

# Industry's Contribution to Refractive Surgery





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In recent decades, the ophthalmic industry has played a significant role in the growth and development of refractive surgery. While ophthalmic pioneers, such as Dr. José I. Barraquer invented many of the instruments needed to perform the early procedures, it was the dedicated collaboration and resources of ophthalmic manufacturers that facilitated the perfection and refinement of instruments and technology for wider distribution and access.

Industry leaders such as Alcon, Inc., Bausch & Lomb, Inc., Advanced Medical Optics, Inc. and Nidek Co., Ltd. have all worked closely with surgeons around the world on technological and educational innovations. With their continued support, scientific societies such as the ISRS/AAO will successfully provide worldwide educational programs that help surgeons improve the quality of life for patients around the world.

We have to acknowledge that without support from industry, the history of refractive surgery would have been different and less brilliant. Refractive surgery is an excellent example of how technology can deliver practical applications for patients.

We are pleased to acknowledge those companies that have contributed to this book by highlighting their own stories about their individual roles and contributions to refractive surgery.



## The Alcon Approach to Improving Refractive Technology

Alcon, Inc.'s approach to refractive surgery is threefold: focus efforts on forms of visual impairment that require attention, use applied research to determine new treatments as quickly as possible and collaborate with clinicians worldwide to quickly help patients most in need.

Progress in refractive surgery depends upon continued advancements in scientific knowledge resulting from the exchange of information and sharing of ideas. Alcon supports this progress by adopting a collaborative approach with those whose area of expertise complements that of their own corporation. This approach enables Alcon to research and develop new technologies with the goal of improving patient care and visual outcomes.

Alcon is proud to support scientific societies such as the ISRS/AAO. Since its inception, the ISRS/AAO has shaped and influenced the ophthalmic industry by creating opportunities to share ideas that ultimately lead to innovations. Leaders in the Society have worked closely with Alcon to identify and develop the tools necessary for safe and successful refractive surgery procedures. Alcon's partnership with refractive surgery leaders has made an immeasurable impact on their research and development efforts and ability to deliver innovative solutions for refractive surgery practitioners worldwide.

## Role in the Evolution of Modern Refractive Surgery

### The Excimer Laser

An estimated 58 percent of individuals worldwide suffer from some type of ametropia. Fortunately, refractive surgery procedures can correct the natural limitations of the human eye while enhancing vision and providing better quality of life for those affected individuals.

Alcon has always been at the forefront of customized LASIK surgery and continues to develop new technologies for the surgical correction of a wider range of refractive errors—ultimately reducing people's dependence on spectacles or contact lenses.

In 2000, Alcon purchased Summit-Autonomous in order to offer physicians a complete range of refractive surgery products. Alcon executives were pleased with Summit-Autonomous' innovative and interesting approach, including wavefront-guided custom ablations. Summit-Autonomous' laser technology led to the launch of Alcon's signature laser platform, the LADARVision® 4000, which provided Alcon with a strong worldwide presence in the refractive laser surgery market.

In late 2002, Alcon was the first ophthalmic manufacturer to gain FDA approval for wavefront-guided corneal ablations, which expanded the indica-



tions of the LADARVision® System to include CustomCornea®. This procedure allows clinicians to account for and treat higher-order aberrations, which were previously uncorrectable with other laser, vision systems.

### **Future in Refractive Surgery**

Alcon is committed to furthering refractive surgery technology and is constantly evaluating new and existing technologies to provide surgeons with a complete refractive solution on a global basis. In fact, we are expanding upon our market-leading AcrySof® platform with the development of an angle-supported phakic lens.

### **Commitment to Improving Global Eye Health**

#### **Quality Products and Dedication to Long-Term Relationships**

We pride ourselves on providing the best health care products and solutions for treating diseases and conditions of the eye. We have developed our leadership, expertise and breadth of ophthalmic offerings for more than 60 years, and are unsurpassed in the marketplace today. We understand that being the global leader requires more than just offering high-quality eye care products. Therefore, we are guided by a culture of accountability and a steadfast commitment to relationships with eye care professionals and other doctors who prescribe our products.

#### **Diverse Research and Development Efforts**

With the largest corporate research and development commitment of any eye care company worldwide, Alcon is currently developing pharmaceutical products to treat glaucoma, retinal diseases, dry eye, infection, inflammation and allergy; surgical products for cataract, vitreoretinal and refractive procedures and consumer products in the areas of contact lens care, dry eye and ocular health. In 2006, we spent \$512 million on research and development, with plans to invest more than \$3 billion over the next five years.

#### **Social Responsibility**

Although our primary corporate focus is to provide the best products and solutions for the treatment of eye diseases and conditions, Alcon is also dedicated to reducing the incidence of preventable blindness worldwide. In 2006, Alcon donated \$73 million in cash and products to charitable activities, including patient access assistance programs for low-income patients and 1,100 medical missions in more than 80 countries that restore vision to those without access to eye care services. Alcon also supports ongoing medical training in the latest eye care technologies by maintaining more than 60 training centers around the world, most of them located in emerging markets.



## Bausch & Lomb, Inc.

Bausch & Lomb, Inc.'s (B&L) long heritage in perfecting vision began more than 150 years ago when John Jacob Bausch first opened an optical store in Rochester, New York, in 1853. Three years later, Bausch formed a business alliance with Henry C. Lomb, resulting in a partnership and the foundation of Bausch & Lomb.

Prior to its entry into the refractive surgery arena, through a series of acquisitions (e.g., Chiron Vision and Storz Ophthalmics), B&L was recognized for developing the highest-quality, vision correction contact and glass lenses, optical instrumentation, diagnostic equipment and ophthalmic pharmaceuticals. Delivering continued innovations and technological advances, designed to improve patient outcomes, is the cornerstone of our philosophy.

B&L was one of the first manufacturers to support formal refractive surgery programs, often developed in cooperation with the ISRS/AAO leaders. Early radial keratotomy courses, conducted at sites around the United States, provided greater access to refractive surgery education and paved the way for industry-supported educational programs that continue to support new innovations and advances.

Since 1991, Bausch & Lomb (then Chiron Vision) has delivered an innovative array of refractive surgery technologies. B&L's initial success in radial keratotomy led to one of the earliest industry-supported educational programs that effectively trained surgeons entering the refractive market and validated the efficacy of the procedure.

In 1993, B&L launched the Keracor 116 excimer laser. Although excimer lasers were initially introduced for PRK, key opinion leaders began to look at the minimal wound-healing effects of LASIK with great interest. The following year, B&L established a LASIK Advisory Board that included 14 of the world's most insightful leaders in the field of refractive surgery. These "pioneers" established a standardized LASIK surgical technique and developed a related training program.

In 1997, Bausch & Lomb established a new surgical division following its acquisition of Chiron Vision and Storz Ophthalmics, which provided the Technolas Zywave wavefront and the Orbscan topography measurement systems.

In 2003, B&L introduced the Zyoptix platform, a new personalized laser vision correction system for sharp, clear and accurate vision.

The combination of these technologies formed the foundation of the Bausch & Lomb Zyoptix® Platform for refractive surgery. The Zyoptix platform, which includes the 217z100 excimer laser, diagnostic workstation and XP microkeratome, has an exceptional record in safety and has played a pivotal role in the development of today's refractive surgery treatments. Innovations within the Zyoptix Platform enable greater predictability and accuracy, faster diagnostics and improved safety and efficiency.



B&L's Zyoptix 217z100 laser system encompasses key refinements and features for enhanced predictability, accuracy and safety that include iris recognition technology, a state-of-the-art multidimensional eye tracking system and a higher-frequency laser source.

The iris recognition feature has been designed with patient safety in mind. A map of the entire iris is created to form a unique patient identification, which is stored with the patient's treatment file. This ensures that the right patient and the correct eye are treated by matching the intended treatment to the patient iris map retained in their file.

Iris recognition also serves as the basis for the new Advanced Control Eyetracking (ACE™) technology, which became available in late 2007. Zyoptix ACE is designed to further improve the accuracy and predictability of outcomes, compensating for intraoperative eye movement. Zyoptix ACE features dynamic compensation for intraoperative cyclotorsion, adjustment for static cyclotorsion between upright and diagnoses versus supine treatment position, 4-Dimensional tracking (X, Y, Z, Rotation) with a sampling rate of 240 Hz and response time of 6.6 milliseconds and compensation for pupil shift in cases where pharmacologic dilation may be required.

The faster Zyoptix 217z100 laser and refined algorithms combine to reduce overall treatment times by 50 percent, decreasing "flap-open" time and minimizing treatment variability due to the effects of dehydration of the stromal bed.

The Zyoptix Diagnostic Workstation (ZDW) is intrinsically linked with the laser system. Corneal topography and wavefront analysis are combined in this single, modular workstation featuring the Orbscan® IIz Corneal Topographer with Zywave® Wavefront Analyzer. The latest-generation Zyoptix Advanced Personalized Technologies (APT) speeds up the diagnostic process, enabling faster and easier data transfer and processing with a 10-fold increase in data storage.

Bausch & Lomb introduced the Zyoptix® Advanced Personalized Technologies (APT) in 2006. APT simplifies the patient workup process by significantly reducing the complexity and time involved to perform true wavefront-guided treatments. The main elements of Zyoptix APT include the following:

- ⦿ Zyoptix no-dilation algorithm eliminates the need to pharmacologically dilate pupils in the majority of personalized treatments. This significantly reduces preoperative workup for same-day procedures, allowing more efficient patient throughput.
- ⦿ Zyoptix Advanced Nomogram creates a personalized nomogram based on each patient's higher-order aberrations to provide improved predictability of visual outcomes. Application of this nomogram in treatments has shown 96.4 percent of patients achieving a predictability of outcome within +/- 0.5D.<sup>1</sup>

- ⦿ Zyoptix Treatment Calculator software standardizes the transition zone for more predictable outcomes and allows surgeons to compare and select the appropriate treatment options for each patient: Personalized, Aspheric or Tissue Saving.
- ⦿ The proprietary Zyoptix Treblinka™ Customer Network Support system allows direct transfer of diagnostic data from the diagnostic workstation to the Zyoptix 217z100 laser with a simplified software user interface, easier acquisition and storage.
- ⦿ TruLink also optimizes system functionality through remote monitoring, proactive service maintenance and the option to back up data.

The Zyoptix Platform provides surgeons with the choice to perform both stromal and epithelial flaps with consistent and repeatable flap thickness using the Zyoptix® XP Microkeratome, a comprehensive multifunctional microkeratome system. The precision-engineered, interchangeable components are easy to use and assemble, with built-in safety features and clinical versatility. The Zyoptix XP Epi Separator is the latest addition to the microkeratome system, catering for patients who may not be candidates for LASIK procedures.

## Zyoptix Treatment Options

Three treatment options are available with the Zyoptix Platform to provide the best choice for each patient:

- ⦿ Zyoptix Personalized combines both wavefront and topography data, to provide an individualized treatment plan that takes into account existing higher-order aberrations as well as compensating for surgically induced aberrations. This option uses iris recognition technology for accurate treatment placement.
- ⦿ Zyoptix Aspheric is based on topography data and generates a treatment profile designed to preserve the natural asphericity of the cornea. Clinical data shows a 77 percent reduction in surgically induced spherical aberration, for better visual outcomes than standard LASIK.
- ⦿ Zyoptix Tissue Saving produces a treatment profile that removes approximately 15 percent less tissue than Planoscan treatments. This treatment type is particularly beneficial to patients with thin corneas or mixed astigmatism.



## Shaping an Innovative Future for Refractive Surgery

Bausch & Lomb's current refractive research and development pipeline targets technologies that aim to provide improved outcomes with increased simplicity, safety, efficiency and predictability.

The need for options for correction of presbyopia is huge and growing with the aging of the "baby boomer" population. We fully expect that the market will support, even demand, a variety of vision correction solutions for presbyopes. It has always been B&L's strategy to explore a range of solutions so we can ultimately offer both doctor and patient an appropriate portfolio of products.

One approach involves Bausch & Lomb's strategic alliance with AcuFocus Inc., a privately owned company based in Irvine, California, that is developing a corneal inlay technology for presbyopia treatment.

The ACI 7000 corneal inlay is implanted in the nondominant eye under a LASIK flap in a simple outpatient procedure. The device incorporates proprietary technology that increases the patient's depth of field, thereby improving near vision. The ACI 7000 has been designed to maintain normal corneal physiology and corneal health. The procedure does not involve tissue removal nor does it permanently alter the cornea, so preimplant vision can be restored if the inlay is removed.

Bausch & Lomb continues to strive toward developing and providing solutions for excellent refractive outcomes. B&L's collaboration with the ISRS/AAO is an invaluable global forum to ensure the advancement of clinical research and assessment of new pioneering technologies.





## Advanced Medical Optics, Inc.

Advanced Medical Optics, Inc.'s (AMO) reputation for innovation began more than three decades ago as the ophthalmic research arm of Heyer-Schulte Medical Optics Center (HSMOC), a division of American Hospital Supply Corporation. The HSMOC would later change its name to American Medical Optics and eventually to Advanced Medical Optics, or AMO, as it is known today.

In 1976, AMO began as a pioneer in the early development of intraocular lenses (IOLs) for cataract patients.

Throughout the 1980s, AMO became known as a technology company, introducing innovative new IOLs, the first U.S.-made YAG laser and a first-generation phacoemulsification system for the removal of cataracts. A later generation of this technology, known as the Sovereign<sup>®</sup> System with WhiteStar<sup>™</sup> software, won the prestigious Medical Design Excellence Silver Award from the Industrial Designers Society of America in 1999 for "excellence in medical product design engineering."

In 1986, American Medical Optics was sold to Allergan Inc., and became known as Allergan Medical Optics.

A few years later in 1989, the company brought the first small-incision foldable IOL through the U.S. Food and Drug Administration (FDA) regulatory process. Foldable lenses were a major advance in cataract surgery because they made it possible for surgeons to insert the lens through a small incision, resulting in fewer traumas to the eye and faster visual recovery from cataract surgery, from months to days.

In 1997, AMO launched the Array<sup>®</sup> IOL, the first multifocal lens to be approved for commercial distribution by the FDA.

AMO became an independent company in June 2002 following a spin-off from Allergan.

In 2004, AMO introduced the Verisyse<sup>™</sup> phakic IOL for treatment of moderate to severe myopia, the first lens of its kind to receive FDA approval. The company also acquired the Tecnis<sup>®</sup> and CeeOn<sup>®</sup> IOLs, the Healon<sup>®</sup> line of viscoelastics and the Baerveldt<sup>®</sup> glaucoma device, marking the company's entrance into the glaucoma market. The Tecnis<sup>®</sup> IOL is the first IOL with a modified prolate optic to have a claim for improved functional vision.

On May 27, 2005, AMO completed the acquisition of Visx, Inc., creating the world's leading refractive surgical business, bringing together AMO's expansive suite of cataract and refractive surgical products with Visx's state-of-the-art laser vision correction systems.

The growth continued in 2007 with the addition of the industry's leading wavefront diagnostic system and femtosecond laser through the acquisitions of WaveFront Sciences and IntraLase Corp., respectively.

These additions give AMO the advanced corneal refractive technologies with the ability to offer a full-systems approach that is without peer in the industry.



Over the years, AMO has pioneered numerous technology “firsts” in the ophthalmic industry, including:

- ⦿ Flexible anterior chamber IOL
- ⦿ Foldable IOL in the United States
- ⦿ Multifocal IOL in the United States
- ⦿ Phakic IOL in the United States
- ⦿ Aspheric IOL with claim approved by FDA for improved functional vision
- ⦿ WhiteStar® technology
- ⦿ Advanced fluidics
- ⦿ Peroxide disinfection system
- ⦿ MPS addressing comfort and dryness
- ⦿ Three-coordinate eye tracking (Visx)
- ⦿ Iris registration (Visx)
- ⦿ Fourier calculation of wavefront data (Visx)
- ⦿ Broadest range for custom LASIK, most recently for high myopia

Today, AMO develops life-improving vision technologies for people of all ages. The company focuses on the development of a broad suite of innovative technologies and devices to address a wide range of eye disorders.

Products in the ophthalmic surgical line include intraocular lenses, laser vision correction systems, phacoemulsification systems, viscoelastics and related products used in cataract and refractive surgery. Products in the contact lens care line include disinfecting solutions, enzymatic cleaners and lens rewetting drops.

AMO is based in Santa Ana, California, and employs over 4,200 people worldwide. The company has operations in 24 countries and markets products in approximately 60 countries. AMO securities are listed as EYE on the New York Stock Exchange.

AMO is dedicated to advancing the science of vision through continual development of innovative technologies that enhance patient outcomes and improve practitioner productivity.

For more information, visit the company’s Web site at [www.amo-inc.com](http://www.amo-inc.com).



Founded in Gamagori, Japan, in August 1971, Nidek Co., Ltd. was the brainchild of seven optics specialists who envisioned a global ophthalmic products company. After receiving a PhD in optics from the University of Rochester, Dr. Hideo Ozawa returned to Japan to start this privately held company with a strong commitment to research and development and the application to vision care through optoelectronic technologies.

Upon its entry into the ophthalmic instrument market, Nidek differentiated itself from the market leaders by offering unique, innovative technologies to diagnose various eye diseases. Dr. Ozawa's background in bio-optics focused Nidek's business strategy on the concept of merging electronics and optics to develop "optoelectronic" ophthalmic equipment.

As Nidek grew, the company diversified its portfolio to include ophthalmic diagnostic and optical laboratory equipment, lenses and coatings, surgical lasers for ophthalmic and other surgical applications, IOLs, semiconductor equipment, bio- and tissue engineering and ophthalmic pharmaceuticals.

Nidek's initial growth was achieved through a major globalization effort based on a distribution network of approximately 100 distributors in 100 countries. Nidek has satellite offices in 12 Japanese cities, eight wholly owned subsidiaries around the world and five service centers for its excimer lasers located in Brazil, France, Mexico, the United Arab Emirates and the United States. To date, Nidek has more than 1,600 patents covering its various products, submitted or approved globally. In the United States alone, Nidek holds 65 patents with the U.S. Patent and Trademark Office in patent category #351 (eye examination, vision testing and correction), many of which have been granted within the last five years. This is the highest number of approved patents for any eye care company and is double the patents held by any other eye care company, as well as the largest number of patents issued for surgical instruments in the United States among eye care, refractive and ophthalmic companies. Nidek has 47 additional patent applications in process.

An area of increasing interest to Nidek was the development of an excimer laser platform. In 1992, Nidek developed and introduced the EC-5000 excimer laser, one of the first scanning slit lasers ever developed. At the time, the decision to pursue scanning slit ablation in place of broad beam ablations was based on the occurrence of central islands common to broad beam lasers.

Continuing the pioneering efforts in the excimer laser field, Nidek was one of the first manufacturers to introduce and commonly use the transition zone. In 1992, Nidek adopted Dr. Paolo Vinciguerra's concept of transition zone and developed the original aspheric transition zone for all of its ablation algorithms. Other manufacturers followed suit years later. The introduction of the transition zone allowed greater stability and the chances of glare and halos symptoms postoperatively, a significant advance for patient and surgeon alike.



While developing the EC-5000 excimer laser, Nidek engineers realized that tilt and focus during laser ablation could pose a significant problem during laser ablation. In 1991, the development team opted to introduce a surgical microscope of unparalleled quality and included slit illumination to provide the surgeon with a slit lamp–like quality during surgery. Nidek’s introduction of the unique, slit illumination system, a full two decades prior to other manufacturers in the industry addressed this issue, allowed the surgeon to determine whether the eye was tilted (due to a Bell’s phenomenon for example) or if there was movement along the z-axis (focus) during surgery.

In late 1998, Nidek received U.S. FDA approval for the treatment of myopia with the EC-5000. The introduction of the EC-5000 in the United States marked a new business approach to the U.S. industry, one that did not introduce user fees to the surgeon. This introduction was marred by lawsuits that were filed by competitors and included claims of patent infringement. However, Nidek prevailed with the courts recognizing the Nidek EC-5000 as a unique excimer laser that did not infringe upon any currently held patents.

As the field of refractive surgery advanced from treating spherical myopia to hyperopia to high astigmatism, it became evident to many that high astigmatism (4D or higher) could not be successfully treated with the standard ablation algorithms of many excimer lasers. Working separately with Dr. Arturo Chayet (1999) and Dr. Vinciguerra (2000), Nidek introduced and patented two groundbreaking methods for treating high astigmatism, using the Bitoric (Chayet) and Cross cylinder (Vinciguerra) approaches that are widely recognized as optimal methods for reducing or eliminating high astigmatism with the excimer laser. The advantage of these methods includes lower tissue consumption, a more physiologic corneal topography, larger effect optical zones and greater stability postoperatively.

A debate among many refractive surgeons about the ablation centration has existed since the introduction of the excimer laser. Some prefer to treat on the line of sight, others on the visual axis and still others will treat based on whether the patient is myopic or hyperopic. In order to satisfy both sides of this debate, Nidek introduced in 1991 a laser arm that could be controlled on the X, Y and Z axes to enable treatment on the line of sight or visual axis or any other point.

With the recent advent of custom ablation, Nidek elected to introduce an aberrometer unique to the industry, called the OPD-Scan as part of its NAVEX custom ablation platform. The OPD-Scan is a combination unit that includes corneal topography, wavefront aberrometry, pupillometry, pupillography, autorefractometry and autokeratometry in one unit. The decision to not incorporate Hartmann-Shack or Tscherning aberrometers was based on the fact that these aberrometers were not robust enough to measure the full spectrum of refractive patients such as those with high refractive error or those with high ocular aberrations. The OPD-Scan allows the surgeon to accurately measure and consequently treat both virgin eyes and eyes that need secondary treatments due to previous surgery.



Custom ablation and wavefront-guided treatments need accurate delivery of the ablation to the cornea. In 2003, Nidek addressed this challenge by being the first in the field to introduce iris-registered torsion error detection in order to compensate for cyclotorsion.

Currently, Nidek is in the final stages of conducting an FDA clinical trial for the treatment of myopia and astigmatism using corneal elevation-based data called customized aspheric treatment zone (CATz), another first in the industry.

Nidek has a rich heritage of product innovations in refractive surgery based primarily on its strong commitment to research and development to advance the field of ophthalmic diagnostics and excimer laser vision correction. Since its inception 35 years ago, Nidek's vision has focused on innovative, user-friendly technology for eye care professionals and their patients.