REVIEW OF OPTOMETRY

Contact Lens Pioneers

The Early History of Contact Lenses

Key Developments in Contact Lens Materials and Design, 1975–2000

Leaders of Yesterday, Today and Tomorrow

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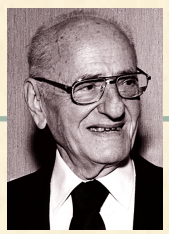





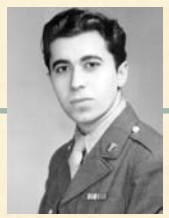

[THE PAST, PRESENT AND FUTURE OF OPTOMETRY]

Review of Optometry presents an important series of articles on the people who have made groundbreaking contributions to the contact lens field. This series represents a rare chance for us to truly make a difference. By educating ourselves about the giants on whose shoulders we stand, we make it possible to keep reaching for new heights. By understanding the scientific, social and technical challenges early contact lens pioneers faced, we can motivate and inspire ongoing technological development. And, by exploring the growth of contact lens specialty practices, we can see more clearly the foundation upon which every successful practice is built.

As the Chair of the American Optometric Association's Cornea & Contact Lens Section, I was thrilled when the editors of *Review* brought this project to me. I am proud to have an opportunity to play a role in documenting our collective history as optometrists and contact lens specialists. Contact lenses, the largest subspecialty in optometry, have shaped our profession. In recent years, optometry's role in therapeutic care, surgical comanagement and other specialty areas has expanded in exciting ways; but contact lenses remain at the core of the optometric practice.

The series begins with a look at the early pioneers who brought us the first practical contact lenses. Next, we'll examine developers of the modern contact lens, contact lens solutions, and our evolving understanding of the requirements of the cornea for successful lens wear. Finally we'll look at the people who built the first specialty contact lens practices. We'll cover not only the history but—equally important—what is happening today and tomorrow in optometry.

This is primarily a story about optometry. Although many others—ophthalmologists, opticians, Ph.D. scientists, and more—have made great contributions to the field, it is beyond the scope of this project to cover them all.

I hope you enjoy and learn from this salute to our profession. Viva la Contact Lens!

—Jack Schaeffer, O.D.

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1508

Leonardo da Vinci describes corneal neutralization with a bowl of water.

1636

Rene Descartes describes corneal neutralization with a water-filled glass tube.

The Early History of Contact Lenses

BY JACK SCHAEFFER, O.D.
AND JAN BEITING

The history of contact lens development is long and rich. As early as the 1500s, the world's best thinkers already had conceived of the basic principles of contact lenses, even if a true contact lens that could be successfully worn on the eye was still centuries away.

In the late 1880s, glass contact lenses were invented, but that was followed by nearly four decades of very little technological improvement. By the mid-1930s, a few pioneering individuals were about to change the contact lens in dramatic ways. We start this series with the stories of the men who invented and undertook the early development of the modern contact lens. They paved the way for a largely theoretical concept to become reality and for contact lens wear to become a practical method of refractive correction for millions of people.

[WILLIAM FEINBLOOM, O.D., PH.D. (1904-1985)]

William Feinbloom graduated from the now-defunct Columbia University School of Optometry in 1923, at the tender age of 19, and began practicing in Buffalo, N.Y. He was dismayed to find that he could do nothing to help one of his very first patients, a severely visually impaired man. The young optometrist began tinkering with spectacle-mounted telescopes—the start of a lifelong interest in low vision rehabilitation.

In 1933, he published a paper about his first 500 patients with "subnormal vision." In 1939, he received a doctorate in physiologic optics. He went on to design more telescopes, low-vision microscopes, and other visual aids, some of which are still sold by Designs for Vision, an optical products company founded by Dr. Feinbloom in 1961 and currently headed by his son, Richard Feinbloom.

Late in life, when Dr. Feinbloom developed macular degeneration himself, he reportedly saw the silver lining in his condition, noting that only now could he truly understand what his low-vision patients had experienced.

1823

John Herschel proposes a glass capsule filled with animal jelly to correct astigmatism.

1880s

Adolph Fick, Eugene Kalt, and August Müller independently invent the first glass contact lenses.

Like many pioneers, Dr. Feinbloom had a strong entrepreneurial spirit. In the 1930s, he developed the Feincone system for fitting scleral lenses and sold the trial lens sets to optometrists all over the country.

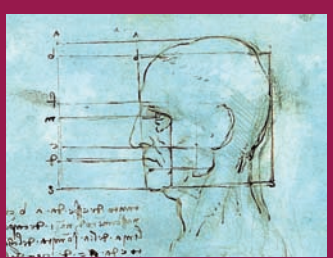
"When I started practice in 1947, I tried to fit some patients with scleral lenses using this system and even wore them myself for a very short time," remembers Robert Koetting, O.D., founder of The Koetting Associates, in St. Louis, Mo.

Dr. Feinbloom was also one of the three original partners in Frontier Contact Lens Company of Buffalo, N.Y. That partnership dissolved long before Frontier

[GLASS CONTACT LENSES: 1500 TO 1935]

In 1508, Leonardo da Vinci sketched out several ideas for neutralizing the cornea through contact with fluid. He understood that corneal power could be altered by submerging the eye in a glass bowl filled with water, for example. Essentially, he described the principles of a contact lens without describing something we would actually recognize as a contact lens.[1] More than a century later, Rene Descartes described a glass tube filled with liquid and attached to the eye. This was hardly a contact lens; but again, the principle of corneal neutralization was clear.

The first written description of a device approximating a contact lens is believed to date to 1823. Sir John Herschel, an English astronomer, proposed "some transparent animal jelly contained in a spherical capsule of glass applied to the surface of the eye" to correct irregular astigmatism.[1] He also suggested that a mold of the cornea might be taken and impressed on some transparent medium. He thought it possible that "a temporary distinct vision" might be obtained through one of these methods, but it is not known whether Herschel ever tried to put his ideas into practice.



In the late 1880s, at least three men are thought to have independently invented the first contact lenses. Adolph Eugen Fick, a Swiss ophthalmologist, and Eugene Kalt, a French ophthalmologist, devised glass lenses with the goal of correcting corneal abnormalities. Around the same time, August Müller, a German medical student who wanted to correct his own high myopia, also produced a glass lens.

These first contact lenses were crude by modern standards, made of blown glass bubbles or ground and polished glass, and were primarily scleral designs that covered much of the eye. They were heavy and unwieldy and let no oxygen through to the cornea. Patients could tolerate the lenses only briefly and usually suffered from signs and symptoms of corneal hypoxia rather quickly. Nevertheless, the improvement in visual acuity that a piece of glass on the eye could provide was encouraging.

Between 1890 and 1935, there were no developments of any great consequence. Two German companies, Karl Zeiss Optical Works and Mueller Co., as well as small labs in the U.S. and elsewhere, continued to make glass contact lenses but demand was very limited. According to the American Academy of Optometry, approximately 10,000 pairs of glass contact lenses were sold in the U.S. between 1935 and 1939.[2]

1936

William Feinbloom introduces contact lens made partially from plastic PMMA introduced in U.S. by Rohm and Haas Co.

1944

Dr. Borish publishes his classic textbook, *Clinical Refraction.*

began making the soft contact lenses that were sold to Johnson & Johnson and eventually became known as the Acuvue brand contact lenses. He even patented some designs for bifocal and trifocal scleral contact lenses in the mid-1930s.

But Dr. Feinbloom's key contribution to the field of contact lenses was recognizing the many advantages of substituting plastic for glass in the eye. In 1936, he introduced and patented the first contact lens containing plastic. This lens had a central glass optic that covered the cornea with an opaque plastic flange over the sclera.

At the time, glass contact lenses were the standard, but had never been very successful. Glass was transparent, but it had a number of disadvantages, including weight and complete lack of oxygen permeability that rapidly led to discomfort and corneal hypoxia for the wearer. The lenses were also difficult to make.

With plastic, the lens weight could be reduced, the material could be formed and shaped easily, it had good compatibility with ocular tissue, and was more comfortable in the eye than glass.

Initially, Dr. Feinbloom used the only plastic available to him—an opaque resin plastic that would not have been effective for the optical portion of the lens. But his ideas were prescient. PMMA, which has superb optical properties, was introduced in the U.S. that same year and rapidly became the material of choice for hard contact lenses.

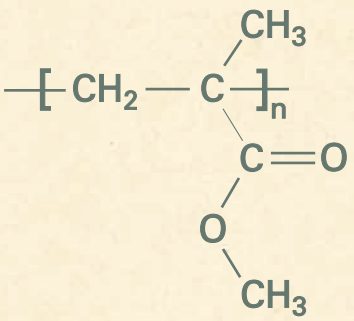
Many remember William Feinbloom as a tireless advocate. "My father was generous with his time and his knowledge," recalls son Richard Feinbloom. "And he was passionate about helping people with low vision."

[KEVIN M. TUOHY (1921-1968)]

In 1948, A California optician who worked for Solex Laboratories, Kevin Tuohy, filed a patent for the first corneal contact lens, which was made entirely of PMMA. His discovery began—as so many do—with a laboratory mistake. A scleral lens was accidentally lathed in two, leaving a smaller corneal button. Tuohy tried the damaged lens on himself to see what would happen. After more experimentation, he filed his patent and published a fitting manual for the new lenses.

Mr. Tuohy's contact lens was a large, thick, flat lens with blunt edges that would hardly be considered revolutionary today. But in the late 1940s, it marked a major shift from scleral to corneal contact lenses.

Poly (methyl 2-methylpropenoate)
PMMA



Prior to this, many fine optometrists, ophthalmologists, and scientists—including Theodore Obrig, Philip Salvatori, Ernest Mullen, Itsvan Gyorrfy, Solon Braff, and Edward Goodlaw—had been designing and producing all-PMMA lenses in scleral designs. PMMA was introduced in the U.S. by Rohm and Haas Company in 1936, and many laboratories began making plastic contact lenses on a limited scale shortly thereafter. These lenses were a vast improvement on earlier glass lenses, especially with fitting modifications and new design elements such as fenestration; but they continued to suffer from the problem that all scleral lenses trapped tears between the lens and cornea, resulting in corneal hypoxia.

Because of this, scleral contact lens fitting remained a very limited procedure undertaken by relatively few people around the world. But after the introduction of the Tuohy corneal lens, contact lens sales increased from 50,000 pairs in 1946 to 200,000 pairs in 1949.[2]

"The primary advantage offered by this revolutionary combination of lightweight plastic and a corneal design was the potential for increased tear exchange behind the lens," Mertz says of the Tuohy lens.[3] Patient comfort was still a limiting factor, but Mr. Tuohy's innovation enjoyed great success by the standards of the day.

The Tuohy lens served as the basis for ongoing design changes to PMMA lenses that dominated the market prior to the introduction of soft contact lenses. The first and most important change was made by George Butterfield, who added peripheral curves to the posterior

1948

Kevin Tuohy patents first corneal contact lens (made of PMMA)
Contact lens sales quadruple.

1950

George Butterfield introduces modern concept of fitting the lens on the Ks.

surface in 1950, introducing the modern concept of fitting the lens on the Ks.[1] During the 1950s and 1960s, corneal PMMA lenses—made by Obrig Laboratories, Breger-Mueller-Welt in Chicago, and the Plastic Contact Lens Co (Wesley-Jessen), among others—also became thinner and smaller.

Unfortunately, PMMA, like glass, is impermeable to oxygen. The resulting corneal oxygen deprivation caused many problems for contact lens wearers that researchers would spend decades more trying to address.

[NEWTON K. WESLEY, O.D., F.A.A.O. (B. 1917)]

Newton K. Wesley, O.D., is often credited with developing the first commercially successful rigid contact lens, in the mid-1950s. His lens, building on what Tuohy and Butterfield had done, was a 9.2-diameter lens, fit on the flattest K. "It's interesting that, all these years later, 9.2 is still the best diameter," said Frank Fontana, O.D., one of the founders of the AOA Contact Lens Section.

But his greatest contribution to the field of contact lenses may have been in his teaching skills. Dr. Wesley and a former student of his, George Jessen, O.D., together started the Plastic Contact Lens Company, later to be called Wesley Jessen VisionCare, Inc., a leading manufacturer of specialty contact lenses, including toric, colored and opaque cosmetic lenses. Wesley Jessen was eventually acquired by CIBA Vision in 2001.

"Wesley and Jessen taught all of us how to fit contact lenses," Dr. Fontana said. "They almost single-handedly developed the market for contact lenses, just by traveling around the country educating people." At the time, contact lens fitting was still a new field, and many thought contact lenses were unsafe; but Dr. Wesley and Dr. Jessen believed wholeheartedly in them. They continued to develop new lenses for decades, achieving FDA approval of their own hydrogel soft contact lenses in 1978.

In 1955, Dr. Wesley founded the National Eye Research Foundation, best known for its orthokeratology and keratoconus work, and remained its chairman for many years. In the 1990s, he pursued software applications for retinal sensitivity analysis. Well into his 80s, Dr. Wesley continued to be an active entrepreneur and innovator.

[OTTO WICHTERLE, PH.D. (1913-1998)]

Otto Wichterle was a brilliant Czech polymer chemist who had already worked on one of the world's first synthetic fibers. In 1954, he and colleague Drahoslav Lim at the Institute of Macromolecular Chemistry of the Czechoslovak Academy of Sciences invented the first hydrogel material, hydroxyethyl methacrylate (HEMA). They were seeking a synthetic biocompatible material for implants elsewhere in the human body and initially published their findings in the journal *Nature* in a 1959 article entitled "Hydrophilic gels for biological use."

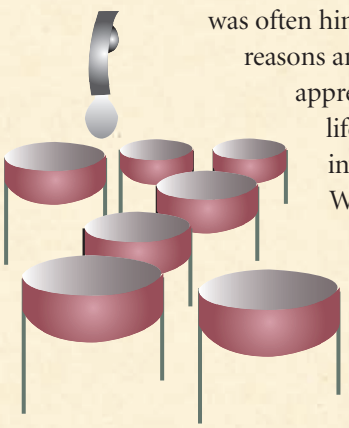
When a chance encounter with an ophthalmologist on a train gave Prof. Wichterle the idea that the gels he was working with would also be effective in the eye, he began his successful quest to make a contact lens. He later worked with American collaborator Robert Morrison, O.D., and others to improve the lenses.

The original Wichterle lenses provided relatively poor acuity with thick yellowish material, but they were comfortable, according to Mandell.[1] The HEMA material was transparent, free of impurities, and was permeable to oxygen and water-soluble nutrients. Prof. Wichterle patented his lenses in the U.S. in 1962 and 1965. Mandell notes that these original lenses were by no means a great success prior to their refinement and commercialization by Bausch & Lomb,[1] which eventually acquired the patents for the HEMA contacts.

Prof. Wichterle quickly realized that he also needed a faster, more reliable method of fashioning the HEMA

material into a contact lens than the closed-mold process he'd been using. With various combinations of his children's construction toys, a hot plate, bicycle parts and a phonograph motor, he built a primitive spin casting device—something that was familiar to polymer chemists for other applications but had never been used for contact lenses.

"This device was no toy," Morrison said. "It was a clever creation in which raw liquid HEMA polymer was introduced via a tube into a mold that was spinning."[4] Heat from the hot plate was the catalyst to turn the liquid HEMA into a gel. Technicians at his institute helped him automate the device, which he would later patent (in 1961) as a method for making soft lenses. He and his wife manufactured 5,500 lenses in 1962 with the spin casting machine.[1] At the time, he reportedly thought the low cost and high reproducibility of spin casting could make a disposable lens approach economically feasible, although it would be many years before that would become reality.[3]



Contacts were formed by filling small molds with liquid plastic and allowing them to harden. These "buttons" were then cut to correct prescriptions.

Prof. Wichterle's contact lens work was often hindered for political reasons and was not fully appreciated until late in his life. When Germany invaded Czechoslovakia in World War II, the Nazis closed the universities, interrupting his research, and even imprisoned him for a few months. Later, when Czechoslovakia came under Soviet influence, he was thrice removed from senior positions in political purges. In one case, he lost his position as head of the Institute of Macromolecular Chemistry (where he developed HEMA), due to his support for the unsuccessful anti-communist Prague Spring uprising. Finally, after the 1989 "Velvet Revolution" and Czechoslovakia's turn toward democracy, he was named president of the Czech Academy of Sciences and recognized for his contributions.

But while Prof. Wichterle struggled against political forces in his own country, his concept of a lens comfortable enough to be worn for a good portion of waking hours had revolutionized the contact lens field elsewhere. Within just a few years after Bausch & Lomb commercialized his lenses (and the spin casting technique, which the company also acquired), the vast majority of Americans wearing contact lenses were wearing hydrogel contact lenses, and millions of people worldwide still wear them.

[ROBERT MORRISON, O.D. (B. 1924)]

Robert Morrison, a self-described "mediocre student," dropped out of college to join the Army during World War II. He decided on optometry because Pennsylvania College of Optometry was accepting veterans without full college degrees. After graduation, the ambitious young doctor built a thriving practice in his hometown of Harrisburg, Pa., which he later expanded to a part-time practice in New York City, as well. He was very interested in contact lenses and had already been making rigid contact lenses in a small optical lab in his office when he heard about Otto Wichterle's paper on hydrophilic gels. In 1961, Dr. Morrison traveled to what was then Czechoslovakia, and brought some of the material back home with him. He wasn't the first person to visit Prof. Wichterle and hear about his new lens technology—but he was the first to embrace the potential of a hydrophilic material for contact lenses.

"Wichterle's accomplishments might have died behind the iron curtain were it not for the persistence of Robert Morrison," said Joe Shovlin, O.D. Dr. Morrison and Prof. Wichterle traded ideas back and forth over several years, and Dr. Morrison became the

first American to fit the lenses in practice. The two were close friends for a while, although the friendship was strained by the legal wrangling that surrounded the transfer of Wichterle's HEMA patents.

Dr. Morrison was eager to have the patents in order to continue his own work with soft contact lenses, but he was forced to share them with a group called the National Patent Development Corporation (NPDC).

The NPDC bought out Morrison's share soon thereafter and eventually licensed the technology to Bausch & Lomb, which refined it and brought the first soft hydrogel contact lens, the Soflens (polymacon), to market in 1971. The FDA decided the lens was a drug, which created a major hurdle for B&L. Once past that hurdle, however, the company enjoyed a three-year monopoly on soft contact lenses in the U.S., during which time it dominated the marketplace and PMMA became nearly obsolete.

In addition to serving as the bridge between Otto Wichterle and the West, Dr. Morrison was a skilled contact lens fitter who truly had one of the first optometric practices to specialize in the young field of contact lenses. He became known as the eye doctor of the rich and famous, treating Hollywood stars and international royalty, and once received a Rolls Royce from Queen Juliana of the Netherlands as payment for his services. More than 40 years later, he still drives that car sometimes.

"Dr. Bob has shown how much one person can contribute to the world during a lifetime, and how much fun and adventure he can experience while doing it," said Dick Thornburgh, former U.S. Attorney General, former Governor of Pennsylvania, and a longtime patient of Morrison's.

Dr. Morrison enjoyed a long career treating patients, lecturing and teaching. He recently published a book about his life and career.[4] "I wrote it for my grandchildren," Dr. Morrison said. "I wanted to make sure they got the facts straight when they hear some of the tall tales about their grandfather."

All of the individuals described here were path-cutters, charting a difficult way in completely unknown territory. They laid the foundations for both rigid and soft contact lenses and established a role for contact lenses in refractive correction that is now taken for granted. But in some ways, they raised more questions than they answered: What were the oxygen requirements of the cornea? Was there a material that would be comfortable and healthy over the long term? How long could contact lenses be worn? How should they be fit? How did one manage a contact lens practice?

In future installments of this series, we'll look at the people and the companies that refined lens material and design, built the manufacturing capabilities to revolutionize the industry, educated their colleagues about fitting, marketing, and the oxygen requirements of the cornea, and built the first contact lens specialty practices.

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[SPECIAL THANKS]

Special thanks to contributors Robert Davis, O.D.; Art Epstein, O.D.; and Glenda Secor, O.D., for their assistance with this series.

1959

Wichterle and Lim publish a paper on hydrophilic gels for biological use.

1960s

A group of researchers at the University of California at Berkeley worked tirelessly in investigating the amount of oxygen needed by the cornea during contact lens wear.

Key Developments in Contact Lens Materials And Design, 1975–2000

BY JACK SCHAEFFER, O.D. AND JAN BEITING

[THE QUEST FOR OXYGEN]

By 1970, contact lens wear had become more practical and more comfortable than in previous decades, and as many as 2 million people worldwide were successfully wearing contact lenses.[1]

For the next decade, Bausch & Lomb's Soflens, the first hydrogel contact lens based on **Otto Wichterle's** lens and the spincasting process by which it was made (also acquired from Wichterle), essentially dominated the marketplace. However, corneal hypoxia or oxygen deprivation of the cornea continued to be a serious impediment to safe and successful contact lens wear, even with the new soft hydrogel lenses just entering the market. As early as 1952, **Edward Goodlaw, O.D.**, had suggested that contact lens wear could cause corneal edema. Further research proved that to be correct. The quest to deliver more oxygen to the cornea was on.

Over the next three decades, the ranks of contact lens wearers would grow to more than 80 million, thanks in large part to the contributions of oxygen researchers in academia and clinical practice.

The Berkeley Group

From the mid-1960s through the mid-1980s, a group of researchers at the University of California at Berkeley worked tirelessly investigating the amount of oxygen needed by the cornea during contact lens wear and the effects of various types of contact lenses on oxygen transmission.

Irving Fatt, Ph.D., F.A.A.O. (1920–1996), and **Richard M. Hill, O.D., Ph.D., F.A.A.O.**, worked together at Berkeley to come up with a method for measuring how much oxygen penetrates a contact lens to reach the cornea. Dr. Fatt, whose expertise was in petroleum and bioengineering, took an engineering approach to the problem, measuring oxygen flux with electrodes. He realized that the same principles of fluid dynamics applied whether one was looking at petroleum, oxygen through plastic packaging or oxygen through a hydrogel device on the eye. He introduced the concepts of material permeability (Dk) and transmissibility (Dk/L) to the contact lens industry,[2] and his research resulted in a universally recognized unit for oxygen permeability (the Fatt unit) that greatly advanced the science behind both rigid gas permeable and hydrogel lenses. He also discovered that oxygen transmissibility of hydrogel lenses is proportional to polymer water content and the reciprocal of lens thickness,[2] findings that were later

1961

Wichterle develops a method for contact lens production by spin casting.

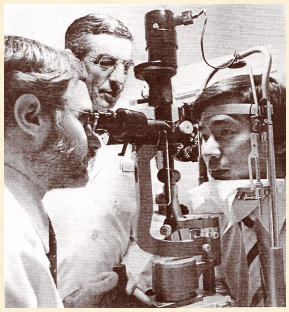
Robert Morrison visits Wichterle and begins experimenting with HEMA contact lenses.

1962

First hydrogel lens patented by Wichterle in U.S.

confirmed by his colleagues.

Dr. Hill took a more physiological approach, exposing rabbit corneas to variously calibrated oxygen chambers and comparing the rates of swelling in those chambers to those of various contact lenses to determine the amount of oxygen being transmitted. This became known as the equivalent oxygen percentage (EOP) method and is still in use today.



Morton Sarver, O.D. (middle), and Michael Harris, O.D., J.D., M.S., F.A.A.O. (left), examining a research patient in 1975.

Dr. Hill later moved to Ohio State University (OSU), where he was a researcher, faculty member and eventually dean of the school of optometry. He continued his work on contact lenses, oxygen, and on the tear film and dry eye. Dr. Hill is renowned for establishing a solid basic science foundation—but one that always had a practical bent. A superb educator, he always sought to translate his research findings in a way that would benefit clinical practice.

At OSU, Dr. Hill collaborated with **William "Joe" Benjamin, O.D.**, to study oxygen transmission in human corneas. Dr. Benjamin continues to carry the oxygen mantle. As the director of clinical eye research at the University of Alabama's Vision Science Research Center, he is still exploring how Dr. Hill's and Dr. Fatt's oxygen measurements relate to one another.

"People like to argue over which method is better, but the truth is that both are very useful and have complemented each other nicely," Dr. Benjamin said. He believes that Dr. Hill's greatest legacy may be that he was able to steer optometric research out of the limited realm of physiological optics and into the physiology of the entire eye, including the ocular surface. "We take it for granted now, but that was a huge jump for the field."

Drs. Fatt and Hill were not the only bright minds at Berkeley focused on the oxygen issue. Senior faculty members **Robert Mandell, O.D., Ph.D., F.A.A.O.**, and **Morton Sarver, O.D. (1922–1986)**, and two young colleagues of theirs, **Kenneth Polse, O.D., M.S., F.A.A.O.**, and **Michael G. Harris, O.D., J.D., M.S., F.A.A.O.**, all collaborated on measuring corneal swelling during contact lens wear, and then correlated the amount of swelling to the amount of oxygen being transmitted. Three of them (Drs. Sarver, Polse, and Harris) eventually formed a research group that examined corneal swelling related to many different contact lens designs, fits and materials.

Dr. Mandell is perhaps best known in the field for his classic textbook, *Contact Lens Practice*. He developed a hand-held topographer for measuring infants' eyes and did a great deal of work on corneal pachometers needed for the contact lens studies he and his colleagues conducted.

Dr. Sarver had been trained as a civil engineer before he went to optometry school, and he brought an engineer's meticulous attention to detail to his optometric research. He was regarded as an outstanding teacher, astute clinician, and giant in the research field. More than 1,500 Berkeley optometry students learned about contact lenses from Dr. Sarver. His faculty duties there were only at the 50% level, because he maintained an active clinical practice, but colleagues say that 50% of Dr. Sarver's time was the equivalent of 110% of a lesser mortal's.

"He combined the best of clinical practice and scientific research," said Dr. Harris, who says it was a tremendous honor for him as a young graduate to work alongside his former instructors, Drs. Sarver and Mandell. They fostered a friendly, nurturing environment for talented researchers at Berkeley.

Dr. Harris, who also has a law degree, has devoted himself not only to contact lens issues but to research and writing on legal issues affecting the practice of optometry. Recently retired, he remains very active in the field.

Dr. Polse established a tear mixing laboratory with an engineering colleague at Berkeley to promote safer and more comfortable contact lens wear. In his university biography, Dr. Polse notes that "discovery and clinical implementation require close collaborative efforts between basic and clinical scientists." This philosophy certainly guided his own career, and he continues to work to ensure that it will continue with a program to

Mid-1960s

Dr. Korb describes the phenomenon of central circular clouding (CCC), or edema, in PMMA lenses.

1967

Dr. Mandell develops the first one-piece monocentric bifocal.

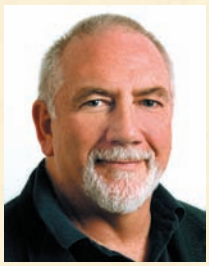
provide grant funding for clinician scientists.

Separately and jointly, the members of the Berkeley group published hundreds of papers about oxygen, the cornea, contact lenses, and patient responses to different contact lenses. They conducted the first *in vivo* corneal deswelling studies, the first contralateral contact lens experiments to show the effects of lens-induced tearing on the cornea and the first experiments on overnight wear of contact lenses. They defined the relationship between corneal edema and its clinical manifestations, and developed criteria for successful contact lens wear.

"I think all of us were passionate about the art and science of contact lenses. We wanted to increase clinicians' knowledge and help industry make better products for contact lens patients," said Dr. Harris.

Australia and Asia

In 1976, **Brien A. Holden, Ph.D., F.A.A.O., D.Sc., O.A.M.**, established the Cornea and Contact Lens Research Unit (CCLRU) at the University of New South Wales in Australia. For many years, the CCLRU was one of the most highly respected and prolific research centers in optometry. Researchers there conducted some of the first studies on extended wear lenses; identified the incidence and causes of giant papillary conjunctivitis, microbial keratitis, and other complications of contact lens wear; and reported much of the early clinical findings about disposable lenses and silicone hydrogels.



Brien A. Holden, Ph.D., F.A.A.O., D.Sc., O.A.M.

The list of scientists and clinicians who have worked and studied there is a veritable who's who of optometry in the United States and abroad. "Almost every standard or base of knowledge in contemporary contact lens research has its foundation in CCLRU work," said former CCLRU fellow **Cristina Schnider, O.D.**, now an executive with Vistakon.

Prof. Holden staked his reputation on the talented people drawn to the CCLRU, supported them and promoted their careers. "He has very high expectations of others, but he's also enormously supportive and kind," Schnider said.

Over the years, Prof. Holden has written or coauthored nearly 300 scientific papers, including two landmark papers with **George Mertz, O.D. (1946–2002)**, that established standards for the minimum oxygen requirements to avoid corneal edema from contact lens wear.[3,4] Dr. Mertz, a former petroleum engineer who received his optometry degree from Berkeley, spent a year at the CCLRU studying the ocular physiological response to extended wear of contact lenses.

He and Prof. Holden developed a micropachometer

[CONTACT LENS CARE SYSTEMS]

Ralph P. Stone, Ph.D.

Contact lens cleaning and care solutions are critical to the safety and comfort of lenses, but they are often given short shrift by practitioners and patients, according to **Ralph P. Stone, Ph.D**. "Unfortunately, even clinicians don't spend enough time instructing patients on the care protocols for their lenses and cases," he said.

One of the earliest pioneers in the contact lens solution realm was **Harry Hind, Ph.D.**, a California chemist and founder of Barnes-Hind who made the first cleaning solution for PMMA lenses. When HEMA lenses were first introduced in the early 1970s, patients had to make their own saline solution using salt tablets. The first big push into chemical disinfection came from a company called Burton Parsons, which was later acquired by Bausch & Lomb. BP licensed the technology to B&L, but the company was ultimately sold to Alcon. Around the same time, Dr. Hinds and **Joseph Krezanoski, Pharm. D.**, were also experimenting with soft lens disinfectants.

Throughout the 1970s and early 1980s, there were numerous exciting developments in the chemistry of contact lens care, and the solutions development paralleled or even stayed slightly ahead of contact lens development. By 1980 to 1981, there were quite a few chemical disinfecting solutions on the soft lens market, sold by Burton Parsons, Allergan,

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1970

Drs. Donald and Joan Korb introduce an important fitting technique, the "Korb fit," in which a PMMA contact lens is fitted to adhere to the upper lid.

1971

Bausch & Lomb receives FDA approval for the Soflens (polymacon) soft contact lens, based on Wichterle's technology.

Contact lens wear becomes much more widely accepted; hydrogel lenses dominate the market.

and an algorithm for measuring overnight corneal edema and then examined the relationship between overnight corneal edema and contact lens oxygen transmissibility. They determined that contact lenses needed to have an average Dk/t of at least 24.1 for daily wear and at least 87.1 for extended wear in order to keep overnight corneal swelling to 4% or less. It would be many years after this 1984 publication before the industry would be able to produce lenses that actually met the overnight wear standards.

A brilliant researcher, Dr. Mertz was known for his encyclopedic knowledge of literature and science, and for his integrity, according to Dr. Schnider. With his gruff manner, Dr. Mertz could be intimidating at first, but closer association revealed "a kind and gentle soul in this big teddy bear of a man," she said. Much of his career was spent in clinical research and professional education in the contact lens industry, where he held executive management positions at Bausch and Lomb, CIBA Vision, and Vistakon.

Prof. Holden continues to be closely involved with contact lens research, but his interests in recent years have broadened to include social justice and public health. He now dedicates much of his time to global blindness prevention efforts as chair of the Refractive Error Working Group of the World Health Organization (WHO) and the Refractive Error Program Committee and board of trustees of the International Association for the Prevention of Blindness (IAPB). He is co-chair of the Vision 2020 Australia group, which strives to eliminate avoidable blindness by the year 2020. He is also executive chair of Optometry Giving Sight, which brings together all the blindness prevention NGOs, the World Council of Optometry and its member affiliates in every country, and the International Centre for Eyecare and Education to raise funds to eliminate blindness and impaired vision due to uncorrected refractive error for 300 million people in need throughout the world.

His longtime colleague at the CCLRU, **Deborah Sweeney, B.Optom., Ph.D.**, said of Prof. Holden, "Not only does he challenge his colleagues to perform at their best, but he has consistently challenged the contact lens industry to make better products." Prof. Sweeney currently serves as CEO of the Vision Cooperative Research Centre (CRC). She has authored numerous clinical papers and scientific works, including a book on silicone hydrogel lenses. She currently serves as president of the International Association of Contact Lens Educators and is a past president of the International Society for Contact Lens Research.

Another important pioneer in the quest for oxygen, **Hikaru Hamano, M.D.**, is a legend in his home country

[CONTACT LENS CARE SYSTEMS] *continued from page 11*

Alcon, and Bausch & Lomb. These were mostly simple disinfectants, preserved with a combination of chlorhexidine and thimerosol, benzalkonium chloride (BAK) and other preservatives, and were used with hard lenses. Consumers still needed to use saline solution along with the cleaner.

The second generation of soft lens care products would encompass hydrogen peroxide cleaners such as AOSept, originally from American Optical Company and later acquired by CIBA Vision. Additionally, enzymatic cleaning products were developed to remove protein deposits on the lenses. Pioneers in this endeavor included **Hemper Karagosian** at Allergan and **Kiran Randiri, Ph.D.,** at Alcon. The early peroxide systems were popular in the early 1980s with the increasing incidence of allergic reactions related to thimerosol and chlorhexidine. With patients not replacing lenses for long periods, enzyme cleaning was a necessity, although these products remained largely peripheral.

In the mid- to late 1980s, scientists introduced the next generation of disinfectants, using polyhexamethylene biguanide (PHMB) and Polyquad preservatives. These included Alcon's OptiFree line and Bausch & Lomb's ReNu (developed by Dr. Randiri; **Lai Ogunbiyi, Pharm. D.**; **Frank Smith, Ph.D.**; **Tom Reidhammer, Ph.D.**; Dr. Stone and others). These products were originally approved and marketed as disinfectants only with separate cleaners; a few years later, they would cross over into the multipurpose solution category.

By this time, earlier problems with lens-solution interactions had been resolved through an FDA-initiated lens classification system that Dr. Stone helped craft. First published in 1985, the new system classified lenses according

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1972

Dr. Korb patents the CSI Lens, the first ultrathin non-HEMA soft lens.

Early 1970s

Dr. Hamano is the first in the world to demonstrate the partial oxygen pressure on the cornea under PMMA lenses.

Dr. Hamano's experiment (1978).

of Japan. In the early 1970s, Dr. Hamano was the first in the world to demonstrate the partial oxygen pressure on the cornea under PMMA lenses. He conducted landmark research into how contact lens wear affects the corneal epithelium, corneal nerves and tear composition.

As the head of the largest private contact lens practice in the world, Dr. Hamano was able to perform numerous large-scale, meticulous clinical studies to validate basic findings on the importance of oxygen transmission to the cornea and examine the properties of new lenses. For example, in 1994, he conducted a study that compared complication rates of various contact lens modalities in 23,000 patients. This study did much to establish the safety of the daily disposable modality.

[LENS MATERIAL AND DESIGN]

In tandem with the growing understanding of the importance of oxygen to the cornea, many exciting new materials have been developed since the old days of PMMA lenses, and lens manufacturers and clinicians have made numerous discoveries of the best way to design and fit contact lenses.

Lens Design Pioneers

In addition to his work on oxygen and the cornea, Dr. Mandell also worked on many contact lens design problems. He conducted studies to determine the optimal contact lens edge contour, prism effects, peripheral curve relationships, minus carrier construction and keratoconus lens design. Dr. Mandell also developed the first one-piece monocentric bifocal in 1967, and later several other bifocal lens designs. Although he retired from Berkeley in 1994, Dr. Mandell still guest lectures there and remains very active in the development of new contact lenses.

Boston optometrist **Donald R. Korb, O.D., F.A.A.O.**, is one of the field's greatest examples of a clinician scientist. His "astute clinical observations and insights have been immensely valuable to the understanding of contact lens behavior," Dr. Mertz wrote.[5]

In the mid-1960s, Dr. Korb described the phenomenon of central circular clouding (CCC), or edema, that occurs with PMMA lenses.[6,7] He advised clinicians to rely on fluorescein staining for an accurate differential diagnosis, something that was contrary to the prevailing wisdom of the time. He also recommended fitting principles to avoid CCC. One of his early papers on CCC was co-authored with Joan Exford, O.D., a young optometrist who would later become Dr. Korb's wife and partner and with whom he would write many more important scientific papers.

Donald R. Korb, O.D., F.A.A.O.

Joan M. Exford Korb, O.D., F.A.A.O., went on to serve as the first female president of the American Academy of Optometry. She is a trustee of the New England College of Optometry and a member of the National Optometry Hall of Fame.

Early on, the Korbs were very interested in the interaction of the lid, cornea and tear film. In 1970, they introduced an important fitting technique, known still as the "Korb fit," in which a PMMA contact lens is fit to adhere to the upper lid. Completely contradictory to common practice at the time, the Korb fit dramatically improved the exchange of oxygenated tears beneath the contact lens.[8]

In 1977, Dr. Korb and colleagues described a syndrome they called giant papillary conjunctivitis, or GPC.[9]

"Don Korb has a dynamic sense of how things work, and the intellectual curiosity to look beyond the obvious," said **Art Epstein, O.D.**

One of the things he noticed was that contact lenses were starving the cornea of oxygen. Inspired by the rabbit's third eyelid, a transparent nictitating membrane, Dr. Korb set out to make a lens that was only as thick as a few epithelial cells, or about 30µm thick. "That was a pretty arrogant proposition," he acknowledges now. At the time, rigid lenses were 200 µm to 300µm thick.

Nevertheless, in 1972, he patented the CSI Lens, the first ultrathin non-HEMA soft lens. Polymer chemist

1974

Drs. Seidner and Gaylord patent the Polycon lens, made of a siloxane-methacrylate polymer that was the first material of its kind.

1976

Dr. Holden establishes the Cornea and Contact Lens Research Unit (CCLRU) at the University of New South Wales in Australia.

Miguel Refojo and others helped create the revolutionary new membrane lens, as it was often called. It was approved by the FDA and launched by Syntex and Sola/Barnes-Hind in 1981.

In addition to his numerous contributions to lens design, materials and fitting, Dr. Korb's greatest legacy will likely be in the area of dry eye and lipid layer physiology.

He considers his best work to date to be a 1980 paper that first named meibomian gland dysfunction (MGD) and identified it as a cause of contact lens intolerance.[10] This work was performed with **Antonio Henriquez, M.D., Ph.D.,** an ophthalmologist, pathologist and corneal surgeon who was and remains very close to the Korbs. One result of malfunctioning meibomian glands is an inadequate tear film lipid layer. In the late 1980s, Dr. Korb invented Soothe, a metastable oil-in-water emulsion that has been shown to more than double the thickness of the lipid layer. It is now marketed and sold by Alimera Sciences.

Edward S. Bennett, O.D., M.S.Ed., and Irvin M. Borish, O.D., F.A.A.O., in October, 1992 at the annual meeting of the Contact Lens Manufacturers Association.

Dr. Korb also recently identified a tiny and previously overlooked part of the eye, akin to a windshield wiper. The "lid-wiper" is the portion of the marginal conjunctiva of the upper eyelid that acts as a wiping surface to spread the tear film over the ocular surface, or the surface of contact lenses. Lid-wiper epitheliopathy (LWE), as described by Dr. Korb and colleagues in 2002[11] and 2005,[12] is highly correlated with symptomatic dryness in contact lens wearers. Since it often occurs in the absence of any corneal staining that would provide clinical confirmation of dry eye, LWE may hold the key to understanding an entire segment of contact lens intolerant patients.

His dry eye research has given Dr. Korb great credibility in the medical eye-care community. "I think we have to credit him with being one of the first anterior segment specialists in optometry," said Dr. Epstein. "If not for the respect he almost single-handedly gained for our profession, we would be nowhere in terms of medical treatment of the eye."

Both Donald and Joan Exford Korb continue to innovate, research and see patients in the practice they founded: Korb & Associates of Boston.

The man who first introduced the Korbs to each other, **Irvin M. Borish, O.D., F.A.A.O.,** is one of the most influential leaders in optometry. No account of pioneers in the field would be complete without him. Dr. Borish is probably best known for his classic textbook, *Clinical Refraction*, first published in 1944, and for expanding optometry's scope of practice by launching the movements for diagnostic and therapeutic prescribing authority in the late 1960s.

He is equally distinguished in the contact lens field. Dr. Borish was one of the first people to wear bifocal contact lenses, and he became an expert in fitting them. His many papers on contact lens patient care show his "profound mastery" of the subject.[12] Dr. Borish was vice president of the Indiana Contact Lens Co., where he developed new techniques for improving optical characteristics of contact lenses. Along with **Joe Goldberg, O.D.,** he founded the Association of Contact Lens Manufacturers. In lectures, Dr. Borish continues to remind his colleagues that optics and contact lens fitting remain at the core of the profession.

Rigid Gas Permeable Lenses

New York optometrist **Leonard Seidner, O.D.,** is considered by many to be the godfather of gas permeable lenses.

An important early contact lens practitioner, Dr. Seidner was also possessed of an entrepreneurial spirit. He and his brother formed Guaranteed Contact Lens Company, a successful small manufacturer. In 1970, they launched the Polymer Optics Contact Lens Company and commissioned polymer chemist **Norman Gaylord, Ph.D.,** to work with them on a new, more oxygen-permeable material.

At the time, Guaranteed was already making lathe-cut soft lenses. But when Dr. Seidner realized that getting a soft lens through the newly created FDA approval process would be cost-prohibitive, he focused instead on finding a better rigid lens material. He and Dr. Gaylord created the Polycon lens, made of a siloxane-methacrylate polymer that was the first material of its

1977

Dr. Korb and colleagues describe a syndrome they called giant papillary conjunctivitis (GPC).

1980s

Scientists introduce disinfectants using PHMB and polyquad preservatives. These include Alcon's OptiFree line and Bausch & Lomb's ReNu.

kind. The lens was patented under Dr. Gaylord's name in 1974 and sold to Syntex Ophthalmics, which brought it to market in 1979.

"Len's early recognition that PMMA lenses caused edema and the intensity of his quest to resolve that problem was a major contribution" underlying later developments, said his close friend and colleague Dr. Korb.

Dr. Seidner never stopped thinking about how to improve contact lenses. "Even when I went to Las Vegas on vacation, standing there in front of the Treasure Island Casino, I had an idea for how I could make a better bifocal design," he said.

In fact, another company Dr. Seidner launched, LifeStyle (now run by his son), made the first disposable bifocal lenses. A joint venture with DuPont resulted in one of the early silicone hydrogel designs, which was later sold to a major manufacturer.

Now retired from active practice, Dr. Seidner continues to work on a new contact lens that he says could take multifocal lenses from specialty to mainstream.

Shortly after the Polycon lens was introduced, two other new entrants further expanded the fledgling RGP field. **Don Ratkowski**, founder of Paragon Vision Sciences, developed the Paraperm series of materials, and **Perry Rosenthal, M.D.**, introduced the first Boston RGP material. An ophthalmologist who became fascinated with contact lenses and founded a company (Polymer Technology Corporation) to make them, Dr. Rosenthal is best known for his more recent endeavors fitting therapeutic Boston Scleral Lenses for patients with keratoconus, Stevens-Johnson syndrome, and other corneal diseases at his Boston Foundation for Sight.

Ultimately, a hyper-permeable lens, Menicon Z (Menicon) was introduced with FDA approval for up to 30 days of continuous wear.

The late 1980s was a time of tremendous growth and innovation in RGP lenses. **Edward S. Bennett, O.D., M.S.Ed.**, who had worked under Dr. Borish and **Sarita Soni, O.D.**, as a clinical investigator for the Polycon lens, co-authored an important textbook, *Rigid Gas Permeable Contact Lenses*, with **Robert Grohe, O.D.**, that was published in 1986. By 1988, Dr. Bennett was executive director of the recently founded GP Lens Institute (GPLI), a position he still holds. GPLI is the education arm of the CLMA and, as such, is the leading source for publications, symposia, advice and other educational resources related to RGP lenses.

Reverse-geometry lens designs, introduced in the late 1980s for post-RK patients, helped create a resurgence in the modality of orthokeratology. The concept of orthokeratology had been introduced decades before by **George Jessen, O.D.**, and advanced by pioneering optometrists such as **Charles May, O.D.**; **Stuart Grant, O.D.**; and **Roger Tabb, O.D.**, but correcting myopia in this fashion was slow and impractical.

The first modern orthokeratology design, the Contex OK lens, utilized a reverse curve, which greatly accelerated the time required to reduce a patient's myopia. This was first reported by **Richard Wlodyga, O.D.**; the first book addressing orthokeratology followed a few years later, authored by **Rodger T. Kame, O.D. (1938-2000)**, and **Todd Winkler, O.D.**

New RGP bifocal designs in the late 1980s also led to an innovation boom that continues to this day. Specifically, the introduction of the Tangent Streak segmented translating bifocal represented the first opportunity to eliminate the problem of "image jump" that had plagued previous GP segmented bifocals. Dr. Bennett believes the presbyopia market is one area in which GP lenses will shine in the future. "If we look back historically, there were many PMMA bifocal lenses that worked really well, except that they didn't provide enough oxygen to the cornea. With modern RGP materials, we're able to meet corneal oxygen needs as well as provide effective near and distance correction," he said.

Also in the 1980s, the first hybrid technology lenses were introduced, beginning with the Saturn lens. The next iteration, the Softperm lens, had a rigid, low-Dk center with a low-water content soft lens surround. Typically worn by hard-to-fit keratoconus patients, it has been plagued by insufficient oxygen transmission as well as tears at the junction of the two materials. Recently the SynergEyes "A" and "KC" lens designs, with a hyper-Dk GP center, hold promise for the successful management of patients who could not wear GP lenses otherwise.

Another major contributor to the rigid lens correction of keratoconus is **Joseph Soper**, who designed a number

of lenses, including one that bears his name: the Soper Cone. **Leonard Bronstein, O.D.**, also deserves credit as an innovative pioneer in PMMA and GP design, especially in the areas of bifocals and irregular corneas. The symposium that still bears his name is one of the most successful contact lens programs in the world, with the 33rd annual meeting held in January 2007.

Hydrogel Lenses

As soft lenses got better, safer and more comfortable, patients and clinicians naturally started to think about longer wearing periods. First in Europe and later in the United States, contact lens wearers became increasingly interested in semi-permanent vision-correction lenses they could sleep in and wear continuously for long periods of time.


John de Carle, O.D.

London optometrist **John de Carle, O.D.**, thought increasing the water content of hydrogel lenses from the low levels (38%) in the early HEMA lenses to approximately 75% would permit such extended wear, especially if the lenses were slightly smaller in diameter than those in use at the time, which were about 14.5mm.

After obtaining a list of suitable plastics from the library, Dr. de Carle carried out experiments in the kitchen of his London flat. He once had to apologize to the neighbors for the odors issuing from his oven when one of the jam pots of plastic he was cooking exploded. He finally created a satisfactory high-water content (72%) polymer, perfilcon A, and used it to make a new lens, which he dubbed the Permalens. He made it 12.50mm in diameter. "To keep a very soft lens of that size in place, it was often necessary to make the inner radius steeper than the cornea," Dr. de Carle explained. "This seemed to work very well and may be why we had far less trouble than some other practitioners." Dr. de Carle sold the rights to the technology, which was eventually acquired by CooperVision.

The Permalens was introduced in the United Kingdom in 1975 and became the first extended-wear lens approved by the U.S. Food and Drug Administration in 1981, with a 30-day extended-wear indication. It helped Dr. de Carle build one of the largest extended-wear practices in the world, at a time when few people

[CONTACT LENS CARE SYSTEMS] *continued from page 12*

to their polymer properties, making it easier to test new lens care products for compatibility.

In the early 1990s, Dr. Stone and **Mary Mowrey-McKee, Ph.D.,** developed the Complete line of products for Wesley-Jessen (later marketed by Allergan and then AMO). After developing Complete, Dr. Stone went to Alcon, where he worked on novel liquid enzyme cleaners and other products, including the fourth-generation preservative Aldox, a key ingredient in the OptiFree multipurpose solutions.

Multipurpose solutions have been overwhelmingly popular for their convenience and ease of use. But, the recall of two major brands (AMO's Complete MoisturePlus and B&L's ReNu with MoistureLoc) has reinforced the importance of the clinician in teaching lens wearers about proper care and compliance with cleaning regimens.

Another challenge for the lens care industry is the growing dominance of silicone hydrogel lenses, which so far have defied easy classification according to the system devised earlier for hydrogel lenses.

"At this point, care systems may be lagging a little behind lens development," said Dr. Stone. "SiHy lenses are certainly forcing us to re-think the way we look at care products."

From the quest to understand the oxygen needs of the cornea, through tremendous efforts of dozens of individuals to improve the materials, design and fitting of contact lenses, and the improvements in care systems, the contact lens field has edged ever closer to its ideal of successful, healthy contact lens wear for all who want to wear lenses. Modern contact lenses have come a long way from the days of the glass vial HEMA hydrogel lenses that dominated the market in the 1970s. Who knows what exciting innovations the future will bring. But, it's a given that industry and clinicians will continue to build on the tremendous progress of the past few decades.

were willing to fit these lenses.

Many of his patients would wear the lenses for three months continuously, returning to his office to have their old lenses replaced with new ones. "I still think we had the right idea," Dr. de Carle said. "Many patients don't like to handle the lenses or touch their eyes. In my opinion, the recent movement toward daily-wear lenses is not progress at all. We should be trying to figure out how to make a lens that is safe for a minimum of three months of continuous wear."

Consumers were certainly attracted to the convenience and freedom of the Permalens and other extended-wear lenses that were introduced shortly thereafter. However, as their popularity grew, so did the reports of clinical complications. By the late 1980s, it was clear that the risk of ulcerative keratitis was much greater with extended-wear lenses than with daily wear lenses; and in 1989 the FDA recommended that continuous wearing periods be decreased from 30 days to a maximum of seven days.

Besides his work on extended-wear lenses, Dr. de Carle is also well known for his bifocal contact lens designs, including the de Carle bifocal. He first had the idea of placing the distance portion of the lens in the center, so that portion would be steeper and allow for better tear exchange. He then experimented with three- and five-zone lenses, including a design on which the Acuvue bifocal is based. Currently, he is wearing a new lens he invented with many zones and is negotiating with industry for potential acquisition of the technology.

Undoubtedly, one of the most important developments in contact lens technology in the last 50 years is the mass production of disposable contact lenses.

Michael Bay, M.D., a Danish ophthalmologist and entrepreneur, is believed to be the first to have produced a lens intended for regular disposal. His Danalens, marketed in Denmark, intrigued executives from several contact lens manufacturing companies. The material and the lenses themselves were not particularly impressive, but the manufacturing process—stabilized soft molding, in which lenses could be molded in a hydrated state—had great potential.

Johnson & Johnson's Vistakon division acquired the rights to Dr. Bay's technology in 1984 and paired it with etafilcon A, a material it had acquired three years earlier. Etafilcon A had been invented by **Seymour Marco, O.D.**, a country optometrist who ran Frontier Contact Lens Co. of Florida. Dr. Marco was already making lenses from the new material, with limited success. **Hank Green**, then president of Vistakon, had the vision to put a considerable amount of Johnson & Johnson research muscle and money into refining both the material and the manufacturing process. Over a four-year period, through the efforts of many scientists and engineers at Vistakon, the company went from making 100,000 lenses a day to 1 million lenses a day—a scale large enough to make disposability a reality.

By the time Acuvue disposable soft lenses were launched in 1987, the company's biggest challenge was probably winning over practitioners, who were reluctant to dispense lenses without verifying the clinical performance of each and every lens on the patient's eye. **Stanley J. Yamane, O.D., F.A.A.O.**, was one of those recruited to serve on a panel of experts that had early access to the new lenses. "I was initially very skeptical," he said. "But after three months of dispensing these lenses to my patients and seeing that the reproducibility of the lens parameters, the quality of the lenses and the vision that patients were able to enjoy was exactly as the company claimed, I became one of their strongest advocates." Dr. Yamane would later serve as Vistakon's vice president of professional affairs.

Once it was proven that disposability could work, other manufacturers rapidly launched their own frequent replacement lenses in the now-familiar blister packs. The concept of disposability was taken even further with the introduction by Vistakon, in 1995, of the first single-use lenses, 1-Day Acuvue.

Silicone Hydrogel Lenses

As contact lens developers sought to make lenses that would allow more oxygen to reach the cornea, silicone seemed like a natural fit due to its high oxygen transmission and exceptional clarity. **Joseph L. Breger, O.D.**, spent more than a decade, beginning in 1959, trying to make contact lenses from pure silicone elastomer. A 100% silicone lens, the Silsoft lens, was introduced by Dow Corning in 1981 and is still made by Bausch & Lomb for specialty cases. But, silicone would eventually be successful only in combination with a hydrogel

1985

Dr. Stone helps craft a new system for classifying lenses according to their polymer properties, making it easier to test new lens care products for compatibility.

1986

Drs. Bennett and Grohe author the important textbook, *Rigid Gas Permeable Contact Lenses.*

material. Silicone is hydrophobic, making comfort and wettability in the eye a challenge. Adhesion of early silicone materials to the cornea— the "suction cup effect"—was also a major challenge.

CIBA Vision introduced the first successful silicone hydrogel (SiHy) contact lens, the Night & Day lens, to the global market in 1998; it became available in the United States in 2001. "What you need to keep a lens moving on the eye is ion permeability, or the ability for lenses to transport solubilized salt across the lens. That was a key learning," said **Lynn Winterton, Ph.D.**, a researcher at CIBA Vision in the early days and now the company's global head of research.

Dr. Winterton and other chemists at CIBA Vision, including **Tim Grant, O.D.**, and **John McNally, O.D.**, worked closely with **Deborah Sweeney, Ph.D.**; **Eric Papas, Ph.D.**; **Lisa Keay, Ph.D.**; and others at the CCLRU in Australia to develop the Night & Day and O_2Optix (AirOptix) SiHy lenses. Underlying every successful new product, Winterton says, are fundamental ocular science contributions from the giants in the field, as well as dozens of research "failures" that remain in obscurity but provide key knowledge.

Bausch & Lomb had been working on silicone lenses since the mid-1970s, with many lessons learned that paved the way for its 1999 introduction of the PureVision (balafilcon A) SiHy lens. The company built up a cadre of chemists to work on silicone lenses, including **Kai Su, Ph.D.** (who later became an executive at CIBA Vision), **Jay Kunzler, Ph.D.**; **Yu-Chin Lai, Ph.D.**; **Ron Bambury, Ph.D.;** and **David Seele, Ph.D.** The latter two would eventually invent the balafilcon formulation. Contact lens R&D Director **Dominic Ruscio, Ph.D.**, who helped refine the original Soflens many years before, had the idea to use a plasma surface treatment to make the lens more wettable. It was the last piece of the puzzle the engineers needed.

CIBA Vision's SiHy lenses also had surface modifications to make them more comfortable in the eye. Other manufacturers that came to market a bit later took different approaches. For example, Vistakon's Acuvue Advance (galyfilcon A), which was introduced in 2003, has an embedded wetting agent in the lens itself.

We are already seeing the second generation of silicone hydrogel lenses, including O_2Optix (lotrafilcon B, CIBA Vision), Acuvue Oasys (senofilcon A, Vistakon), and Biofinity (comfilcon A, CooperVision), with other new SiHy lenses soon to be released.

According to Health Products Research data, SiHy lenses overtook hydrogel lenses for the first time in the first quarter of 2007, with 51% of all new spherical fits and re-fits going to SiHy lenses. Toric silicone hydrogels entered the market a little later, but they have already gone from just 13% of the market in 2005 to 40% now. And the first SiHy mutlifocal lens has captured 20% of the presbyopic soft lens market in its first year.

In the final installment in this series on contact lens pioneers, *Review of Optometry* will look at the people who built the first contact lens practices, leaders in the contact lens field today and the rising stars who are likely to be its innovators in the years to come.

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[SPECIAL THANKS]

Special thanks to contributors Robert Davis, O.D.; Art Epstein, O.D.; and Glenda Secor, O.D., for their assistance with this series.

Late 1980s

Reverse-geometry lens designs are introduced for post-RK patients.

Dr. Korb invents Soothe, a metastable oil-in-water emulsion that has been shown to more than double the thickness of the lipid layer. It is now marketed and sold by Alimera Sciences.

Leaders of Yesterday, Today and Tomorrow

BY JACK SCHAEFFER, O.D. AND JAN BEITING

Following the introduction of contact lenses in the 1940s and 1950s and the rapid proliferation throughout the 1970s of new lens materials and designs, the first true contact lens specialty practices began to emerge.

In Part III of our series on pioneers in the contact lens field, we examine the groundbreaking practitioners who first eschewed spectacles to establish contact lens-only practices. Many of these individuals had an early interest in contact lenses and had been fitting rigid PMMA lenses since their introduction. So few doctors were fitting contact lenses at all that they rapidly became the recognized experts in their own communities, the educators of their peers and consultants to industry. And their practices flourished. Many are still considered leading practices today.

[LAYING THE FOUNDATION]

Harold E. Davis, O.D., opened his practice in an industrial area near the Chicago stockyards and slaughterhouses in 1945. A -12:00D myope who wore contact lenses himself, Dr. Davis often spent his lunch hour talking shop with his friends **George N. Jessen, O.D.,** and **Newton K. Wesley, O.D.,** whose Wesley Jessen Plastic Contact Lens Company was located about 15 minutes away. "The science of contact lenses just embraced me," Dr. Davis said. By the late 1950s, his practice was dedicated to them.

He continues to practice full-time at Davis Eyecare Associates, along with his son, **Robert L. Davis, O.D.** "Although we have been successful, economics did not and still does not drive us," said Dr. Harold Davis. "If you try to do the best you can for your patient, the rest will follow. That's always the answer."

The same year that Dr. Davis launched his practice in Chicago, **Charles "Ted" Bayshore, O.D.,** was opening his doors in Orlando, Florida. An early fitter of PMMA corneal lenses, Dr. Bayshore developed his own system of fitting and lectured about it around the world. By the early 1950s, his was a contact lens-only practice, as well. But, in addition to an interest in lens technology, Dr. Bayshore—who had run a Naval hospital in World War II—brought military organization to his civilian practice. He put a recall system in place, established state-of-the-art communication systems, and was one of the first to inventory and market his lenses, according to **Jack Joseph Yager, O.D.,** who joined the practice in 1973 and now owns it.

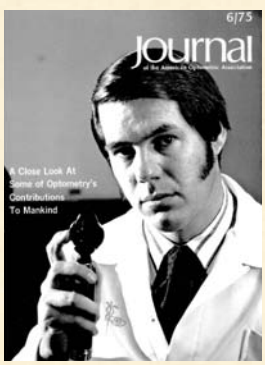
Further up the East Coast, **Paul Farkas, O.D.,** and **Theodore W. Kassalow, O.D.,** established one of the nation's premiere, high-end optometric practices in New York City in 1958. The partners long ago decided not to accept third-party insurance (other than Medicare) and still don't. They situated their practice on the second floor because ground level was considered "too commercial," but Farkas & Kassalow was among the first practices to strike a middle ground between the business-oriented practice and the purely professional practice to form an

organization that sought to be profitable by providing the best professional care for each and every patient.

Key to the practice's long-term success, says **Barry Farkas, O.D.,** nephew of the founder, is having the flexibility to grow and change with the market, but always maintaining a specialist mentality. "That requires one to get involved early with the newest technologies to figure out who they work for and who they don't," he said. "And you can't just rely on one or two favored lenses. We work with well over 300 different contact lenses, including many RGP lenses, daily disposables, multifocals, toric lenses, and specialty lenses for patients with keratoconus and other challenges." The practice has evolved considerably as the younger generation joined—first Dr. Barry Farkas, followed by Theodore's son **Jordan Kassalow, O.D.,** and **Susan Resnick, O.D.**

In St. Louis, another optometrist who had started dabbling in contact lenses early was **Robert Koetting, O.D.,** the grandson of an optician and son of an optometrist. "In 1962, I began to take contact lenses seriously and limited my practice to them," he said. He decided early on that his key market was affluent presbyopes, and did whatever it took to reach that market segment, including advertising in airline magazines for business travelers, hiring a PR agency, and becoming an arts patron.

"Koetting and the other early contact lens practices converted a novelty into a successful specialty practice and showed the way for the rest of us," said **Carmen F. Castellano, O.D.,** who now owns Koetting Associates. "The way I practice today is all based on Koetting's philosophy of going above and beyond the standard," he said.



N. Rex Ghormley, O.D., on the cover of the AOA journal in 1975, five years after establishing his contact lens specialty practice.

Another of Dr. Koetting's lasting contributions was the concept of the contact lens technician. He was one of the first to utilize technical assistants and multiple exam rooms to see more patients in a day. It was a concept that **N. Rex Ghormley, O.D.,** refined in his own practice. He opened Vision Care Consultants in St. Louis in 1970, after working for Dr. Koetting for a few years, and focused exclusively on contact lenses for the next two decades. Whereas a typical practitioner at the time might have seen seven or eight patients in a day, Dr. Ghormley would see 30. "I think we helped to educate people about how best to make use of technical staff and advanced, automated equipment in a professional practice," he said.


Frank D. "Uncle Frank" Fontana, O.D.

Other key early practitioners that laid the groundwork for the modern contact lens practices of today include **Neal Bailey, O.D.,** in Ohio; **Rodger T. Kame, O.D.,** and **Melvin J. Remba, O.D.,** in California; **Robert Kennedy, O.D.**, in Minnesota; **Jack Solomon, O.D.,** in Florida; and **Clarence McEachern, O.D.,** and **Wayne S. Cannon, O.D.,** in South Carolina.

Others made tremendous contributions to contact lens practice through academic research, developing novel devices and identifying corneal anomalies. Many of them, including **Donald Korb, O.D.,** in Boston, **Robert Morrison, O.D.,** in Pennsylvania, **Leonard Seidner, O.D.,** in New York and **Morton Sarver, O.D.,** in California, have been profiled already in this series.

[LEARNING FROM EACH OTHER]

In addition to establishing their own successful practices, the early contact lens practitioners shared their expertise with each other and with future generations. Many set up study groups specifically to share best practices.

The first of these was spearheaded by Dr. Koetting in the 1960s. He convinced a group of practitioners (Harold Davis, Clarence McEeachern, Danny Klaff, Jack Hill, George Bournachal, Bill Fleishman, John Kennedy, Tom Scarborough, Bob Head, Ted Kassalow, Burtt Holmes, and himself) to meet and discuss their successes every six months for 40 years.They called themselves the American Society of Contact Lens

Specialists but were soon dubbed "The Dirty Dozen," after the movie by the same name. The doctors in the study group became close friends. They shared tips on business practices, marketing, financials, lenses and solutions, fitting techniques, and personal problems and successes. They would all become prominent authors and sought-after lecturers in the field.

Left to right: Rick Weisbarth, O.D., Richard Hill, O.D., Kenneth Polse, O.D., Donald Korb, O.D., and Robert B. Mandell, O.D., at the 2006 CLCS Awards Reception.

In the 1980s, many other practice management groups modeled themselves after the Dirty Dozen. They had names such as the EyeCare Management Group, the Obscene Thirteen, and the Mustache Group. These three, along with the original Dirty Dozen, and a second-generation spinoff of that group, all came together in the early 1990s for a joint meeting in Phoenix, which they called the Contact Lens and Anterior Segment Society, or CLASS. CLASS was a valuable source of contact lens education until the Attorneys General for Florida and several other states initiated investigations into these types of contact lens meetings.

[TODAY'S LEADERS]

Pioneers in the contact lens field are not hard to identify. Perhaps more challenging is to consider who leads the field today, now that contact lenses are an integral part of nearly every optometric practice. In advance, we offer the caveat that many fine individuals who played major roles in the development of the contact lens specialty have no doubt been left out. The oversight is our own, and we apologize in advance.

Certainly a good place to start is with the two organizations that have clearly led the way in contact lens practice. The Cornea and Contact Lens Section of the American Academy of Optometry (CLSAAO) was established in 1947 and was the source of nearly all formal contact lens education in the early years of the field. Its members are qualified as contact lens specialists or Diplomates, a distinction that is difficult to earn.

The American Optometric Association's (AOA) Contact Lens and Cornea Section (CLCS) was founded in June of 1981 by **G. Burtt Holmes, O.D., James A. Boucher, O.D., M.S., Harold E. Davis, O.D.,** and **Frank D. "Uncle Frank" Fontana, O.D.** They hired **Arthur R. Giroux, O.D.,** a retired Army colonel, to serve as director. "We had 300 members before it even got off the ground," Dr. Fontana recalled. Today, there are more than 9,000 members, and the CLCS is a major force in educating practitioners, working closely with government agencies and the CLSAAO to protect consumers, and consulting with industry to bring better contact lens devices to market.

The past chairs of CLCS and the CLSAAO are all giants in the field who have helped to shape the contact lens industry over the past 60 years. They are listed on page 22. Following them, we list leading contact lens practitioners, including those in traditional private practice settings, university-based and multiple-specialty practices, academia, and industry. Finally, we add to the list young optometrists who have already demonstrated great abilities and accomplishments in their careers and who will likely be recognized as some of the leaders of the next generation.

We have endeavored to list individuals only once in this article, even though they may fit into several different categories.

[SPECIAL THANKS]

Special thanks to contributors Robert Davis, O.D.; Art Epstein, O.D.; and Glenda Secor, O.D., for their assistance with this series.

1994

Dr. Hamano conducts a large-scale study comparing complication rates of various contact lens modalities in 23,000 patients.

1995

The concept of disposability led to the introduction by Vistakon of the first single-use lenses, 1-Day Acuvue.

Today's Leaders

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1998

CIBA Vision introduces the first successful silicone hydrogel (SiHy) contact lens, the Night & Day lens, to the global market; it became available in the United States in 2001.

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