Silicone Hydrogel contact lens

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Contact Lens

Contact Lenses are shaped pieces of transparent material, which are place on the cornea of the eye, usually with the aim to correct the refractive error (long or short -sightedness) of an individual. Approximately 120 million people globally wear contact lenses. Over 600 million people need and can afford to wear lenses Source.

Types of Contact Lenses

There are two general categories of contact lenses ? soft and rigid gas permeable (RGP).

- **Soft Contact Lenses**

Soft contact lenses are made of soft, flexible plastics that allow oxygen to pass through to the cornea. Soft contact lenses may be easier to adjust to and are more comfortable than rigid gas permeable lenses. Newer soft lens materials include silicone-hydrogels to provide more oxygen to your eye while you wear your lenses.

- **Rigid Gas Permeable (RGP) Contact Lenses**

Rigid gas permeable contact lenses (RGPs) are more durable and resistant to deposit buildup, and generally give a clearer, crisper vision. They tend to be less expensive over the life of the lens since they last longer than soft contact lenses. They are easier to handle and less likely to tear. However, they are not as comfortable initially as soft contacts and it may take a few weeks to get used to wearing RGPs, compared to several days for soft contacts.

- **Extended Wear Contact Lenses**

Extended wear contact lenses are available for overnight or continuous wear ranging from one to six nights or up to 30 days. Extended wear contact lenses are usually soft contact lenses. They are made of flexible plastics that allow oxygen to pass through to the cornea. There are also a very few rigid gas permeable lenses that are designed and approved for overnight wear. Length of continuous wear depends on lens type and your eye care professional?s evaluation of your tolerance for overnight wear. It?s important for the eyes to have a rest without lenses for at least one night following each scheduled removal.

- **Disposable (Replacement Schedule) Contact Lenses**

The majority of soft contact lens wearers are prescribed some type of frequent replacement schedule. ?Disposable,? as defined by the FDA, means used once and discarded. With a true daily wear disposable schedule, a brand new pair of lenses is used each day.
Some soft contact lenses are referred to as ?disposable? by contact lens sellers, but actually, they are for frequent/planned replacement. With extended wear lenses, the lenses may be worn continuously for the prescribed wearing period (for example, 7 days to 30 days) and then thrown away. When you remove your lenses, make sure to clean and disinfect them properly before reinserting.

- **Specialized Uses of Contact Lenses:** Conventional contact lenses correct vision in the same way that glasses do, only they are in contact with the eye. Two types of lenses that serve a different purpose are orthokeratology lenses and decorative (plano) lenses.
- **Orthokeratology (Ortho-K)**

Orthokeratology, or Ortho-K, is a lens fitting procedure that uses specially designed rigid gas permeable (RGP) contact lenses to change the curvature of the cornea to temporarily improve the eye?s ability to focus on objects. This procedure is primarily used for the correction of myopia (nearsightedness).

Overnight Ortho-K lenses are the most common type of Ortho-K. There are some Ortho-K lenses that are prescribed only for daytime wear. Overnight Ortho-K lenses are commonly prescribed to be worn while sleeping for at least eight hours each night. They are removed upon awakening and not worn during the day. Some people can go all day without their glasses or contact lenses. Others will find that their vision correction will wear off during the day.

- **Decorative (Plano) Contact Lenses**

Some contact lenses do not correct vision and are intended solely to change the appearance of the eye. These are sometimes called plano, zero-powered or non-corrective lenses. For example, they can temporarily change a brown-eyed person?s eye color to blue, or make a person?s eyes look ?weird? by portraying Halloween themes. Even though these decorative lenses don?t correct vision, they?re regulated by the FDA, just like corrective contact lenses. They also carry the same risks to the eye. These risks include:

- conjunctivitis (pink eye)

- corneal ulcers
- corneal abrasion
- vision impairment or blindness

Lens Type - By Implantation: Collectively, types of contact lenses are as follows Source

- **Bifocal Contact Lenses** - They provide both near and distance vision
- **Colored Contact Lenses** - They give your eyes a subtle or dramatic change
- **Disposable Contact Lenses** - They enable a healthier wearing experience
- **Extended Wear Contact Lenses** - They are for safe overnight wear
- **Gas Permeable (GP) Contact Lenses** - They are for the ultimate in crisp vision
- **Monovision** - They are an alternative to bifocals for presbyopia
- **Orthokeratology Lenses** - They are for overnight corneal reshaping
- **Prosthetic Contact Lenses** - They are mask eye injury or disfigurements
- **Silicone Hydrogel Contacts** - They transmit more oxygen to your eyes
- **Special-Effect Contact Lenses** - They let you become a leopard or cheetah
- **Specialty Lenses** - They are for the "hard-to-fit" patient
- **Toric Contact Lenses** - They provide good vision if you have astigmatism

Classification of lenses

Lens Types	Advantages	Disadvantages
Rigid gas-permeable (RGP) Made of slightly flexible plastics that allow oxygen to pass through to the eyes.	Excellent vision... short adaptation period... comfortable to wear... correct most vision problems... easy to put on and to care for... durable with a relatively long life... available in tints (for handling purposes) and bifocals.	Require consistent wear to maintain adaptation... can slip off center of eye more easily than other types... debris can easily get under the lenses... requires office visits for follow-up care
Daily-wear soft lenses Made of soft, flexible plastic that allows oxygen to pass through to the eyes.	Very short adaptation period... more comfortable and more difficult to dislodge than RGP lenses... available in tints and bifocals... great for active lifestyles.	Do not correct all vision problems... vision may not be as sharp as with RGP lenses... require regular office visits for follow-up care... lenses soil easily and must be replaced.
Extended-wear Available for overnight wear in soft or RGP lenses.	Can usually be worn up to seven days without removal.	Do not correct all vision problems... require regular office visits for follow-up care... increases risk of complication... requires regular monitoring and professional care.
Extended-wear disposable Soft lenses worn for an extended period of time, from one to six days and then discarded.	Require little or no cleaning... minimal risk of eye infection if wearing instructions are followed... available in tints and bifocals... spare lenses available.	Vision may not be as sharp as RGP lenses... do not correct all vision problems... handling may be more difficult.
Planned replacement Soft daily wear lenses that are replaced on a planned schedule, most often either every two weeks, monthly or quarterly.	Require simplified cleaning and disinfection... good for eye health... available in most prescriptions.	Vision may not be as sharp as RGP lenses... do not correct all vision problems... handling may be more difficult.
American Optometric Association		

Conventional Vs Silicone Hydrogels - Status

- Newer Silicone Hydrogel Contact Lenses Offer Significantly Improved Comfort Over Hydrogel Lenses in Adverse Environments. American Optometry Society
- Morgan et al reported for the fifth time on the survey for international contact lens prescribing and suggest that during 2005 non-disposable soft lenses were down to 10 percent of soft lenses prescribed to new patients for all countries surveyed and as low as 1 percent in Norway and 2 percent in the United Kingdom Source
- A survey of lens fitting within 15 countries found that silicone hydrogel lens materials now account for more than 90% of soft lens extended-wear fits. The two exceptions: Russia, where silicone hydrogels comprise 78% of soft lens extended wear fits, and the United States, where they account for 48%. In the United States, the number of silicone hydrogel lenses prescribed for daily wear has increased approximately eightfold since 2003 Blue Book of Optometry

Silicon Hydrogel Contact lens

They are a new generation of "super-permeable" contact lenses can transmit unprecedented amounts of oxygen to your cornea and, in some cases, enable 30 consecutive days of wear without removal.

Silicone hydrogel contact lenses represent a breakthrough over traditional hydrogel soft contact lenses, because silicone lets so much oxygen (essential for a healthy cornea) pass through the lens
Source

Working

Traditional soft contact lenses are made from hydrogel polymers (soft, water-containing plastics). The plastic itself is not oxygen permeable, so the water performs the job of carrying oxygen through the lens to the eye. But water can carry only so much oxygen ? and the more water a lens contains, the greater its tendency to dehydrate after long periods of wear.

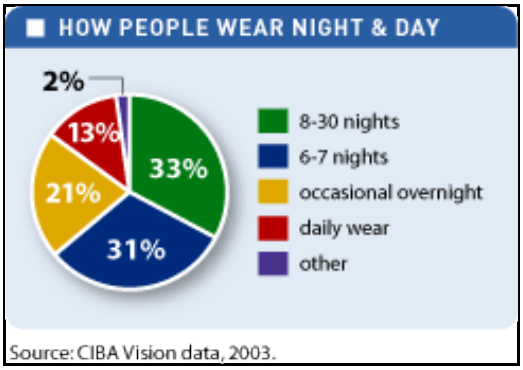
Silicone is oxygen permeable. So silicone hydrogel lenses use both their water and polymer content to transmit oxygen to the eye.

Benefits to wearers include comfort and convenience

Silicone hydrogel contact lenses contain less water than traditional hydrogel lenses. As a result, they aren?t as prone to dehydration while you?re wearing them. For some people who wear their lenses for long days, this can mean better end-of-day comfort.
Silicone hydrogels also have made 30-day contact lens wear ? sometimes called "continuous wear" ? available once again.

Different flavors of silicone hydrogel

Because silicone hydrogel lenses provide increased oxygen to your eyes, 30-day wear isn?t the only reason to consider using them. And in fact, not all silicone hydrogel brands are approved for 30 days of wear Source



Flavours
The table shown below describes the current brands of spherical silicone hydrogel lenses available, in order of highest oxygen transmissibility to lowest and two brands of toric (astigmatism correcting) silicone hydrogel lenses Source

Spherical Silicon hydrogel lens			Toric Silicon hydrogel lens		
Company	**Brand**	**Wear time**	**Company**	**Brand**	**Wear**
CIBA vision	Focus Night & Day	30 day continuous wear	Bausch & Lomb	PureVision Toric	30 day wear
Vistakon	Acuvue Oasys	2 week daily wear or 6 night extended wear	Vistakon	Acuvue Advance	2 week lens
CIBA vision	O2 Optix	6 days continuous wear or 2 weeks daily wear			
Bausch & Lomb	PureVision	30 days continuous wear			
Vistakon	Acuvue Advance	2 week disposable lens			

Brands

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Lens solution

- Among various lens maker lens solution is important source of revenue and there is lot of research going on in this field.
- Dry eye, which affects up to 34% of the general population, is a condition resulting primarily from a disturbance of the tear film caused by either deficiency (i.e., reduced tear production or excessive evaporation) or poor quality.
- Dry eye symptoms are much more prevalent in patients who wear contact lenses (affecting about 50%) than in the non-lens wearing population.
- Contact lens wearers are 12 times more likely to report symptoms of dry eye than clinical emmetropes and 5 times more likely to report symptoms than spectacle wearer.

- About 18 million contact lens wearers in North America experience dryness symptoms, but on a positive note, about 90% of these patients employ strategies such as reducing their wearing time or use rewetting drops that allow them to continue lens wear.
- Guillon et al. noted that contact lens wearers are more likely to report ?dryness? symptoms, whereas nonwearers tend to report symptoms of ?soreness? and ?burning.? Source

Future research ideas for improving comfort, reducing complications

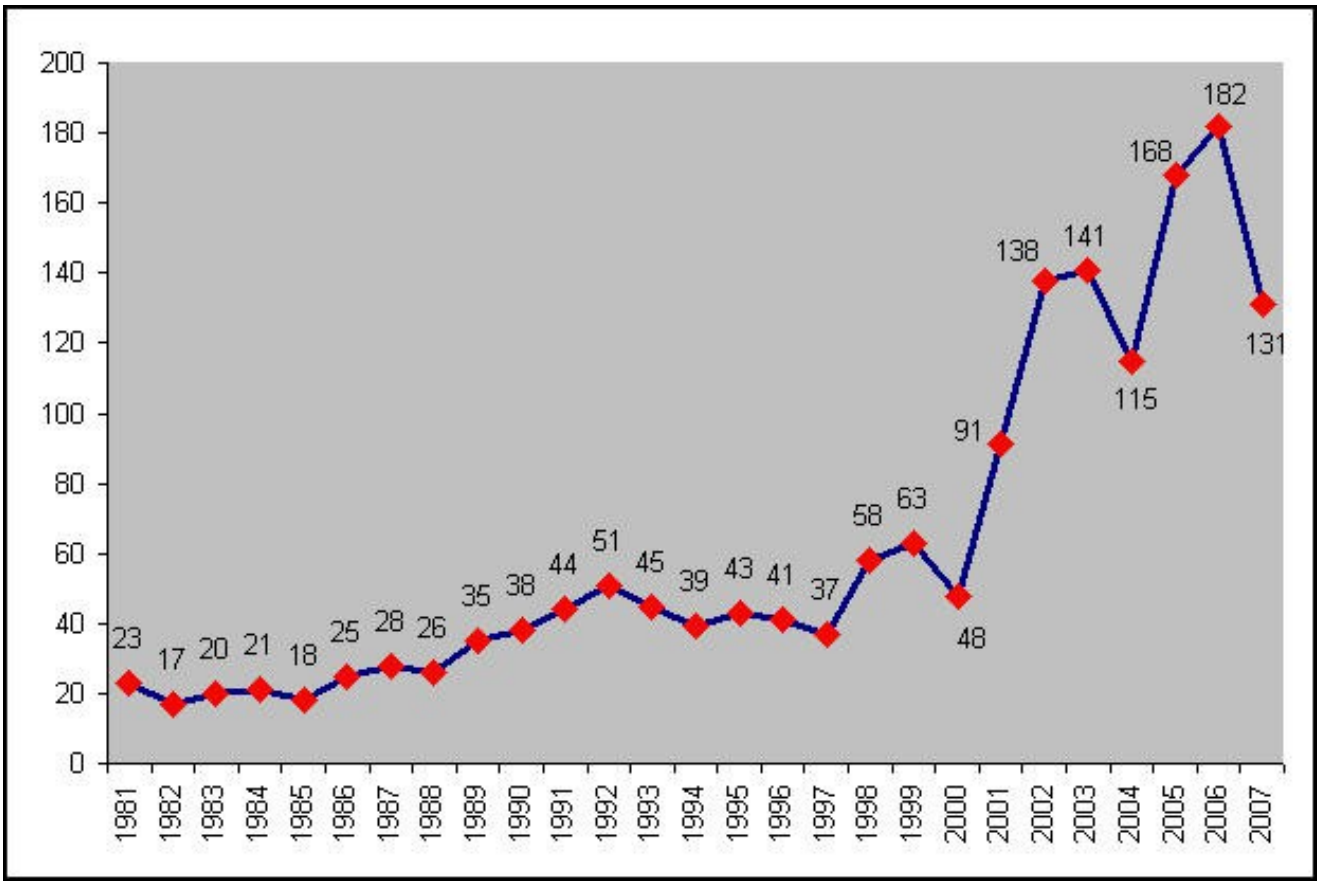
- The advent of silicone hydrogel lenses has indeed shown that in their highest Dk/t modality they virtually eliminate all hypoxic side effects. Further, if Dk/t is maintained above 125 across the whole lens it is a reasonable proposition that it will allow lenses to be worn for decades without corneal metabolic malfunction or physiological failure due to hypoxia.
- The peripheral cornea is an important consideration in both the short-term and long-term health of the cornea, as the limbal region is the source of epithelial stem cells. Current Dk/t at the limbus with thick periphery silicone hydrogel lenses may not be high enough. Thin periphery lens designs should be tried to increase the Dk/t.
- New research directions are necessary to achieve a truly biocompatible lens that causes fewer disturbances to the tear film, cornea, and conjunctiva. Modification of materials, designs, solutions, and better surfaces to limit the adherence of deposits and inhibit microorganism colonization are under investigation.
- Recent studies on antibacterial contact lenses coated with selenium in rabbits and lens cases impregnated with silver in a 1-month clinical trial showed that there was less adhesion of microbes and bacterial contamination in the test lenses and cases than in the control ones. These are promising results, but the components used must be effective against micro-organisms and at the same time not cause any adverse reaction to the ocular tissue. This new technology should reduce the risk of infection and infiltrative corneal conditions during contact lens wear.
- Recent polymer soaking solution additives designed to keep the lens moist over time have made some headway, but a new approach is needed to optimize the polymer-surface-solution to achieve the next breakthrough in comfort. Source

IP Analysis

Patent Search Strategy

Search scope: US Granted US Applications EP-A EP-B WO JP (bibliographic data only) DE-C,B DE-A DE-T DE-U GB-A FR-A; Full patent spec.
Years: 1981-2007
Text: (((Silicone and hydrogel) or SiHy or siloxane) and (contact adj1 lens*))
Number of records: 1686 records

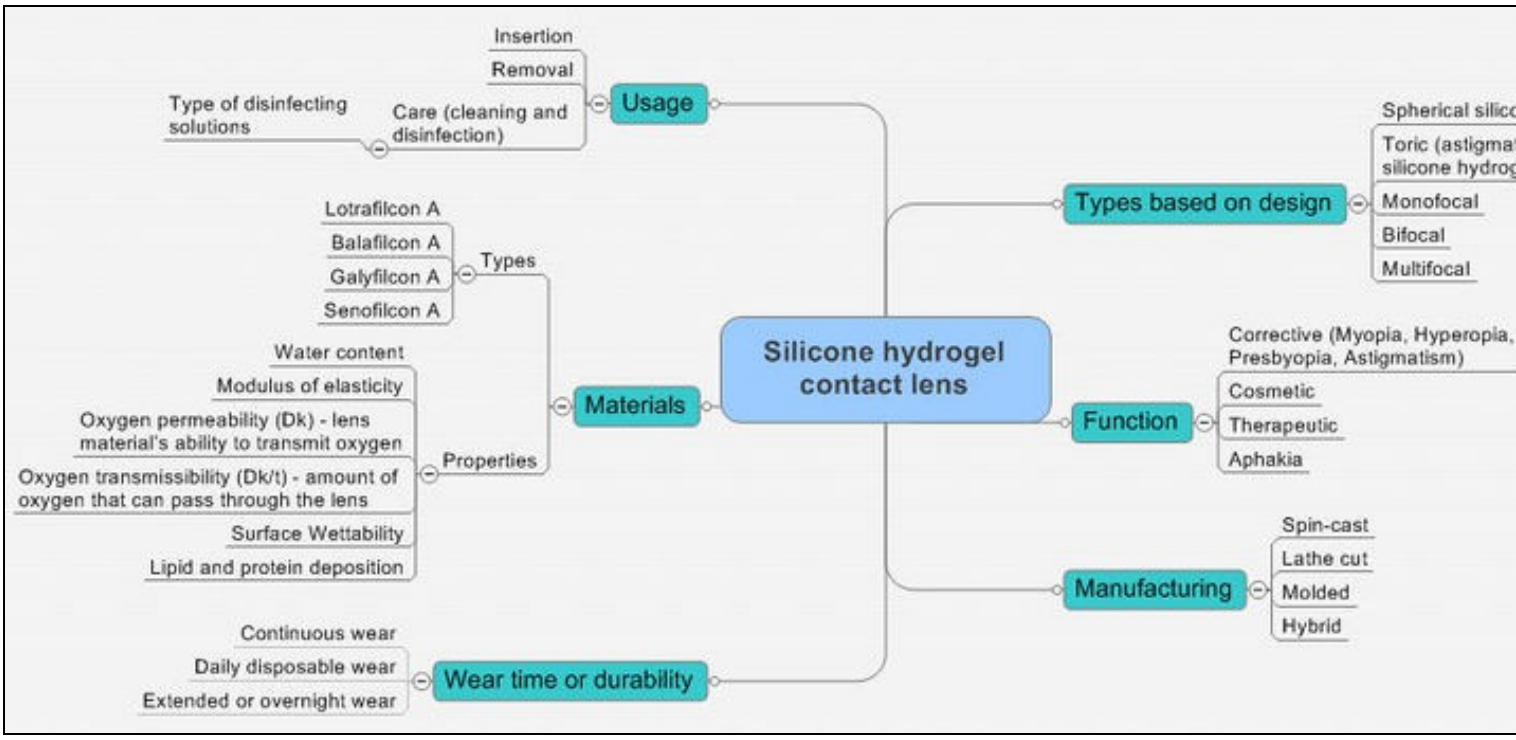
IP Trends over publication years



IP Trends

Taxonomy

- The technology mapping parameters are based on general study of the silicon hydrogel lens technology.
- These parameters are used as guidelines when studying patent information. The patent information analyzed is then classified into each of these parameters, which in turn provides guidelines of research trends over time and competitor focus areas.



Taxonomy

Market Information

- It has been estimated that about 125 million people use contact lenses worldwide (2%), including 28 to 38 million in the United States and 13 million in Japan.
- By 2009, silicone hydrogel lenses are expected to account for more than two-thirds of U.S. soft contact lens sales (in dollars), according to equity research firm Robert W. Baird & Co.
- Spurred by favorable trends, the world contact lens and lens care solutions market is expected to reach US$6.7 billion by 2010 Source.

Clinical information

- A British study conducted at the University of Manchester and published in 2005 found that people who slept in traditional hydrogel lenses were five times more likely to develop keratitis than those sleeping in silicone hydrogel lenses.

Statistics in USA

- Currently, more than 34 million people wear contact lenses in the United States.
- Approximately 85% of wearers use soft contact lenses and 15% wear gas permeable hard lenses.
- Eighty percent are using daily wear or flexible wearing schedules whereas 20% of patients use an extended-wear schedule.
- An estimated 4.1 million people were wearing contact lenses in an extended fashion by 1987, with more than 97% of those wearing the lenses for cosmetic correction.
- An incidence of ulcerative keratitis of 0.2% in patients with extended wear, a risk five times that of daily wear contact lenses.
- Because of the concerns of increased risk of infectious keratitis the percentage of people using contact lenses in extended wear in the United States dropped from 21% in 1995 to approximately 10% in 2002.
- A survey of 93 members of the Contact Lens Association of Ophthalmologists (CLAO) conducted in 2001 indicated that only 10% of ophthalmologists, optometrists, and opticians prescribed extended wear, and that even with the approval and promise of the high-Dk silicone hydrogel lenses only 15% of ophthalmologists and 18% of optometrists anticipated prescribing them for extended wear (CLAO Survey, Foulks GN, 2001). Source

Medical practioner survey information

- A recent online survey asked Eye Care Professionals if they prescribed silicone hydrogel contact lenses and given the numerous benefits of these lenses, the results were somewhat of a surprise. Of those participating in the survey, 36% prescribed for 30-day wear, 27% for daily wear, 16% for 7-day wear and a remarkable 21% of eyecare professionals did not even prescribe these lenses. Source
- In a survey conducted to find the use of Silicone Hydrogel Contact Lenses by Canadian Optometrists from 2000 ? 2006, Soft contact lenses were fit to 91.3% of the patients. Of the soft fits the percentage of silicone hydrogel lenses increased from 5.4% in 2000 to 42.9% in 2006. Initially, silicone hydrogel lenses were prescribed for continuous wear exclusively. In 2004 two new daily wear silicone hydrogel lenses were introduced into the Canadian market. The proportion of silicone hydrogel lenses being fit for daily wear increased from 33.7% in 2004 to 86.1% in 2006. Silicon Hydrogels.org

Company surveys and findings

- Bausch & Lomb (manufacturer of Purevision, Purevision Toric and Purevision Multifocal contact lenses) reported that 40% of new contact lens fits are now silicone hydrogel contacts. They claim that 94% of wearers of their sector leading Soflens 66 Toric contacts can be migrated to the Purevision Toric lens without a script change.
- Vistakon, manufacturer of the Ultra-Comfort series of contact lenses which comprises the Acuvue Advance, Acuvue Advance for Astigmatism and the Acuvue Oasys says their silicone hydrogels are all addressing the issue of end-of-day comfort for contact lens wearers. Prescription parameter ranges are being expanded for each of these lenses (most recently, plus powers for Oasys were made available). Acuvue Oasys was also recently given FDA approval for up to 7 days of continuous wear. Vistakon claims to have the number one silicone hydrogel with their Acuvue Advance and the number one new-wearer toric in the Advance for Astigmatism Source
- A post approval study of one year was conducted by CIBA vision, the study followed the experiences of 6,000 people who were prescribed Night & Day for up to 30 nights of consecutive wear. In the study, the incidence of microbial keratitis (an infection that can result in vision loss) was less than 0.18 percent, and the rate of microbial keratitis resulting in reduction of visual acuity was less than 0.04 percent. These rates are higher than for daily wear, but are still considered reasonable by many as a tradeout for the benefits of continuous wear.

- Focus Night & Day were the subject of a three year study by Ciba Vision. In particular, the study of 317 patients showed that Focus Night & Day wearers had less problems with red eye, reduced dryness (22%) and neo-vascularization (the development of new blood vessels in the cornea) was reduced by 13%. During the first 8 months of 2005, Silicone Hydrogels represented 24% of all soft contact lens sales ? more than double the figure for the same period of 2004. Ciba lenses represented almost 50% of silicone hydrogel sales during this time.

Key Companies

- Alcon
- Bausch & Lomb
- Ciba Vision
- Jonhson & Johnson (Vistakon)
- Cooper vision
- Art Optical Contact Lens
- RX Optical Corporate
- Unilens
- 1-800 Contacts Inc.

Research Collaborations (from patent searches)

Collaborations	No. of records
Menicon Co., Ltd. | Shin Etsu Chemical Co., Ltd.	6
Genencor International, Inc. | The Procter & Gamble Company	5
CIBA Vision Corporation | Commonwealth Scientific and Industrial Research Organsation	4
Shin Etsu Chemical Co., Ltd. | Toyo Contact Lens Co., Ltd.	3
Santen Pharmaceutical Co., Ltd. | Li, Fumian	2
Novartis AG | Commonwealth Scientific & Industrial Research Organisation	2
California Institute of Technology | The Regents of the University of California	1
Chitogenics, Inc. | The American National Red Cross | Coalition for Hemophilia B	1
Biopolymerix, Inc | Surfacine Development Company, Inc.	1
Organogenesis, Inc. | The President and Fellows of Harvard College	1
Japan Synthetic Rubber Co., Ltd. | Ricky Contact Lens Research Institute Inc.	1
Asahikasei Aime Co. Ltd. | CooperVision, Inc.	1
Southwest Research Institute | Keraplast Technologies, Ltd.	1
Takiron Co. Ltd. | Osaka Municipal Government	1
Adeka Corporation | The Kansai Electric Power CO., INC.	1
The University of North Carolina at Chapel Hill | North Carolina State University | Synecor, LLC	1
Quick Med Technologies, inc. | University of Florida Research Foundation, Inc.	1
Combinatorx, Incorporated | Angiotech International Ag	1
Sosei Co., Ltd. | Tanabe Seiyaku Co., Ltd. | Combinatorx incorporated	1
Smart Holograms Limited | Ciba Vision Corporation | Cambridge University Technical Services Ltd.	1
Kuraray Co Ltd | Sagami Chem Res Center	1

Based on general web search

Company 1	Company 2	Collaboration year	Collaboration type	Collaborated for Link	Link
Fenway Partners	1-800 Contacts Inc.	2007	Buy out	Replacement contact lenses	Source
Implantable Vision Inc	Ciba Vision Inc.	2006	Licensing agreement	Acquire patents and intellectual property regarding an inside-the-eye contact lens for $1 million	Source
Cooper Inc.	Occular sciences Inc.	2004	Merger	Merger will result in worlds 3rd largest contact lens company	Source
Vision CRC	IER and CCLRU	2004	Research study Collaboration	The study is to study rates of corneal infection with contact lenses	Source

CIBA Vision	Wesley Jessen corp.	2001	Merger	Merger of two Novartis contact lens subsdiaries	Source
CRC	CIBA Vision	1997	Research Collaboration	To develop silicone hydrogel contact lens that can be worn for 30 days and nights and also for daily wear lens	Source
Allergan	Ioptex Research global intraocular lens	1994	Licensing agreement	Intraocular lens product line	Source
Engineering and Physical Sciences Research Council	Vista Optics Ltd		Jointly funding agreement	To develop new generation of ophthalmic biomaterials	Source
CIBA vision	Laboratories Faure	1993	Licensing agreement		Source
Unilens	Novartis		Licensing agreement	Aquaflex and Softcon EW contact lens products	Source

Venture capital

- Bausch & Lomb Inc., the eye-products maker rocked last year by financial restatements and the recall of its contact-lens solution, agreed to be bought by private equity firm Warburg Pincus for $3.67 billion in cash. Source
- To develop a handheld reader that takes the glucose readings from the lens and to conduct early clinical trials, CIBA vison has raised CHF 10.7 million (?6.5 million) in a Series A round led by Swiss-based BioMedinvest and Life Sciences Partners, a Dutch venture firm in 2006 Source
- Bausch & Lomb Ireland has announced a ?42m expansion of its contact lens plant in Waterford Source
- E-Dr. Network, Inc. (E-Dr.) announced today that it has received venture capital financing of $8 million led by Noro-Moseley Partners of Atlanta, Georgia, with a co-investment from Benchmark Capital of Menlo Park, California. The company is the leading web-based business-to-business, e-commerce provider in the vision care segment of the U.S. healthcare industry. Source
- Scottish Equity Partners (SEP) invested an initial £1 million and in 2002 injected a further £2 million to fund additional production lines at Provis? manufacturing facility in Hamilton International Technology Park Source
- Ophthonix has raised $35.1 million in "Series D" financing for its vision correcting products/lenses. Source
- Cooper vision in 2005 announced its plans to introduce a two week continuous wear re-usable silicon hydrogel lens.

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