometrists who are luminaries of the profession – those who have made significant and long-lasting contributions to the optometric field.

\*denotes posthumous inductee

## FROM THE EDITOR: THEME ISSUE ON THE HISTORY OF SOFT CONTACT LENSES

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In the previous issue of Hindsight and in this one, we present articles on the history of soft contact lenses to celebrate the 50<sup>th</sup> anniversary of their introduction into the market in the United States. Just how revolutionary soft contact lenses were can be illustrated by the fact that no one seemed sure what to call them. Noted contact lens expert Robert Mandell wrote in 1974 that “there has been considerable confusion with regard to the terminology which should be used for gel contact lenses. They have been referred to by various names including: soft lenses, flexible lenses, hydrophilic lenses, hydroscopic lenses as well as many other generic and trade names.”<sup>1</sup> The new soft contact lenses were a disruptive technology, to use today’s parlance.

The comfort, easier adaptation, and various applications of soft contact lenses rapidly made them extremely popular, and they greatly impacted the practice of optometry. We thank the authors of

the six articles in these two issues for sharing their expertise on the history of soft contact lenses. A special thanks goes to Dr. Raymond Myers, member of the Optometric Historical Society Committee, for drawing up a list of potential topics, recruiting an outstanding group of authors, and then authoring two papers as well, thus making this interesting and informative collection of papers possible.

### Reference

1. Mandell RB. New thoughts on gel lenses. *Internat Contact Lens Clin* 1974;1:24-26.



*David A. Goss, O.D., Ph.D.*

# THE EARLY PIONEERS OF GLOBAL SOFT CONTACT LENS DEVELOPMENT

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## ABSTRACT

*This article outlines the history and development of the first hydrophilic biocompatible plastic, called PHEMA. The story traces the notable leaders in its development and provides a timeline from the initial discovery of the hydrogel material to its evolution into the modern soft contact lens.*

## KEYWORDS

*Otto Wichterle; Drahoslav Lim; Robert Morrison; Allan Isen; Martin Pollak; National Patent Development Corporation; HEMA*

## INTRODUCTION

The origin of soft contact lenses is well documented and agreed upon as beginning with Otto Wichterle and Drahoslav Lim and their groundbreaking discovery of the plastic, polyhydroxyethyl methacrylate (PHEMA), in Czechoslovakia during the early 1950s. As with all history, soft contact lens development did not escape the political, social and economic happenings of its time and is intertwined with the major events following the end of World War II and transition to the Cold War era in central Europe. Despite many hurdles that had to be overcome, Drs. Wichterle and Lim are responsible for changing the entire landscape of the contact lens industry in the latter half of the 20th century with their revolutionary discovery.

## OTTO WICHTERLE

Otto Wichterle was born in Prostějov, in central Czechoslovakia on Oct. 27, 1913, into a well-to-do, industrial family. Like his grandfather and father, Otto was supposed to take over the family business related to the manufacturing of farm equipment and motor vehicles; however, his interests were always more focused in the field of science.<sup>2</sup> In 1936, Otto graduated from the Czech Technical University in Prague, and in 1938 he married his life-long companion Linda. Linda Wichterle would later play a major role in the production of the first soft contact lenses.



*A young Otto Wichterle. (Image courtesy the Wichterle family)*

In 1939, Otto Wichterle earned the first of his two doctorates in chemistry; however, his professional career was quickly halted with the dawn of World War II and the German invasion of Czechoslovakia.<sup>3</sup> Under German rule, the universities were closed

and students and professors at higher-educational institutes were often arrested and placed into concentration camps. In 1940, Wichterle was able to escape this fate by finding employment in the chemical research department at Bat'a Shoe Company in Zlin, Czechoslovakia.

It was during this period that Wichterle contributed to the development of Silon, a similar material to nylon for synthetic socks and tights.<sup>1</sup> In 1942, the often-outspoken Wichterle was imprisoned by the Gestapo and held for five months, though it is unclear as to why he was arrested.<sup>3</sup> It is rumored that a top German chemist was familiar with Otto's work and contributed to his eventual release.

At the end of the war in 1945, Wichterle started work on his second doctorate in organic chemistry at the University of Prague, where he became a professor within the department of plastics.<sup>2</sup> His interest in the chemistry of plastics had impeccable timing, as the age of plastics in the 1950s was about to begin.

### **DRAHOSLAV LIM**

Born Sept. 30, 1925, Lim was several years younger than Otto Wichterle. Similar to Wichterle, he had a Ph.D. in chemistry, and he and Wichterle were working in the same polymer research department at the University of Prague. Not as much is known about Dr. Lim; however, he would be equally credited with the development of the first hydrogel plastic, the material that would change the contact lens industry forever.<sup>2</sup> While Dr. Lim contributed significantly to the development of the PHEMA material, his involvement became less prominent as the plastic evolved into soft contact lenses. Later in life, Dr. Lim migrated to the United States to continue work as a chemist. He worked at the University of California on plastics involved in artificial kidneys and at Revlon in their department of research on nail enamel. Lim passed away on Aug. 22, 2003, in San Diego, California.

### **1952 - LET THE STORY BEGIN**

The idea of a hydrophilic biocompatible plastic is said to have originated on a train ride in 1952, when Wichterle happened to be sitting next to Dr. Pur, a Ministry of Health official who was reading a medical journal containing an advertisement on metal prosthetics used in ophthalmology.<sup>4</sup> A conversation ensued that sparked Wichterle's interest in developing a biocompatible plastic for human tissue replacement.

Dr. Lim was the only colleague of Wichterle's interested in joining him in the research and a short six months later they had successfully synthesized the first hydrophilic plastic known as polyhydroxyethylmethacrylate (PHEMA); and so began what would become Wichterle's lifelong journey.



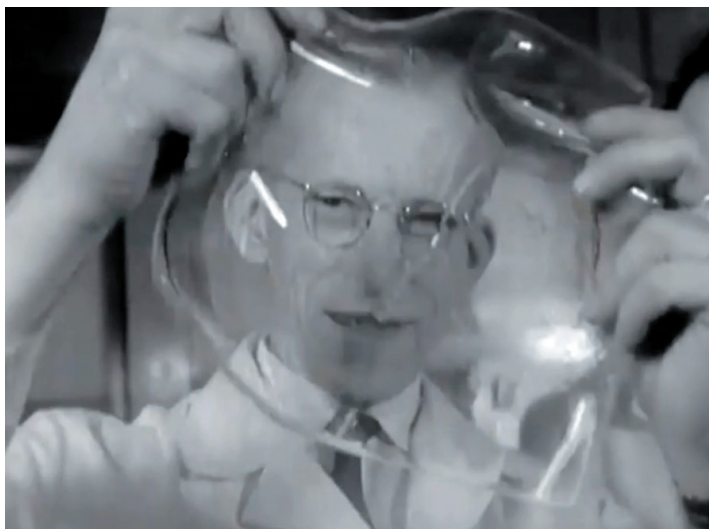
*Otto Wichterle (left) with colleague Dr. Drahoslav Lim (right) and their synthesized hydrophilic gel known as polyhydroxyethylmethacrylate (PHEMA), 1955. (Image courtesy the Wichterle family)*

### **1953**

Following the development of the PHEMA material, various iterations of the plastic were sent out for toxicology testing. Samples of the materials were implanted into the orbits, sclera and anterior chambers of rabbits, and the gels that were found to be inert were selected.

### **1955**

At this point, the hydrophilic plastic's use, as a contact lens, was not the intended purpose, and Wichterle and Lim immediately applied for several other medical patents.<sup>2</sup> It was only by chance that the flexible and oxygen-permeable material also turned out to be extremely clear. One of the earliest applications of the HEMA plastic was in an orbital implant surgery in 1955.<sup>2</sup> Wichterle's son tells us that it was the clarity of the plastic gel that led Wichterle to be curious as to how this property could be used elsewhere.<sup>3</sup> Wichterle's idea of creating a soft contact lens was brought forth to the Ministry of Health in Czechoslovakia but, with no interest or support, he was forced to work on the development on his own with willing colleagues and little financial backing.<sup>2</sup>



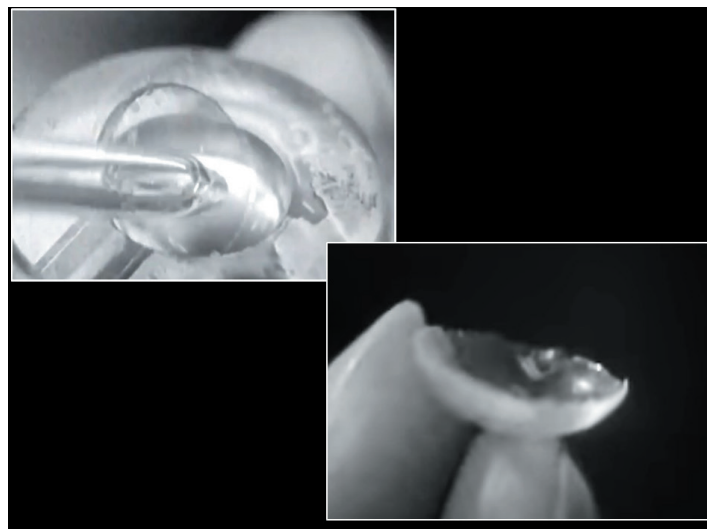
*By chance, the hydrogel material was flexible, oxygen permeable and extremely clear. (Image courtesy the Wichterle family)*

### 1957

The majority of contact lenses during this era were full-sized scleral lenses, as corneal lenses were a relatively new innovation. Historically, scleral lenses were manufactured using a molding process to shape the hard plastic (PMMA) and so Wichterle originally attempted to manufacture his water-soluble gel in a similar molding fashion. Unlike its PMMA plastic counterpart, the molded gel material resulted in thick lenses with rough edges. Despite the discomfort one of these lenses would induce, Wichterle is reported to have been the first to apply one of his lens designs onto his own eye in 1957.<sup>2</sup>

### 1959

In 1959, Wichterle left the University of Prague and began work as a director at the Institute of Macromolecular Chemistry (IMC).<sup>3</sup> It was at the IMC that Wichterle and his colleagues were able to create a more optically pure lens by changing their molds from plastic to a glass material. The “rough edges” dilemma was still an issue as these lenses would often stick to the molds upon removal. To minimize the irritation to the eye, each lens was meticulously filed down, creating a tedious process for Wichterle and his colleagues. With about 100 lenses manufactured, it was time for trial on additional eyes. Dr. Maximillian Dreifus of the Second Ophthalmological Clinic in Prague is said to have fit some of the first soft lenses demonstrating only limited success with the prototype lenses.<sup>2</sup>



*In 1957, Wichterle produced around 100 soft contact lenses from closed polystyrene molds; however, because of contraction of the material during polymerization the edges split and tore as they were removed from the molds. They therefore required hand finishing. (Image courtesy the Wichterle family)*



*In 1959 Dr. Maximillian Dreifus of the Second Ophthalmological Clinic in Prague fit some of the first soft lenses in practice. (Image courtesy the Wichterle family)*

### 1960

The first published work on the groundbreaking material was published in *Nature* and authored by Otto Wichterle and Drahoslav Lim.<sup>5</sup> This article titled, “Hydrophilic Gels for Biological Use” started to gain international attention from investors and companies looking to harness the new technology to their benefit. This article was such a landmark publication that it would be referenced by scientists and clinicians for decades to come.

**Hydrophilic Gels for Biological Use**

PLASTICS today enjoy wide use in many fields, and it is natural that the possibility of their employment in permanent contact with living tissues has been seriously considered. A study of the literature shows that almost all known plastics have been proposed for this purpose at various times. The question of structural similarity with the tissue has not, however, been emphasized although physiologically unfavourable effects were observed in most cases of application of normal type plastics.

The extensive application of plastics for alloplastic and prosthetic uses requires solution of the problem of compatibility of the material with the live tissue. It is indisputable that non-biological material represents a foreign body having contact surfaces showing large deviations from normal physiological behaviour.

The result of poor compatibility is either an immediate severe local irritation or a tumorous growth which sometimes appears only after a longer interval. The cause of these phenomena, as has been ascertained, is to be found among other factors in the mechanical irritation or in the long-term slow diffusion of low molecular irritant substances from the plastic itself, so that every plastic must be judged from this point of view. All high polymers used so far in medicine are impermeable to metabolites. The majority of them are hard solids so that they can cause mechanical irritation. Further, one must expect a certain slow leaching of irritating substances from them. Polyvinyl alcohol is an exception; but it has the major disadvantage that it is absorbed.

The demands to be placed on a suitable plastic after consideration of the above-mentioned effects are thus: (1) a structure permitting the desired water content; (2) inertness to normal biological processes (including resistance to the degradation of the polymer and to reactions unfavourable to the organism); (3) permeability for metabolites.

Materials with these properties must have hydrophilic groups. Further, they must have a three-dimensional structure with at least enough cross-linkages to prevent absorption.

Of a large number of plastics we found co-polymers of glycolmonomethacrylate with several tenths per cent of glycoldimethacrylate to be the most suitable. They hydrolyse only with difficulty, even under severe conditions, and are indifferent to biological materials. A further advantage is that their mechanical properties and water content can be adjusted to most requirements. They withstand heat sterilization without damage.

Hydrophilic materials of a marked polyelectrolyte character (with basic groups, or with carboxyl groups) have unfavourable effects on the organism, swell excessively and their chemical stability does not attain the stability of glycol esters.

Gels based on glycolmethacrylates are also noteworthy for their transparency (in the case of polyglycolmonomethacrylate with a water content less than 20 per cent and with the higher glycols at all concentrations). The water content, and thus the shape of the object, is, after attaining equilibrium at the given temperature, constant and depends on the structure and number of cross-linkages. The appropriate monomers can be prepared by the alcoholic re-esterification of methylmethacrylate with glycol followed by selective extraction of the di- and mono-esters from the reaction mixture. The desired shapes are prepared by polymerization of aqueous solution in suitable moulds. Balloon-like and soft gels can be stiffened by polyamide fibres either in the form of flock or threads. Before use it is necessary thoroughly to leach out the shapes.

The formation of a porous structure by the rapid polymerization of glycolmonomethacrylate is of great interest. With a water content greater than corresponds to the equilibrium capacity of the gel, a porous structure will arise by coalescing of the water-phase droplets into interconnected channels. The size of the pores depends on the polymerization conditions. On drying the porous sample, a transparent solid material is formed which takes on the original shape and structure on immersion in water.

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After more than four years of testing, these materials have now passed through the stage of application such as filling after emulsation of the eye. Promising results have also been obtained in experiments in other cases, for example, in manufacturing contact lenses, arteries, etc.

Detailed biological results will be published in due course.

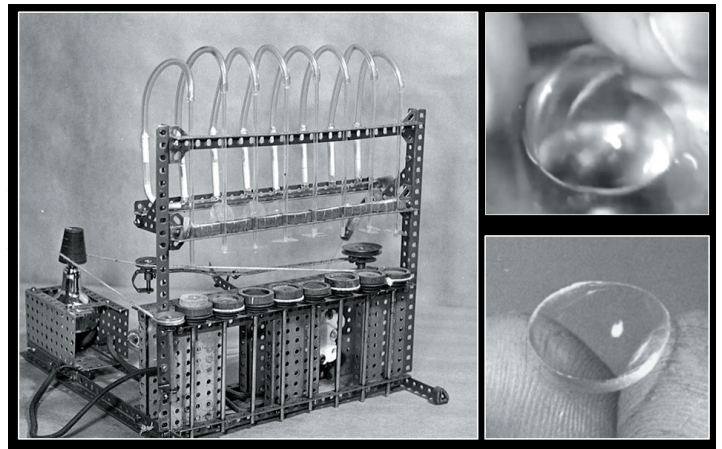
O. WICHTERLE  
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Prague.

The first paper published on soft contact lenses, "Hydrophilic Gels for Biological Use," by Otto Wichterle, Ph.D., and Drahoslav Lim, Ph.D., *Nature*, Jan. 8, 1960. (Image courtesy the Wichterle family)

**1961**

With further budget cuts and reduced funding, the public investigation of hyalogen for the use in contact lenses was ceased.<sup>2</sup> This forced the passionate Wichterle to continue his research and experiments at home. The primary problem he needed to solve was the issue of lens discomfort. In the early months of 1961, Wichterle conceived the idea of applying a spin-casting method to the manufacturing process. Like many great inventions, inspiration is often drawn from the simplicity in everyday life happenings. Wichterle found his while stirring a cup of coffee!<sup>6,7</sup> Being an observant man, he noticed how the edges of the cup formed a capillary interaction with the coffee inside. He imagined this being applied to his contact lenses, and so the spin-casting idea was born. At this point in time, spin casting was reported elsewhere in the world for mirror design.<sup>2</sup> It was his hope that by having a rotating mold, the lens adherence and edge roughness problem would be solved for the HEMA lenses. With a lack of resources (that Wichterle was accustomed to at his research lab), he had to be innovative in building a machine capable of working the fine

gel material into a finished contact lens. He recruited the help of a local glassblower to make the molds as an initial step in putting together a manufacturing process.<sup>4</sup>



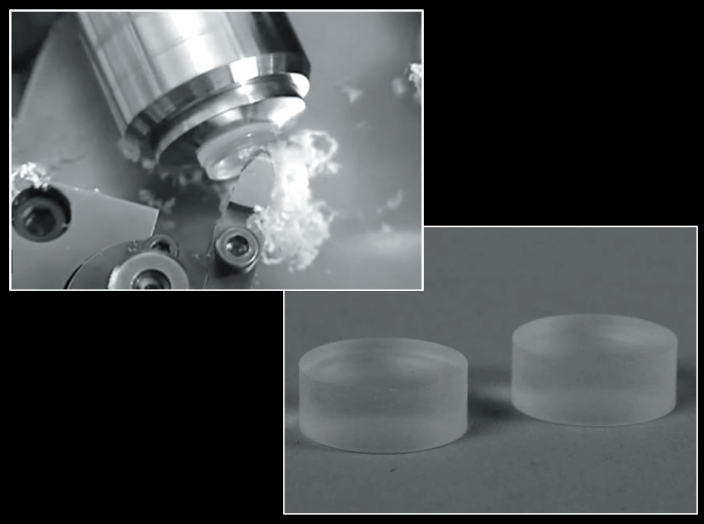
On Christmas Eve 1961, Wichterle built the first spin-cast machine using his son's Merkur (Erector) set and the generator from his bicycle light transformer. On the afternoon of Christmas Day 1961, Wichterle produced the first four usable spin-cast soft lenses on the family's kitchen table. (Image courtesy the Wichterle family)

The following day, Christmas Day 1961, the first four soft contact lenses were produced in the kitchen of the Wichterle household by Wichterle and his family.<sup>2,4</sup> As one can imagine, Christmas at the Wichterle household in 1961 was not a typical holiday celebration; however, this was a landmark moment in the history of contact lenses and one that would go on to spark a multibillion-dollar industry in the years to come. Wichterle did not waste any time, and the next day the soft lenses were trialed in clinic again at the Second Ophthalmological Clinic by Dr. Dreifus.<sup>2</sup>

**1962**

As Wichterle's spin-cast soft lens design offered both comfort and optical success, the next goal aimed at increasing the production of these lenses. Adjustments made to the spin-casting machine, such as increasing the number of spindles from four to 15 and adding a more powerful gramophone motor, exponentially increased lens production.<sup>2</sup> Soft lens manufacturing became a Wichterle family affair, as both his sons, Kamil, Ivan and his wife Linda contributed to the process. Kamil, a trained chemist with mathematical expertise, helped formulate an equation to determine an appropriate spindle rotation speed and the amount of material required for production.<sup>4</sup> With the help of his wife, an estimated 5,500 lenses were manufactured in their home within the first four months of 1962.<sup>2</sup>





In 1963 Wichterle recreated his hydrogel plastic in a dehydrated state and called this material Xerogel. (Image courtesy the Wichterle family)

## 1964

In April of 1964, Wichterle presented the world's first lecture on soft contact lenses at a conference organized by his new acquaintance, Pierre Rocher.<sup>2</sup> This was only the second annual contact lens conference called the Journées d'Études de Royaumount hosted in Rocher's home country of France. Later in the year, Wichterle began a tour of America, presenting his research in various U.S. cities. While on his tour it is legend that Wichterle enjoyed boasting about the durability of his lens and the ease of lens cleanliness. According to his wife, the professor claimed the fastest way to clean the lens at the time was to put it in one's mouth.<sup>7</sup> He often demonstrated this at various events by dropping a lens on the ground, squishing it with his shoe and then proceeding to wet the lens by rinsing it with his saliva and reapplying it to his eye.<sup>7</sup> In contrast to the knowledge we have today about microbiology and sanitization, individuals in 1964 were more fascinated with how robust this lens was during the demonstration. Wichterle's influence began to spread outward from his home country as more people learned about his work. Eventually the news made it to the United States and, in particular, reached an optometrist by the name of Robert Morrison.

Morrison graduated from the Pennsylvania College of Optometry in 1948 and established a contact lens specialty practice in Harrisburg, Pennsylvania, where he quickly gained a reputation as a skilled contact lens clinician. Dr. Morrison expanded his reach providing contact lens fitting for celebrities and patients of royal descent throughout the world. A well-connected man, Morrison became involved with soft contact lenses through his connection with Pierre Rocher.<sup>8</sup> When Rocher's company decided not to pursue Wichterle's new lens modality, he was free to pass along the information to colleagues in the field. Morrison later related a phone call he had with Rocher describing the new material and its potential as a contact lens polymer. Intrigued by the new technology, Morrison is reported to have taken a flight to Czechoslovakia the next day in hopes of meeting and learning more from Otto Wichterle.<sup>8</sup> Morrison worked with Wichterle, and the two men developed a lifelong friendship. Like Rocher, Morrison was given samples of the material to take

home. He proceeded to work with the plastic at his own contact lens laboratory, Morrison Laboratories.<sup>8</sup> In contrast to the spin-casting method used in Prague, Morrison began trying to adapt the lathing method that was already an industry standard for manufacturing rigid contact lenses.

Another early suitor for developing soft lenses technology was a company called National Patent Development Corporation (NPDC) based in New York City. The company was founded in 1959 by two attorneys Martin Pollak and Jerome Feldman.<sup>2</sup> The Wall Street company specialized in purchasing patents that had failed to gain traction in the world market and selling them to interested parties.

At around the same time as when Morrison began working with Wichterle, Martin Pollak was in the USSR exploring different patents for the NPDC.<sup>2</sup> It was rather unusual for an American company to be conducting business in Russia at this time, especially while the events of the cold war were taking place. Contrary to what one might think, Pollak was treated very well in the communist country as they viewed him as a man of high status because he was one of few Americans still in Russia. Pollak eventually explored other Soviet countries, which lead him to Czechoslovakia and at last to Otto Wichterle. As a businessman, he saw great potential in Wichterle's patents and the monopoly that he had on the new, fascinating area of medical technology. The NPDC believed in the product to such an extent that they were willing to change their business model from acting solely as a company that would transition a product into the hands of someone capable of production to one that wanted to become actively involved in its manufacturing and commercial success.

## 1965

The rights to the HEMA gel and its production method in the United States were eventually awarded to not just one of the interested parties but both Robert Morrison and the NPDC.<sup>2,8</sup> Because of the Czechoslovakian political system at the time, Otto Wichterle was only indirectly involved in the deal. The Czech Academy of Science (CAS) was the organization responsible for selling the rights to Morrison and the NPDC, though it is said that Morrison was unaware of any other involved parties until the day the deal was to be signed.<sup>8</sup> The original agreement was recorded on paper as a transaction between the Czech Academy of Science and a company named Flexible Contact Lens—another blindside to Morrison.<sup>2</sup> It was on that same day that he found out he was supposedly a 50/50 owner of the company alongside Pollak, Feldman and the NPDC.<sup>8</sup> In fear of losing out on the soft contact lens opportunity, he reluctantly signed the agreement with the Czech Academy of Science and officially gained rights to the patent for HEMA lens development. Morrison also had Pollak sign an agreement stating his claim in the company to make certain he wasn't being cheated, something that is said to have been written on the inside cover of a torn-out book.

From Otto Wichterle's standpoint, both Robert Morrison and Martin Pollak had their advantages in fulfilling Wichterle's dream of global soft lens development. Morrison was passionate about the science and applicability of a new lens modality. Being an optometrist, he was able to envision how something like HEMA might be able to benefit patients not only medically, but cosmetically as well. Wichterle and the NPDC fit together with a

shared goal of large-scale expansion and production of the lens. This was something that had significantly limited Wichterle under the communist regime of Czechoslovakia and his power struggle with them for autonomy. The Czech Academy of Science also felt more secure about having two groups working on their invention as the deal that was signed was dependent on contact lens sales and the success of the product.<sup>2</sup>

Another revelation came about when Dr. Morrison found that the stock certificate to the new company included a name besides Martin Pollack and Jerome Feldman's, that of Allan Isen.<sup>8</sup> Dr. Isen was an optometrist from Buffalo, New York, who graduated from Columbia University in 1950.<sup>2</sup> His interest in contact lenses commenced shortly after he began the challenging process of fitting monocular aphakes. He started a contact lens laboratory in 1957 called Frontier Contact Lenses and became a prominent name in the contact lens industry. It is reported that Isen was in attendance at the 1964 Indianapolis and New York meetings in which Wichterle had lectured.<sup>2</sup> Isen even went on to present what he had learned from these lectures at the annual American Academy of Optometry meeting.<sup>2</sup>

## 1966

After all of the turmoil that occurred with obtaining the rights to Wichterle's patents, Robert Morrison hired a lawyer by the name of James Purcell and filed a lawsuit against the NPDC, Martin Pollack, Jerome Feldman and Allan Isen for \$15 million each.<sup>8</sup> They settled outside of court in an agreement to part ways and make payments to Morrison in return for the NPDC having exclusive rights to the license. The settlement was reported to be for a total of \$250,000, a sum worth millions today taking into account market inflation. Morrison claims that if it wasn't for his signed makeshift deal on the inside of the book cover, he may have never had any rights to the patents at all.<sup>8</sup> He also is said to have offered to buy out their share at the time but lost the opportunity on a coin toss. At this time, the NPDC was still a relatively small company in terms of capital and part of the settlement agreement stated that if they missed one payment over the next 5 years, all rights would be forfeited back to Robert Morrison.<sup>2,8</sup> He was advised by his lawyers that this was a real possibility given the circumstances. However, he would have to wait to find out. Unfortunately for Morrison, the NPDC went elsewhere to cover their financial situation, and in October they brought on Bausch & Lomb to completely pay off their debt.<sup>2</sup> This effectively ended Morrison's connection to official licensure of soft contact lens production in America. B&L in return gained half ownership of the license, and it was at this point that the background work for U.S. production started to commence.<sup>2</sup> Allan Isen's involvement became more prevalent at this point but was also short lived. With the Bausch & Lomb agreement, Isen became the head of NPDC's soft lens division. He also consulted for B&L, but quickly realized he had a distaste for the corporate environment and left to work on his own contact lens laboratory, Griffin Contact Lenses, in Toronto, Canada.<sup>2</sup>

## 1968

Behind the iron curtain in Czechoslovakia, Otto Wichterle's involvement in scientific innovation became less prominent as he took on a more active role as a spokesperson in a rise against communism. In the past he had been restricted on travel, fired from various university positions and investigated by the secret police for his leftist political affiliations.<sup>3</sup> In the first half of 1968, liberalization protests had begun, and Wichterle was among 70 highly esteemed Czechoslovakians to sign a document known as the 2,000 Word manifesto.<sup>2,3,7</sup> Wichterle was very outspoken against the Eastern Bloc policies and occupying power in his country. In August of the same year, Warsaw Pact troops and Soviet tanks invaded the country ending the movement known as the Prague Spring. At this time, Wichterle and his family left the country with fears that outspoken individuals similar to Wichterle were going to be executed.<sup>7</sup> After months of living outside of their country's grasp and no such executions taking place, the Wichterle family returned home.<sup>7</sup> This was not without consequence, as upon his return, Wichterle was again restricted on travel, speech and work. It is around this time that Otto Wichterle retreated to a life of semiretirement in Czechoslovakia and focused on family life moving forward.

Back in America, Bausch and Lomb continued with their development of the soft contact lens. They voluntarily made an inquiry with the FDA in 1967 as to whether their developed soft lenses would be treated as a medical device and therefore require FDA testing and approval.<sup>2</sup> Initially, they were informed that they would not be required, and for a brief period in 1968 they began to introduce lenses on an experimental basis to the public.<sup>2</sup> Henry Knoll, a lead B&L scientist, reported that 140 patients were fitted in the lens and followed closely.<sup>9,10</sup> The protocol at this time included boiling the lens daily for disinfection and regular wear.<sup>9,10</sup> The lens appeared to have enough oxygen permeability as early indications pointed toward good corneal health and few adverse effects. On Dec. 12, 1968, however, the FDA ruled that soft contact lenses would be classified as a drug, which changed the course for soft lens production in the United States and significantly delayed the release of the technology.<sup>2</sup> Martin Pollack speculated that hard contact lens manufacturers were behind the change in the FDA's decision, but this has never been proven.<sup>2</sup>

Allan Isen at this time had already formed Griffin Laboratories in Canada and began to develop soft lenses outside of the U.S. and away from the NPDC, B&L and the FDA. Working with a University of Waterloo chemist by the name of Ken O'Driscoll,<sup>2</sup> they were able to develop a variation of the HEMA plastic, one that was reported to have 57.5% oxygen transmissibility.<sup>11</sup> They called the new material Bionite, which would become the basis for their branded soft contact lens, the "Naturalens" or the "Griffin Lens."<sup>2</sup> For Isen, one of the main advantages of the soft, highly permeable lens was its therapeutic use. Like Morrison and others before, Isen produced this lens through a lathe cutting technique due to the greater understanding of this method in the contact lens industry at the time.



In 1968 the politically outspoken Wichterle was expelled from the Institute of Macromolecular Chemistry and his travel was restricted. It is around this time that Otto Wichterle retreated to a life of semiretirement in Czechoslovakia. (Image courtesy the Wichterle family)

**Bionite Diagnostic Set**

- 7.3 / 14.0
- 7.5 / 13.5
- 7.8 / 13.5
- 7.8 / 14.0
- 8.1 / 14.0
- 8.1 / 14.5
- 8.4 / 14.0
- 8.4 / 14.5

In 1969 Allan Isen formed Griffin Laboratories in Canada and began to develop soft lenses outside of the U.S. and away from the NPDC, B&L and FDA. They called the new material Bionite, which would become the basis for their branded soft contact lens, the "Naturalens" or the "Griffin Lens." (Image courtesy the Contact Lens Museum)

Spin casting was new and very few people had experience with this process outside of Wichterle and B&L, who had acquired rights to the patents. During the 1960s, pseudophakic bullous keratopathy was a prevalent complication of cataract extraction, due to a higher risk of damage to the corneal endothelium. Isen's Naturalens was applied as a bandage to the cornea of patients experiencing painful, recurrent corneal erosions and ruptured bullae. The Bionite lens would go on to be one the first HEMA lenses made by lathe cutting that became mass produced for the public.<sup>2</sup> Later versions of the lens were well known in the market as the Softcon lens.

## 1969-1970

In Canada, Isen began working with Josh Josephson, O.D., at his contact lens practice in Toronto to fit patients with the new Bionite material. During the late 1960s, the soft lens still had not received FDA approval but word had spread, and Isen's soft lens design became increasingly coveted. American patients in search of an opportunity to be fit in this new contact lens modality flew across the border to see Drs. Isen and Josephsen. It was reported that patients would fly in with Allan Isen on a weekday, and Drs. Isen and Josephson would fit patients late into the night and fly out the next day. Dr. Josephson was an early, soft-lens clinician and made many observations and theories about how to properly fit a soft lens. Unbeknownst to most people, he was the person behind the push for soft lens evaluation.<sup>2</sup>

Bausch and Lomb during this time period was diligently working on their FDA approval, filing an Investigatory New Drug application in April 1969, a second New Drug Application in September of 1969, and another revamped New Drug Application in July of 1970.<sup>2</sup> Meanwhile, several other contact lens laboratories also began producing lathe cut soft lenses. It is estimated that several hundred companies infringed on the Wichterle patents during this time as "off-label" soft contact lenses began to emerge throughout the world.<sup>2</sup> Many costly and time-consuming court cases arose in the coming years with the NPDC and Bausch and Lomb attempting to prosecute the many laboratories that wrongfully profited without proper licensure.

## 1971

On March 18, 1971, Bausch & Lomb was granted FDA approval to market their "C-Series" Soflens in the United States. The lenses were FDA approved with a daily heat disinfection system that consisted of a modified baby bottle heater and saline made by combining a single salt tablet with non-sterile distilled water.

The 13.5 mm "C-Series" lenses were manufactured through a modified version of Wichterle's original spin-casting technology in which the base curve radius of the lenses decreased as the anterior surface power increased. Therefore, the base curves of the initial "C-Series" lenses were exceptionally steep.

"C" Series Power	Base Curve Radius
-1.00 D	8.00 mm (42.00 D)
-5.00 D	7.45 mm (45.25 D)
-10.00 D	6.90 mm (48.87 D)
-15.00 D	6.40 mm (52.75 D)
-20.00 D	5.95 mm (56.50 D)

The B&L Soflens was initially launched in the Pacific Northwest in 1971, followed by a national rollout that was highlighted by educational symposiums. By Thanksgiving, 1971, they had completed the nationwide launch of the new modality.

The "C Series" fitting set consisted of 72 lenses in a range of different powers. Practitioner cost for each set was \$2,800 (\$39.00 per lens). Additionally, practitioners had to attend one of the Bausch and Lomb regional training seminars at an additional cost of \$25.00 to be certified to fit the new lenses. To put those numbers into perspective today...

Lens cost: \$39 per lens in 1971 = \$252 per lens today

Trial set cost: \$2,800 in 1971 = \$18,079 today

Typical patient fees: \$300 in 1971 = \$1,937 today

Because the "C-Series" lenses tended to fit steeply on the eye, it was not long before Bausch and Lomb released two additional lenses this time with an overall diameter of 12.5 mm, the "Flatter" fitting F-Series lenses and the "Normal" fitting N-Series lenses.

-2.00 D., 12.5 mm F-Series Base Curve Radius = 8.35 mm

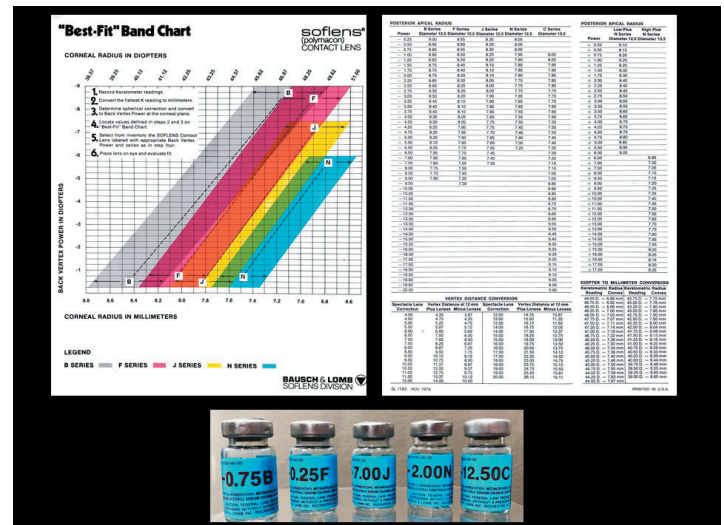
-2.00 D., 12.5 mm N-Series Base Curve Radius = 7.80 mm

This was quickly followed by two additional lenses, one the even flatter B-Series lenses and the steeper J-Series lens to fill the gap between the F and N Series lenses.

-2.00 D., 12.5 mm B-Series Base Curve Radius = 8.70 mm

-2.00 D., 12.5 mm J-Series Base Curve Radius = 8.10 mm

To aid practitioners with the initial lens selection, in 1974, Bausch and Lomb introduced the Best-Fit Band Chart describing the appropriate lens selection for the 12.5 mm B,F,J and N series lenses.



In 1974 Bausch and Lomb introduced the Best-Fit Band Chart. (Image courtesy the Contact Lens Museum)

**WICHTERLE RECOGNITION**

Due to Wichterle's political affiliations and his work being mostly conducted under a communist regime, he did not receive proper recognition for his contribution to the contact lens world until decades after completing his innovative work. In a capitalist country he may have been a very wealthy individual; however, this was not the case in Czechoslovakia. The income laws at the time were amended to reduce his income so that he would not receive more pay than high-ranking political officials.<sup>7</sup> The licensing deal that had occurred with his soft contact lens designs was considered one of the most profitable transactions in the country for a long time. However, recognition finally came to Otto Wichterle after Czechoslovakia transitioned away from its socialist ideologies.

In all, Otto Wichterle:

- wrote six textbooks
- had over 100 scientific publications
- held over 180 patents
- was appointed as president of the Czech Academy of Science in 1990
- had an asteroid (#3899) named after him in 1993
- was honored with a statue erected outside the Institute of Macro-Molecular chemistry in 2005
- was honored in 2013 by the Czechoslovakian government on the 100th anniversary of his birth with the issue of a commemorative currency
- was honored by the issuing of a commemorative Czechoslovakian stamp on Oct. 16, 2013.

There is no doubt that Wichterle was fundamental in the innovation and development of soft contact lenses. On Aug. 18, 1998, he passed away in his home country and forever remains a legend in the history of contact lenses.



On March 18, 1971 Bausch & Lomb was granted FDA approval to market the Bausch and Lomb Soflens. The B & L "C" Series was the first hydrogel lens approved by the FDA for the U.S. market. (Image courtesy the Contact Lens Museum)



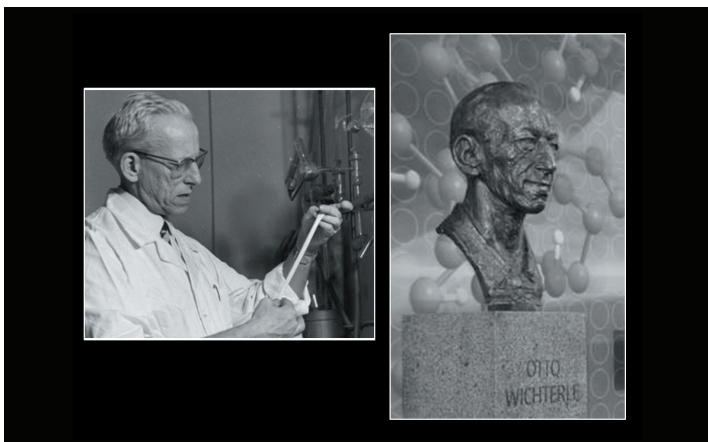
The "C-Series" lenses were FDA approved with daily heat disinfection that consisted of a modified baby bottle heater and saline made by combining one salt tablet with non-sterile distilled water. (Image courtesy the Contact Lens Museum)



Czechoslovakian commemorative currency issued at the 100th Anniversary of the Birth of Inventor and Chemist Otto Wichterle. (Image courtesy the Contact Lens Museum)



Czechoslovakian Stamp issued Oct. 16, 2013 commemorating Otto Wichterle's birth in 1913. (Image courtesy the Contact Lens Museum)



Otto Wichterle passed away on Aug. 18, 1998 at the age of 84. (Image courtesy the Wichterle family)

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# TOWARD DISPOSABILITY OF CONTACT LENSES

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**ABSTRACT**

*This article provides a history of the evolution of soft contact lenses and discusses the advancement of manufacturing and packaging techniques that ultimately led to the development of disposable lenses. This article covers contact lenses from the first soft lens polymer produced in 1961 to the first disposable in 1987 and the evolution into toric and multifocal markets.*

**KEYWORDS**

*Hydrogel lenses, disposable contact lenses, Wichterle, Soflens, spincast, cast molding, stabilized soft molding, form cast, ACUVUE®, Maximize process*

The contact lens industry prior to the introduction of disposable lenses could be compared to the Wild West. Fortunately, there have been many players and characters that brought soft contact lenses to the frontier as we know it today. The sharpshooters kept advancing the contact lens industry with new lens materials, manufacturing techniques and wear schedules. It was not until 1968 that the U.S. government wanted some control over this revolution.

The involvement of the Food and Drug Administration (FDA) was encouraged by contact lens companies.<sup>1</sup> Contact lens laboratories who used rigid materials, such as polymethyl methacrylate (PMMA), were exempt from the proposed new regulations, and they urged the government to classify the new and upcoming hydrogel lens material as a “drug.”<sup>2</sup> In 1968, the U.S. government decided that a soft hydrogel contact lens should be “regarded as a drug” and would need FDA approval before it could be made commercially available. Moving forward, any new lens materials would go through the drug approval process of clinical trials, pre-market toxicological trials, regulations and documentation.<sup>1</sup> This decreased the introduction of new materials and designs in the U.S.<sup>1,3</sup>

**PMMA LENSES**

Prior to FDA regulations of contact lenses and the invention of the hydrogel lens, PMMA which was developed in 1936, was the primary material for contact lenses.<sup>4</sup> PMMA lenses were unlikely

to be worn overnight. Although the lenses were durable, the physiological responses from patients were significant.<sup>3</sup> Hard lens wearers may well have been satisfied with their lenses, but they expressed albeit an unconscious relief in removing their lenses including vigorously rubbing of their eyes. This complaint barely existed with the new hydrogel materials.

**HYDROGEL LENSES**

Hydrogel lenses were able to improve wear and comfort for patients when compared to prior lens materials.<sup>5,6</sup> Hydrogel lenses became popular in the 1970s. When these soft lenses first appeared, wearers could envision the new ways in which these lenses might be worn, starting with all-day wear with little or no lens awareness.<sup>3</sup>

Soflens by Bausch + Lomb was the first soft hydrogel lens to come to market in the U.S. in 1971.<sup>4</sup> Soflens was destined to become a three-year monopoly for cosmetic wear lenses once it was approved by the FDA, because it took this long for the next U.S. approval.<sup>4</sup> This material was due to the combined work of Otto Wichterle, a Czech polymer chemist, and his associate Drahoslav Lim.<sup>4</sup>

Hydrogel lenses improved oxygen performance.<sup>6</sup> Due to the high risk of hypoxia with PMMA lenses, an increase in Dk was a great feature of the new hydrogel lenses. Dk refers to the oxygen permeability of lens material. This is a calculated variable and is used to compare lenses by the amount of oxygen flow.<sup>7</sup> Dk/L

is the transmissivity of the lens and the higher the Dk/L, the higher the oxygen levels being transmitted to the eye.<sup>7</sup> Oxygen permeability, or Dk, of a lens depended on the lens water content and thickness.<sup>7,8</sup> These new hydrogel lenses had low (38%), medium (50-65%) or high (68-80%) water content. Therefore, the Dk or oxygen permeability would vary between the lenses.

There were complications experienced by hydrogel lens materials. Protein, among the most bothersome deposits on HEMA lenses, could create a short wearing life. Research showed that proteins could begin early. Among patients who were high producers, the hydrogel lenses would begin to spoil within 30 minutes of wear time and deposits could be detected after one minute of wear.<sup>6</sup> As a result of inflammation, patients also experienced neovascularization and papillary conjunctivitis with hydrogel lenses.<sup>6</sup> In addition, the first hydrogel lenses were less durable when compared to PMMA lenses and had variable optics.<sup>1,6</sup>

Cleaning was also challenging for these early lenses. Care systems for hydrogel lenses included hydrogen peroxide systems, cold chemical systems, a proteolytic enzyme, heat disinfection, and homemade saline solutions. Early contact lens disinfecting systems had their own complications and were known to cause corneal staining, palpebral hyperemia, itching and dryness. Many early chemical systems contained chlorhexidine and thimerosal which led to ocular reactions.<sup>9</sup> The complications from solutions resulted in discomfort and dryness, which are the main reasons that lens wear was discontinued.<sup>10,11</sup>

In the 1970s to the 1980s, lenses were prescribed with no clear instructions given regarding replacement schedules of contact lenses.<sup>12</sup> The early soft hydrogel lenses were usually worn until the lenses became too uncomfortable to wear, were lost or damaged, caused eye infections, or negative reactions to the lens were noted.<sup>5</sup>

Due to the early soft contact lens issues of lens deposition and spoilage, these factors impeded successful long-term wearing of contact lenses.<sup>12</sup> The obvious solution would be a regular replacement, but the cost was still prohibitive at the time.<sup>5,12</sup> A testament to the history of the soft contact lens was its inventor, Otto Wichterle. He was a Czechoslovakian chemist and a lifelong political dissident, who initially had little knowledge of hard contact lenses. Having the means to produce multiple soft lenses economically, as early as 1963, he was also the first to introduce and propose disposable contact lenses. At a 1980 meeting of the International Society for Contact Lens Research, Wichterle's comments to a group of researchers defined the many areas which would confound the field for the next 25 years. Wichterle said<sup>3</sup>:

"I think the problem of deposits have so many variables involved that it is impossible to make any general statement.

"The materials vary widely... along with patient reaction. I met an elderly lady recently in Vienna who was wearing a lens I prescribed 20 years ago. She has never cleaned or disinfected

the lens and it is absolutely water-clear. I am sure you can bring me examples of lenses covered by deposits after one week. Environment also plays a great role.

"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 [1963], 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."<sup>3</sup>

## MANUFACTURING ADVANCEMENTS

The advancements in the manufacturing of contact lenses helped with the development of new lenses, which would eventually lead to disposable contact lenses. In early contact lens history, labor was one of the largest contributors to manufacturing cost. For example, early lenses were magnified and inspected more than 10 times by trained technicians for any flaws or imperfections.<sup>12</sup> As production techniques improved, these inspections were no longer required. Each new method reduced production costs and improved quality. The improvements eventually allowed disposable lenses to become possible.

PMMA and early hydrogel lenses were produced by lathe cutting. This process was more expensive since it required a lathe to cut each lens out of dry material and secondarily hydrate the final product.<sup>13</sup> Lathe cutting had poor reproducibility and required an evaluation of every lens before being dispensed to the patient.

### Spin casting

Spin casting, which was used to create the first hydrogel lens, was created by Professor Wichterle.<sup>5</sup> Wichterle used a mechanical "erector set" he borrowed from his son using a glass mold for the films. He built this spin-casting device on Christmas Eve 1961 in his kitchen by using a centrifugal casting to form polymeric thin films, an axle from his son's bicycle to spin the mold and a motor from a phonograph.<sup>4,12</sup> Wichterle's polymer HEMA hydroxyethyl methacrylate was heated with a hot plate and was added to the mold through a tube as it was spinning.<sup>4</sup> The patent application for the spin casting of HEMA hydroxyethyl methacrylate lens was finished by New Year's Eve 1961.<sup>7,12</sup>

Spin casting allows the lens optics to be varied by changing the speed of rotation and/or the mold shape.<sup>13</sup> It allows for higher production of lenses than lathe cutting.<sup>13</sup> The original HEMA lens had poor quality and was made of thick yellow material but had improved comfort for the patients.

In 1966, Bausch + Lomb received the sublicensing of the Wichterle patent. The company received exclusive rights for the spin-casting process and nonexclusive rights to hydrogel lens distribution based on this technology.<sup>3</sup>

Bausch + Lomb used Wichterle's polymer to help design the first hydrogel lens in the U.S., Soflens. Due to FDA regulations, Soflens did not come to market until 1971.<sup>7</sup> Cost was still prohibitive at this time for disposable lenses to become a reality. Manufacturers used techniques to further lens life, as well as explored surface and materials modifications that would improve performance.

Over the next 10 years, other polymers evolved and the distribution rights benefitted from the nonexclusive license. This opened the door for competitors to the soft lens market.<sup>7</sup>

### **Cast Molding**

Cast molding started being used in contact lens production in 1980, however, the cast molding process was not a new process. This had been used for years in the manufacturing of plastic products.<sup>12</sup> Cast molding begins by placing a plastic monomer between two molds. This plastic polymerizes between the molds. After polymerization is complete, the molds are broken apart forming the end product, in this case, a contact lens.<sup>12</sup> The contacts were then hydrated and placed in packaging and were now ready to be sold.<sup>12</sup> In November 1980, American Hydron was the first contact lens company to receive FDA approval for this process. This process was used to produce low-water content polymacon lenses and increase production capacity tenfold without additional labor.<sup>12</sup> American Hydron was purchased by Allergan in 1983.<sup>12</sup>

### **Stabilized Soft Molding**

Johnson & Johnson started in the contact lens arena by acquiring Frontier Contact Lenses in 1981.<sup>4,12</sup> Dr. Sheldon Wechsler from the University of California Berkeley School of Optometry attended and likely heard Dr. Wichterle introduce the idea of disposable contact lenses. Dr. Wechsler helped Johnson & Johnson/Vistakon introduce the first disposable contact lens. In 1984, the contact lens division was renamed Vistakon and it purchased the Stabilized Soft Molding (SSM) process through a Danish manufacturer.<sup>12</sup> SSM is a cast-molding process that allows high water content lenses to be manufactured with "minimal expansion on hydration."<sup>12</sup> By adding an inert diluent to the initial formula, it occupies space that is later replaced by water and the diluent is extracted. This process results in minimal expansion during hydration.

When Johnson & Johnson/Vistakon acquired the SSM process, they also attained the Danalens technology, which used the SMM process. The Danalens, which was released in 1982 and was the world's first disposable contact lens, was completely revamped for the U.S. by Johnson & Johnson/Vistakon. Johnson & Johnson/Vistakon changed the polymer formulation, packaging and molding technology.<sup>5,12</sup> They introduced the first disposable

contact lens using multi-lens plastic packaging. The Danalens and SMM technology were used in the production of the ACUVUE lens in 1987, the first FDA-approved disposable contact lens.<sup>2,5,12</sup>

The FDA defines a disposable lens as a single-use lens that is thrown away and not used again.<sup>12,14</sup> Single-use is the qualifying feature, as no cleaning or disinfecting is required.<sup>12,15</sup> Two modalities fit this definition, a weekly disposable worn seven days/six nights and discarded upon removal and a daily disposable worn up to one day and discarded upon removal at end of the day.

ACUVUE, a 58% mid-water content lens made of etafilcon A ionic material, was one-week extended wear (EW) lens. Initially, Johnson & Johnson/Vistakon lenses were EW in order to provide a safer lens, since hygiene and lens handling were thought to be the source of increased infections with contact lenses.<sup>7,16</sup> This was incorrect, and disposable EW were not safer than conventional EW contact lenses.<sup>7</sup> Even though safety did not improve with disposable extended wear lenses, they succeeded in changing the industry and patients found the new lenses to be an appealing option.<sup>7</sup>

### **Spin-cast Front, Lathed Back**

Bausch + Lomb developed this method in the mid-1980s for their conventional Optima lenses which were a premium design of daily wear and EW lenses. It was also used for the second generation of their disposable products, SeeQUENCE 2.<sup>12</sup> This was used due to a decline in the popularity of the spin cast design lenses.<sup>12</sup> The process used a reverse process III or RP III which formed a spin-cast front surface and posterior surface and was then lathed and polished.<sup>12</sup>

## **PACKAGING**

Advancements in packaging also helped disposable lenses become a possibility. In the past soft lenses were placed in glass vials, sealed with silicone stoppers and crimped with aluminum caps.<sup>12</sup> Johnson & Johnson/Vistakon were the first to develop small individual blister packs. It had acquired the blister pack technology from the Synoptic group; however, Johnson & Johnson/Vistakon encountered issues with the original design as it was not always airtight, leading to possible contamination.<sup>12,17</sup>

Soft lenses were eventually packaged in multiple packages or boxes, so as to have a supply that the practitioner adapted to the patient. With the new packaging, lenses were shipped in multipacks containing six blister packs.<sup>12</sup> Johnson & Johnson/Vistakon reduced costs by producing molds and packaging into blister packs on a production line. This process lowered the per lens cost by reducing labor costs and increasing automation.<sup>5,12</sup>

## **DISPOSABLE LENSES**

### **Daily**

Dr. Hikaru Hamano, who had the largest contact lens practice in the world at the time, educated Johnson & Johnson/Vistakon on the need for a daily disposable lens.<sup>5</sup> Dr. Hamano showed this

through his clinical and research experience. Johnson & Johnson/Vistakon listened and developed their first daily disposable lens in 1995, the 1-Day ACUVUE.<sup>5,18</sup> The company had to commit large amounts of capital and human resources to create a second-generation manufacturing process. This was needed to lower costs to make daily lenses an affordable product.<sup>5,12</sup> This process was called MAXIMIZE.<sup>12</sup> The MAXIMIZE process, optimized polymerization, and hydration time established the use of conveyors, robotics, a computerized high-resolution inspection of lenses and other improvements. This process integrated the SSM manufacturing process, which was the main contributor to the success of Johnson & Johnson/Vistakon in the disposable lens business. By 1994, more contacts were manufactured using this process than by all other processes worldwide.<sup>12</sup> These new daily disposable lenses were shown to have fewer symptoms, fewer deposits and better vision. The use of trial lenses allowed for more accurate prescriptions than the previous non-disposable lenses.<sup>11,19</sup>

With the success of the daily disposable lenses, more lens wearing options were introduced to provide contact lenses for more wearers. The first daily disposable astigmatism lens design was Focus Dailies by Ciba Vision. It was introduced in 2002.<sup>18</sup> The first daily multifocal lens design was Focus Dailies Progressives, also by Ciba Vision. More and more disposable wearing options continued to be marketed and entered into the contact lens industry.

### **One Week**

As previously mentioned, ACUVUE from Johnson & Johnson/Vistakon was the first weekly disposable introduced in 1987. In the expansion of its product lines, the company designed the first disposable presbyopic lens, ACUVUE Bifocal.<sup>20</sup> This was introduced in 1998 and was a one-week extended wear lens.<sup>20, 21</sup> It was a center distance concentric design that used alternating distance and near zone powers. The add powers available were +1.00 to +2.50 in half diopter steps.<sup>22</sup>

### **Two Week**

After the success of ACUVUE, Johnson & Johnson/Vistakon turned around and introduced the Surevue. It was its first lens manufactured as a daily two-week replacement lens.<sup>12</sup> Patients were to remove the lens daily for cleaning and storage and dispose of the lens at the end of two weeks.<sup>12</sup>

### **Monthly**

In 1999, PureVision from Bausch + Lomb was the first lens approved for 30-day continuous wear.<sup>23,24</sup> This was due to the silicone hydrogel material. The new silicone hydrogel material improved oxygen transmissibility and helped with hypoxia.<sup>11,25</sup> Silicone is highly oxygen permeable and hydrogel has a fluid and ion transport benefit.<sup>24</sup> Silicone hydrogel is considered to be one of the most important advancements in contact lenses since Wichterle developed the hydrogel lens.<sup>5</sup>

Also, in 1999 Ciba Vision launched the first disposable toric lens, Focus. This was a monthly disposable lens.<sup>18</sup> It was shown that comfort could be equal between toric and spherical contact lenses.<sup>18</sup>

### **Multimonthly**

Bausch + Lomb's FRESHLENS program began in 1985. This was the first three-month disposable lens. This extended wear program enrolled patients wearing the O3 or O4 series lenses for three months. The patient was enrolled after receiving their initial pair in office. They were mailed two weeks later two glass vials marked right and left and tweezers to remove from the vials with instructions. Three months after receiving their initial pair, they were mailed a reminder to replace the initial lenses with the new pair. The lenses would then be returned to the provider at six months and the cycle was repeated. This program was not accepted by everyone due to many being uneasy at releasing home addresses to the manufacturer.<sup>12</sup>

By the year 2000, 43% of all wearers were in disposable contact lenses. The other 21% of wearers were in frequent replacement and the remaining 36% were conventional wearers.<sup>19</sup> In less than 15 years the contact industry had made a huge shift in usage.<sup>14</sup>

### **VISUAL PERFORMANCE AND SATISFACTION WITH DISPOSABLE LENSES**

The early disposable lenses were inconsistent in visual performance and handling due to manufacturing and designs. Subjectively, the 1-Day ACUVUE lenses performed visually superior to conventional and frequent replacement lenses.<sup>15</sup> However, the original handling of the 1-Day ACUVUE was clinically more difficult than conventional lenses. Since handling is a learned procedure, this was not a major issue.<sup>15</sup> Most patients ranked their satisfaction higher with disposable lenses than with conventional lenses at that time.<sup>15</sup>

### **Convenience of Disposable Lenses**

Convenience has been the primary factor driving the increased usage of daily disposable lenses.<sup>10,26,27</sup> Children and teens are a large population that is attracted to daily disposable lenses.<sup>10</sup> Parents find these lenses appealing for safety reasons.<sup>10</sup> Also, since there is no lens care required, this eliminates the possibility of running out of solutions at an inopportune time. Before the availability of disposable lenses, the thought of losing or tearing a lens made parents apprehensive to purchase contact lenses for their children. Having access to disposable lenses allows for early replacements which can help address the concerns of lost or torn lenses.<sup>10,15</sup>

Disposable contact lenses are also helpful for patients with occupations where conventional lenses do not work well. These include dusty environments, chemical plants and other places where a fresh lens would aid in comfort and safety for the patient.<sup>10</sup>

For the practitioner, convenience meant more competition. The options of mail-order contact lenses began in the 1980s. These were initially small businesses set up within locally established labs.<sup>7</sup> State laws limited these businesses and issues with the release of contact lens prescriptions by doctors limited their growth.<sup>7</sup> The Federal Trade Commission put into effect the law, Eye Glasses I. This law mandated that the patient had a right to their prescription.<sup>7</sup> Laws are now in effect that allow contact lens manufacturers to sell directly to these mail-order contact

lens businesses and they continue to grow with health care plans mandating where lenses may be purchased and increased internet usage.<sup>7</sup> Mail-order companies have found convenience to be the single factor driving business to them in the contact lens market, ranking higher than price.<sup>28</sup>

### **Ocular Health with Disposable Lenses**

None of the early disposable lenses met the oxygen requirements for extended-wear, thus leading to early hypoxic reactions.<sup>12</sup> In 1987, the FDA changed approval for extended wear from 30 days to only seven days.<sup>9,14</sup> As technology advanced, several disposable lenses were able to meet the Dk/t requirements for extended wear. Dk/t refers to the oxygen permeability in relation to the thickness of the contact lens. The minimal DK/t for daily wear is 24.1 and overnight or EW is 84.0.<sup>6,29</sup>

According to clinical opinion in the 1980s, lens handling played a large part in the incidence of microbial keratitis.<sup>7</sup> This general opinion helped advance disposable lenses when they arrived in 1987.<sup>7</sup> The use of disposable lenses grew due to increasing concerns over microbial keratitis and corneal ulcers noted with EW lenses in the 1980s.<sup>12,30</sup> The Contact Lens Institute reported 5-15 times higher incidence of ulcerative keratitis in EW patients than seen with daily wear (DW) patients. However, studies by the Contact Lens Institute in the late 1980s showed disposable EW lenses caused sterile peripheral ulcers versus EW conventional lenses that caused more sight-threatening infectious microbial ulcers.<sup>12</sup>

Studies in the 1990s all agreed that daily disposable lens usage was the most convenient and healthiest lens option.<sup>12</sup> Daily disposables decreased the incidence of corneal staining, epithelial cysts, corneal edema, tarsal abnormalities and infection versus conventional and frequent replacement lenses.<sup>6,15</sup> Daily disposables also caused fewer allergy symptoms.<sup>10,26</sup> Daily disposable lens wearers were three times less likely to experience complications versus conventional lens wearers.<sup>6,31</sup>

A three-year study was performed in the early 1990s comparing the performance of 229 subjects wearing a daily-disposable lens, frequent replacement lens, or conventional DW lens. The results supported the clinical advantages of daily disposable.<sup>12</sup> It showed decreased reports of redness, cloudy vision, dryness and foreign body sensation.<sup>12</sup> Better visual acuity, comfort and overall satisfaction were noted.<sup>12</sup>

Disposable lenses eliminate ocular health problems related to contact lens disinfectants.<sup>32</sup> These lenses require no care, eliminating solution sensitivity and toxic reactions.<sup>32</sup> New lenses do not degrade and cause vision and fit variations.<sup>32</sup>

### **Marketing**

Commercialization of hydrogel lenses can be attributed to Martin M. Pollak and Jerome J. Feldman of National Patent Development Corp. through licensing Wichterle's technology to Bausch + Lomb.<sup>14</sup> This got the ball rolling for the contact lens industry. Johnson & Johnson/Vistakon introduced the ACUVUE Disposalens in 1986.<sup>12</sup> In early test markets in Florida, little

excitement about the lenses was noted.<sup>12</sup> The key to acceptance was a low price and complimentary diagnostic lenses. The lens was released nationally in June 1988. This was the beginning of a new era in contact lenses.

Johnson & Johnson/Vistakon was the first manufacturer to do direct advertising of the prescription product to the public.<sup>7</sup> This was a multimillion-dollar investment.<sup>7</sup> The advertisements were based on increasing patients in the providers' office.<sup>7</sup> This led to other pharmaceutical companies following suit and advertising prescription products which is a common practice today.<sup>7</sup>

In conclusion, one can see the great achievements these pioneers have accomplished within 60 years. Continuously, new products are emerging supplying practitioners more lenses than they can even begin to contain within their practices. Practitioners have to continually assess their collection of lens designs for their practice and patients' needs. Through more education, they are able to pick and choose what they believe will suit their patient's needs and wants. There is no doubt that disposability is the future and to think it all started on Christmas Eve 1961.

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# COUPLING OF THE INTERNATIONAL SOCIETY FOR CONTACT LENS RESEARCH WITH THE EVOLUTION OF SOFT CONTACT LENSES

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**ABSTRACT**

*The advent of soft contact lenses and the paucity of knowledge of the new modality encouraged some leading minds of the time to form a new society, the International Society for Contact Lens Research. The purpose was to provide a forum for the exchange of information on the most current research and developments of contact lenses and its effects on the eye. The limited membership of the society that the founders proposed was to stage scientific meetings that would have minimal presentation time to allow for maximum discussion time of the presented information. Unconcerned about the risk of failure and recriminations of establishing a society of limited membership, the bold steering committee invited researchers involved in this new science and development of contact lenses to become members. The steering committee also realized that it was necessary to enfold the contact lens industry and their scientists in the society. Here we outline that journey from 1978 and how the society has maintained currency. The society, through its scientific meetings, can lay claim to fostering research that led to important developments in the field of contact lenses.*

**KEYWORDS**

*Contact Lens, history, hydrogel, ISCLR, Scientific meeting*

**HISTORY OF THE SOFT CONTACT LENSES**

The 1970s heralded the development and expansion of the contact lens industry. The use of PMMA as a reliable material for corneal and scleral lenses had been established but had significant limitations, primarily discomfort and close to zero oxygen transmission. At the time of the launch of soft lenses in the United States of America (US) there were only 3.962 million rigid contact lens wearers in the US according to a survey conducted by the U.S. Department of Health, Education and Welfare.<sup>1</sup> The U.S. company Bausch and Lomb acquired the license for spincasting soft contact lenses (SCL) developed by Otto Wichterle described by Myers.<sup>2</sup>

As for the rest of the world, the Czechoslovakian government had agreed to a worldwide rights agreement with the National Patent Development Corporation (NPDC) for use of the latheable hydrogel material option. The NPDC enabled companies in three key markets to emerge: Australia (Hydron); England, where

John DeCarle consorted with Cooper Labs to develop the Permalens, Philip Cordrey developed the Sauflon lens; and finally in Germany, Titmus Weicon and Wohlk to develop their SCLs. The big advantage of a latheable hydrogel material was that these hydrogels could be manufactured by adapting the lathes that laboratories used to generate PMMA lenses.

**THE GENESIS OF THE INTERNATIONAL SOCIETY FOR CONTACT LENS RESEARCH (ISCLR)**

Knowledge and science of the emerging soft contact lens field in the mid-seventies was limited. This led to different emphases around the world and created an opportunity to harmonize the communication of knowledge through an international association of ophthalmic professions according to Myers<sup>3</sup>. A group of forward-thinking individuals discussed a plan to establish an umbrella organization of national contact lens

associations (Contact Lens Association of Ophthalmologists in the U.S., British Contact Lens Association, the Australian Contact Lens Society and other contact lens sections of various ophthalmology and optometry associations). Alternatively, individual practitioners could become members of an international contact lens association. The initial individual 'thinkers' formed a steering committee which was notable by their diversity;

Professor Montague Ruben, ophthalmologist and director of the Contact Lenses and Prosthetics at Moorfields Eye hospital in the United Kingdom

Raymond Myers, optometrist, Manager of International Professional Services at Bausch and Lomb, Rochester, New York

Robert Koetting, optometrist in St Louis, Missouri

Brien Holden, optometrist and lecturer, School of Optometry, University of New South Wales, Sydney, Australia

Antonio Gasset, ophthalmologist, Gainesville in Florida

Michel Guillon, optometrist and PhD student, Moorfields Eye Hospital



Montague Ruben



Raymond Myers



Brien Holden



Michel Guillon

This founding group discussed how to integrate contact lens research and then disseminate the information. At that time ophthalmology and optometry were disparate. Ophthalmology recognized the potential benefits of contact lenses for therapeutic and drug release use and optometry was focused on vision correction. To add to the complexity, at the national

level relationships between these two professions were wide ranging, as was the scope and ability of optometry. The steering committee recognized the mutual benefits of collaboration at an individual level, but how to facilitate that at an international level was a challenge. The first meeting of this committee occurred at Moorfields Eye Hospital (London, England) in June 1978, was funded by the NPDC and was attended by those listed except for Dr Gasset. Discussion ensued about the political difficulties between the professions (particularly in Europe). Holden, who was a late arrival at the meeting, proposed an alternative to a contact lens association of practitioners to overcome the political differences by "establishing a research society of active researchers within academia, ophthalmology and optometry that would be devoid of political affiliation." The group finally agreed that "it was the dissemination of research, rather than the collegiality of a larger group, that would make the difference in contact lens research and development"<sup>3</sup>. They decided on the name, the International Society for Contact Lens Research (ISCLR).

Prior to the steering committee meeting at Moorfields, the members had contacted a number of international acquaintances, some of whom had expressed interest in an international contact lens association. As a result of the change to a research society, a new group of potential members were contacted, some of whom were on the original list that would have basic or clinical research credentials, to fulfill the needs of the society. The committee also felt that it was critical to include manufacturers of soft contact lenses because of the international growth of their field and because of the nature of the society, it was felt that the company scientists would be useful contributors.

Soon after the meeting of the steering committee at Moorfields, planning began for the first ISCLR symposium to be held at the Royal College of Surgeons in London, England on September 5-6, 1980. The inaugural two-day meeting attracted an attendance of 50 researchers and industry representatives including soft contact lens inventor Otto Wichterle. In Ruben's welcoming address he announced that Professor Wichterle would be the patron of the new research society. The steering committee was replaced by the Society Council of 21 members and the following slate of officers:

Patron: Otto Wichterle

President: Montague Ruben

President Elect: Brien Holden

Vice President: Michael Lemp

Vice President: Miguel Refojo

Secretary-Treasurer: Raymond Myers

Assistant Secretary: Michel Guillon

The invited manufacturers/sponsor representatives in attendance were: Allergan, Alcon Laboratories, Bausch & Lomb, CIBA Geigy, Cooper Labs, Dow Corning, Hydron, Hydrocurve, Kelvin Lenses, Smith and Nephew, Syntex and Toyo.

The inaugural meeting schedule was set to reflect the key topics of the day:

Corneal oedema and oxygen needs

Physiological and pathological responses to contact lenses

Systems for disinfection

Lens spoilation

New measurement techniques

One of the most prophetic comments about lens spoilation was Dr Wichterle's remarks that the solution to lens deposition was to replace the lens because he believed that technological development will dramatically decrease the cost of the soft contact lens and approximately seven years later Vistakon launched disposable contact lenses.

## MEMBERSHIP

The steering committee effectively set the credential criteria and "standard" for prospective members of the ISCLR. While an attempt was made to invite individuals with a high level of research ability to the first meeting in London of this fledgling society, the steering committee was mindful to include clinicians with some research experience in the contact lens field as well as a reasonable publication record. The aim was to establish a society with a complexion of active researchers in the field of contact lenses that included optometrists, ophthalmologists and scientists in allied fields who could contribute fresh perspectives to help understand the nuances of contact lenses and resulting ocular responses.

The council met at the first symposium in London in 1980 to determine the size of the society. The decision was to limit the number of members primarily because the type of symposium that was envisaged by the council would be focused on "discussion" that would follow short presentations. There was also a concern about how to finance the society and whether members could afford the cost of attending the meeting due to international air travel. It was then agreed to limit the membership to 100.

In order to continue to hold membership within the society, members had to attend at least one of two consecutive scientific meetings as the criterion for active membership was attendance and participation at these meetings. The vibrancy of the society was influenced by new developments and to entice young researchers in the field to become members to ensure turnover of membership. This was made possible by those who lost interest in the society or deviated to other fields ceasing membership. By way of example, between the periods 2010 to 2020, 54 new members joined the society. Approximately 30 applications are received during each two-year cycle of membership review. Prospective members, based on acceptance as members of the society following ratification by the council, were also invited to attend the meeting.

## THE SCIENTIFIC MEETING

Lengthy deliberations of the council over the first several meetings led to a format for future scientific meetings that would include keynote addresses by selected experts who were not necessarily members of the society and short presentations by members that would follow the keynotes in selected session themes. Each session would be controlled by a moderator. This would be followed by discussion amongst panelists in each session with encouraged participation by the rest of members. The intention was to devote the majority of the time for discussion in each session of the symposium, rather than presentations. This "think-tank" concept was similar in style to

the Gordon Conferences that various members had attended. The meeting would be "closed," meaning that it was restricted to the members, invited keynote speakers, prospective members and eventually graduate students. The principle was to allow members and their students to present unpublished research of novel concepts to elicit discussion. Contact lens corporation research and development employees were also invited to participate. Following the first meeting in London, future meetings spanned five days in duration. Another stipulated restriction was that the leading-edge research presented and discussed could not be published (in the form that it was presented), publicized, quoted or cited nor distributed, other than through the written or recorded transactions by the Society to the meeting attendees and members of the society who were not in attendance.

It wasn't until 1990 that the vision of the society was finally and suitably described by Michael Lemp: "The basic framework of the organisation was to bring together, in an informal setting, a limited number of individuals from different disciplines, united by their interest and proven expertise in the field of contact lens research." And so the blue print was established for an exchange of new ideas and the most current research on contact lenses and allied fields. The meeting format developed continues to this day. It was decided that the meeting would be held every two years, rotating though North America, Europe and Asia Pacific. This reflects the goal of keeping the society and its membership truly international. Twenty-one scientific meetings have been held since 1980.

## THE CONTACT LENS AND ALLIED CORPORATIONS

The steering committee realized that involvement by the manufacturers was critical to the launch and success of the society for a number of reasons. The growth opportunities in the hydrogel contact lens market was highly dependent on the innovation, research and development of each corporation and their scientists. These researchers would obviously benefit from the scientific interaction at the ISCLR meeting, could also contribute important knowledge (without divulging proprietary information) and would meet the leading researchers and clinicians in the field.

In return for participation, the manufacturers were asked to make a financial contribution to support the scientific meeting. This was done and the companies have contributed to every one of these meetings held biannually for 40 years. This can be counted as an astounding success story where companies who would normally be competitive, collaborated to pursue scientific advancement of the field.

## INVOLVING THE NEXT GENERATION

One of the great features of the ISCLR and its meeting is it offers an opportunity for higher degree research students to attend and present their work that could be discussed in real time with some of the leading researchers from the society and invited keynote speakers. In turn, members were able to assess the students as potential members for the society. According to Myers' records<sup>3</sup> graduate students attended the first meeting in London in 1980 and for the next symposium in Montreal, four students were invited. In the latter years the number of student attendees was increased to 16 from approximately 30 solicited applications per meeting. Not all were offered the opportunity to do short verbal presentations, but all students presented their work as posters. The

students had to be affiliated with members of the society.

## RESEARCH AND DEVELOPMENT IN THE SOFT CONTACT LENS FIELD SPAWNED AND STIMULATED BY THE ISCLR

This biannual meeting would fundamentally be like no other in so much that it was focused on the science of contact lenses with a debating/discussion meeting style. The meeting design has continued to the present day, with the philosophy to continue to bring great contact lens minds together, and to seek out leaders in other fields that might help unravel problems that have plagued our industry and to develop concepts and ideas on how to improve contact lens success.

All the researchers (basic and clinical) who were attracted to the ISCLR were independently and collectively conducting research in this new science and did not necessarily need the ISCLR to guide their research endeavors. However, the ISCLR can lay claims for assembling the members and synthesizing their information that in many cases provided the impetus for direction. This has been the case over the past 40 years but it is far beyond the scope and space allocation of this paper to describe the 21 scientific meeting discussion and transactions but some important ones that had significant influence on the field will be included. Myers' book<sup>2</sup> provides some information but does not include communication from the meetings beyond 2009. Members can access the ISCLR web site for more details on these meetings.

### THE FIRST SCIENTIFIC MEETING, LONDON 1980

The extraction from the program and transactions of the first scientific meeting in London is a great example of the themes that were discussed. The two-day meeting comprised of 6 sessions: corneal oxygen needs and edema, responses of the ocular tissues to contact lenses, pathological responses, systems for disinfecting lenses, new techniques for patient evaluation and lens spoilation.

In the first session, consider the topics: measurement of corneal oxygen consumption and its relationship to corneal swelling, the minimum oxygen tension to avoid corneal swelling, etiology of hard and soft lens induced edema, corneal oxygen requirements for open and closed eye conditions with and without lens wear; epithelial, endothelial and sensory response to contact lenses, pathological responses such as inflammation, chronic hyperemia, vascularization and the "red eye" syndrome, reaction to solutions cytotoxicity and corneal infections; discussion on the tear layers and meibomian glands and lens deposits. At this first meeting, discussions on how to reduce the cytotoxicity from lens care systems highlighted the issues that occurred from the preservatives used in lens care. We had to wait seven years for the first multipurpose lens care system (Renu) to be launched.

### AN EMPHASIS ON OXYGEN

Many of these themes continued at subsequent meetings in Montreal, Canada, two years later and in Cambridge, England, in 1984. Specifics from the Montreal meeting are important to mention because of the research that emanated, such as contact lens-tear film interaction that included pre- and post-lens tear film structure, lens wetting and surface characteristics and preventing deposits. In the session on material development and performance, the topics of oxygen permeability measurement,

lens water content and evaporation were discussed. That was followed by the effects of contact lenses on the anatomy and physiology of the eye, extended wear and the meeting ended with the discussion on lens design and behavior.

There were at least two important developments from the early meetings that revolved around oxygen. The first was trying to understand how much oxygen was needed to avoid corneal edema. It wasn't until 1984 that Holden and Mertz<sup>4</sup> published their landmark paper on this topic describing the minimum oxygen requirement to avoid corneal swelling during both daily and overnight contact lens wear. As a consequence of the discussion on the levels of oxygen needed to avoid corneal edema was the knowledge that there was inconsistency in the methods to measure oxygen permeability of contact lens materials. This led to a global debate and eventually an alignment on how these measures needed to incorporate the edge effect and boundary effect adjustment and that there were two recognizable measurement methods; the coulometric<sup>5</sup> and the Fatt method<sup>6</sup>. This resulted in a second development which was unique for the ISCLR: it sanctioned an "interest group" to meet specifically to standardize a method for reporting permeability (Dk) measurements by having different groups around the world measure the same set of 'standard' lenses. This resulted in an important paper published by the ISCLR group.<sup>7</sup>

### OPTICAL PERFORMANCE AND EXTENDED WEAR

At the meeting in Cambridge in 1984 a new and timely topic, Optical Performance and Image Quality, was introduced that took up an entire session. The program outline showed a clear deviation from the principle of ISCLR of minimum presentation time in this session by including 10 speakers on various optical performance and image formation topics in this emerging field. There must have been good reason to include so many even if the presentations were very short. That was followed by Material Properties of Hard and Soft Lenses and sessions three and four were devoted to the Effects of Daily and Extended Wear on the Cornea. Numerous concepts that stemmed from observations related mainly to the effects of extended wear of soft contact lenses were presented and discussed, notably how corneal physiology altered (e.g. changes in corneal thickness, loss of corneal sensitivity, etiology of microcysts and endothelial changes) but seemingly little was discussed about corneal infections. That would change dramatically beginning in 1990 at the meeting in Monte Carlo, Monaco.

### REFRACTIVE SURGERY AND CONTACT LENS VISUAL PERFORMANCE

For the first time refractive surgery was included in the program in S'Agaro, Spain in 1986. Although ophthalmologists only represented about 10-15% of the membership over the years, there was considerable interest amongst many other members in the procedures (although limited at that time), as there was much to learn about the effects of altering corneal shape to eliminate refractive error (predominantly myopia at that time). Refractive surgery would become a standard session inclusion in many of the future meetings. Coupled to the surgery was the exciting advancement of techniques to measure corneal topography discussed in the same session. An extensive list of subjects was

included in the Ocular and Contact Lens Surface session such as lens deposition, lens wettability and elegant dynamic imaging presentations of the pre-lens tear film.

As far as we could tell, three other novel concepts were introduced: the idea that osmolarity was a useful measure to indicate tear stability (the report of the National Eye Institute Dry Eye workshop published in 1995 that confirmed its value<sup>8</sup>); that contact lens-induced papillary conjunctivitis had an immunological basis; and that dehydration and soft contact lens comfort are linked.

Contact lens visual performance of aspheric rigid gas permeable single vision lenses was a hot topic but it seemed that there was even more discussion time on the visual performance of monovision and the latest bifocal lenses.

### **THEMES THAT DOMINATED THE MEETINGS IN THE 90s AND 2000s**

The epidemiology and etiology of microbial keratitis (MK) and corneal inflammatory events (CIE) have been a significant part of each program during the 20-year period and was well established both independently and within the ISCLR that these conditions were more prevalent with extended wear of soft contact lenses. There was great anticipation that silicone hydrogels would minimize or even eliminate MK because of the significant increase in oxygen transmission but society members who studied this phenomenon found that the incidence did not alter compared to low Dk hydrogel lenses. In addition, research presented at the ISCLR scientific meetings in the last decade has demonstrated that there is an increased incidence of CIEs with silicone hydrogels compared to hydrogels for both daily and extended wear. Evidence of microbial attachment to lens surfaces and to corneal epithelial cells was presented as a more likely cause of infections and inflammation.

The development of silicone hydrogels was the big breakthrough that commanded considerable discussion time during the 2000s because of the virtual elimination of hypoxia but these lenses did cause mechanical complications due to high lens modulus in the first generation lenses.

This would be the segue to mention the ISCLR'S preoccupation with the illusive contact lens discomfort and dryness etiology which has also been part of the programs over the last three decades. Great discussions on this subject has led to the conclusion that the cause is multifactorial: mechanical which includes lens modulus, design, inflammation, hypoxia, the anterior lens surface/tear film/tarsal conjunctival interaction. It was well established that the most common reason for discontinuation of lens wear was discomfort. This has significantly retarded the growth of contact lens wear.

Daily disposable lenses (DD) were introduced to the market about the same time as silicone hydrogels and these lenses were also purported to mitigate MK from extended wear, but that was not the case. However reports at the meetings showed that the incidence of CIEs decreased quite significantly with DD lenses.

The spinoff of visual decrement from refractive surgery was the development and use of wavefront aberrometry to measure higher order aberrations. This explained so much about the effects of altered corneal topography particularly from the early

refractive surgery procedures and the fairly recent reemergence of orthokeratology (OK). Both instruments have become invaluable in understanding corneal shape pathologies such as keratoconus. Confocal microscopy and optical coherence tomography demonstrated how useful these instruments are in studying "in depth" features of ocular tissue associated with lens wear.

### **THE LAST DECADE**

Contradictory results have been presented on the relationship between lens induced discomfort and dryness and lid wiper epitheliopathy. The hypothesis is that the anterior lens surface changes (dehydrates?) causing increased friction between the lens and tarsal conjunctiva leading to localized trauma and symptoms. Researchers have been able to use tribology to successfully measure resistance or lubricity of the lens surface but those are in-vitro techniques. Contact lenses are mostly corrective devices, but one important therapeutic use that has been expounded is the use of hydrogels as drug delivery devices.

There have been many remarkable and ingenious discoveries in the last 50 years of the eyecare business. Arguably the two most significant have been the soft contact lens and refractive surgery but these two would be dwarfed by a contact lens device and/or pharmacological agent that would predictably retard the development and progression of myopia. Society scientific meetings involving this subject started discussions well before the last decade about research on the epidemiology and etiology of myopia and use of both SCLs and OK designs to control myopia progression.

At the last meeting in Singapore in 2019 the three themes were: minimizing infection and inflammation, improving comfort and functions and new applications: myopia control and alternative uses of contact lenses. Alas, then COVID derailed society plans for a meeting in 2021.

### **WHAT OF THE FUTURE?**

The ISCLR is in a very healthy state. Sixteen new young members were admitted to the society in 2019. An active and energetic executive committee and council with a set of officers already planning for the next meeting in 2022. Industry support is stronger and more engaged than ever.

We can all be very thankful for the foresight and ingenuity of "The Three Musketeers," Monty Ruben, Brien Holden and Ray Myers and ably assisted by Michel Guillon who forged ahead and watched the ISCLR grow into a unique and apolitical society. Using a think-tank model for open, unadulterated discussion on the latest research and ideas amongst clinicians, researchers, students, industry colleagues and authoritative scientific outsiders who offered fresh perspectives to our field, created an opportunity for frank exchange of knowledge and direction for future research.

We apologize for not naming the many past and present members who have contributed tirelessly in administrative capacities and for unselfishly sharing their knowledge, research and ideas.

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