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Making Sight Affordable (Part I)

Aurolab Pioneers Production of Low-Cost Technology for Cataract Surgery

Blindness from causes treatable by modern medicine afflicts millions of people every year. Cataracts, the single largest cause of preventable blindness, can be treated by a simple and quick surgical procedure that restores sight; sadly, extreme poverty and its consequences limit access to the medical technologies and infrastructure needed for the surgery. As a result, the crush of blindness continues unabated worldwide.

In theory, the solution to this public challenge seems simple: increase access to care and reduce the cost of the medical technologies needed to restore sight enough to permit cataract surgery to be performed on a mass scale (see inset text box "The Burden of Blindness"). In practice, in the one place where the goal of restoring sight affordably to the many has been achieved, success has required three decades of effort by a dedicated team led by a visionary leader: Dr. Govindappa Venkataswamy, an ophthalmic surgeon in Madurai, India. The living legacy of Dr. Venkataswamy's leadership is the Aravind Eye Care System, one of the largest eye care systems in the world, with five hospitals in the Indian State of Tamil Nadu, together performing over 200,000 cataract surgeries a year. Dr. Venkataswamy refused to accept that people must remain blind solely because they lack money. His thirty-year crusade has addressed the financial, organizational, and technological barriers to affordable eye care treatment.

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The Burden of Blindness

Of the estimated 161 million people worldwide who suffer from some form of visual impairment, 90 percent live in developing countries.* In 2000, blindness is estimated to have cost the world economy $US20-25 billion in lost productivity; blindness and low vision cost India alone an estimated US$4.4 billion annually.** The need for constant care of the blind placed by families and communities exacerbates the impact of blindness, creating a significant burden in resource-poor settings.

Beginning in the early 1970s, the World Health Organization deemed blindness such a critical issue that they created and the International Agency for the Prevention of Blindness. Spurred on by this global effort, the government of India along with nongovernmental organizations focused on building the capacity to diagnose and treat cataracts in India's rural areas—where 70 percent of the population lives. This monumental task required training more ophthalmologists, increasing the number of hospital beds dedicated to eye care, and expanding ophthalmic services into the hinterland using eye screening camps and primary health clinics.

Cataracts represent the single largest cause of preventable blindness worldwide. In India, cataracts are responsible for approximately 80 percent of blindness.*** According to the last World Health Organization (WHO) National Programme for Control of Blindness (NPCB) survey, 12 million people in India are blind (defined as less than 6/60 visual acuity), and 3.8 million people yearly suffer from newly formed cataracts. India currently has the capacity to perform about 1.6-1.9 million cataract operations per year, but 5-6 million operations per year would be needed to tackle the accumulation of cases.****

* The 10th Revision of the of the WHO International Statistical Classification of Diseases, Injuries and Causes of Death defined low vision as visual acuity of less than 6/18, but equal to or better than 3/60, or corresponding visual field loss to less than 20 degrees, in the better eye with best possible correction. Blindness is defined as visual acuity of less than 3/60, or corresponding visual field loss to less than 10 degrees, in the better eye with best possible correction. Visual impairment includes low vision as well as blindness.

** Shamanna BR, Dandona L, Rao GN, Economic burden of blindness in India, Indian Journal of Ophthalmology, 1998;46(3):169-172.

*** Vajpayee RB, Joshi S, Saxena R, Gupta SK, Epidemiology of cataract in India: combating plans and strategies. *Ophthalmic Res*. 1999;31(2):86-92.

**** Vajpayee et al., 1999.

The development of the Aravind Eye Care System (AECS) to tackle such a serious problem required a sequence of innovations, both organizational and technical, starting in 1976. This case focuses on Aurolab, the manufacturing arm of Aravind, which has developed critical eye care technologies for the Aravind hospitals. A subsequent case in *Innovations* will describe the development of the Aravind hospital system itself.

Aurolab was founded as a non-profit Indian medical device organization in

Cataracts

The lens of the human eye is responsible for focusing light on the retina—the inner surface of the eye—to create images. A cataract is a clouding of this normally transparent lens that impairs vision. Cataracts are most often associated with aging, but can develop due to trauma, at birth, or due to metabolic causes, as well as potentially being a result of environmental factors. Advanced cataracts can cause complete blindness, but almost all cataracts are treatable. Surgery is the only intervention that can treat cataracts. Cataract surgery involves removal of the clouded lens; typically, this lens is replaced with a permanent, artificial implant known as an intraocular lens (IOL). The IOL focuses light on the retina, replacing the functionality of the natural lens.

Before the IOL, cataract surgery was performed using a procedure known as ICCE, or intra-capsular cataract extraction, that involved removal of several parts of the eye. This surgery typically subjected patients to bed rest of a week or more. Since much of this surgery was performed before the wide availability of IOL, patients were often fitted with external, aphakic eyeglasses, also known as "coke bottle" glasses (see Figure 1).

Extra-capsular cataract extraction (ECCE) came later, and involved removal of the cataract through an incision in the lens capsule. Notably, ECCE left intact parts of the eye that were removed during ICCE. The only option for visual correction during ECCE was an artificial lens implant, the IOL.

Compared to ICCE, ECCE required less post-operative care—patients could often go home the same day—and resulted in far superior visual outcomes. Despite this, long after ECCE became the standard of care across the industrialized world, ICCE remained widespread in the developing world.

1992 with the mission to manufacture intraocular lenses at an affordable cost for the Indian market. For cataract surgery to be a viable option in any setting including developing countries, the synthetic intraocular lens (IOL) is an essential component (see inset text box "Cataracts"). Since its founding, Aurolab has played a unique and pioneering role in tackling the challenges of access to affordable ophthalmic technologies in developing countries.[1] Aurolab is driven and sustained by a strong social and spiritual mission to make high quality and affordable medical technologies and supplies; to date, this has mostly involved the technological inputs for cataract surgery.

Aurolab is one of a very small number of non-profit medical device or pharmaceutical companies worldwide, and its unique capabilities in transferring vital eye care technology to India have been paramount to its success. Aurolab's technology development model has three phases. First, Aurolab identifies essential ophthalmic technologies and supplies that are inaccessible because of high cost or limited availability in the Indian market. Next, it assesses the potential of indigenous

Figure 1. Visual rehabilitation of aphakia with spectacles. Left: Intact aphakic spectacles—poor optical correction at best. Right: Partially destroyed aphakic spectacles, leaving only unilateral correction.

Source: Apple, et al., 2000. Cataract Surgery with Intracapsular Cataract Extraction and Spectacles, *Survey of Ophthalmology*, 45:S45-S52 (figure 4.6, p. S48). © 2000 Elsevier Inc. Reprinted with permission.

manufacturing and technology transfer. Finally, Aurolab develops a manufacturing system that leverages the unique capabilities and strengths of Aurolab and India.

Today, Aurolab has grown into an organization with six product divisions (intraocular lenses, pharmaceuticals, sutures, instruments, spectacles, and hearing aids) and more than 200 employees. It supplies the lenses that Aravind uses in more than 90 percent of its annual 200,000 plus cataract surgeries. Recently, work has begun on a new manufacturing facility and business office designed to meet strict global manufacturing standards—both the ISO 9000 standards as well as FDA (U.S. Food and Drug Administration) facility requirements—and to accommodate growth. Aurolab's intraocular lenses and other products are exported to more than 120 countries via a global network of NGO partners (roughly 6 percent of the global market). Aurolab has managed to be the first organization to provide a solution to producing critical eye care technologies that allows the restoration of sight among the many for whom the required surgery was previously unaffordable.

REDUCING THE COST OF A CRITICAL COMPONENT IN CATARACT SURGERY: THE INTRAOCULAR LENS

Cataract surgery is the most common surgical procedure among the elderly in the

United States, and one of the most common surgical procedures worldwide. While the procedure requires little post-operative care, it is often prohibitively expensive in developing countries because of the cost of the synthetic intraocular lens and other surgical consumables (the medical goods used during a procedure). Prior to 1992, the bundle of technologies and consumables necessary to perform cataract surgery cost well over US$100, ensuring that cataract surgery using intraocular lenses was beyond the reach of most in the developing world.

Since the vast majority of medical technologies are developed and produced in the West and targeted toward Western markets, developing countries are often at the mercy of external donations. The West's market for ophthalmic surgical products has been well established for more than two decades, and the international market for intraocular lenses is close to 10 million units with over US$1 billion in sales annually, dominated by only a handful of manufacturers (e.g. Alcon, AMO).[2] Yet charity has provided a miniscule and inconsistent supply of lenses for patients who cannot afford them. The story of Aurolab's success in addressing this issue begins long before its inception in 1992, with the pioneering work of Dr. Venkataswamy.

In 1976, Dr. Venkataswamy founded Aravind to create an alternative model for delivering health care that would supplement existing government services. Its first project was the initial Aravind Eye Hospital located in Madurai, Tamil Nadu. This first clinic, which consisted of eleven beds in a small rented house, had many of the elements that are representative of Aravind today. In expanding its operations initially Aravind innovated to remove the barriers to health care access in a developing country: clinical training, payment, transportation, community education, and quality of care. As it has further developed it has filled the holes in system-level deficiencies such as human resources, access to key technologies, and equipment maintenance. Despite Aravind's many successes, the organization soon faced a significant barrier to offering widespread access to effective cataract treatment—the lack of access to affordable intraocular lenses.

There are three surgical options for the treatment of cataract: (1) intracapsular cataract extraction (ICCE) with aphakic glasses; (2) ICCE with anterior chamber intraocular lens implantation; (3) and extracapsular cataract extraction (ECCE) with posterior chamber lens implantation (the standard of care in the United States). The third option provides the best result, but in most developing regions the ICCE surgery using aphakic glasses is the standard of care.

ICCE surgery is a simple procedure that does not require complex tools or equipment, but since the clouded lens and lens capsule are removed, the eye needs several weeks to fully heal. The main drawback of this approach is the use of aphakic glasses to treat a condition called aphakia, or the absence of the eye's lens. Aphakia is a byproduct of all forms of cataract surgery because of the need to remove the clouded lens, but uncorrected aphakia results in a visual acuity tantamount to blindness. Aphakic glasses (see Figure 1) present two principal problems. First the thick lenses can cause problems with distortion and depth perception, so that visual acuity is not dramatically improved. Second, there are logistical prob-

Medical Technologies and Developing Regions: Key Market Failures

There is little debate about the impact medical technologies have had on the health and well-being of humans; equally indisputable is the unevenness of the impact of medical technologies worldwide. Globally, approximately 90percent of medical research funds are spent on just 10percent of the global disease burden; in other words, most medical research focuses on diseases of the developed world. This is a natural result of the predominant private sector model of medical technology development, which requires a strong profit motive to persist and sustain high levels of research and development. What incentives can be devised to increase spending and attention on developing world markets? As University of Michigan Business School professor C.K. Prahalad has so eloquently argued, developing world markets have enormous purchasing power collectively, and businesses with the right approach can profit from these markets while improving conditions on the ground. The current situation has led to three key failures in access to medical technologies:

- High cost of existing medical technologies compared to the purchasing power of individuals, organizations, and governments in developing societies.
- Lack of state-of-the-art technologies developed specifically for diseases found only in resource poor settings such as India.
- Inappropriate design of existing medical technologies for the health care and environmental context found in many developing societies.

The creation of Aurolab was a direct response to these market failures, and innovation at Aurolab has centered on mitigating many of these challenges. Specifically, Aurolab, has contributed three classes of innovations for the ophthalmic market in developing regions:

- Cost reduction of key surgical consumables required for every cataract operation, specifically the intraocular lens, ophthalmic sutures, and viscoelastic.
- Mitigating supply problems through the production of neglected or unavailable pharmaceuticals and other supplies for diseases prevalent in the Indian context (anti-fungals).
- Redesign of key medical technologies to make them more appropriate for Indian context (shelf life, reusability, and packaging).

lems with providing the glasses after surgery, and problems with breakage and loss. As one scholar noted, "At worst, breakage or loss of the glasses may condemn the patient in a rural setting to a visual acuity as bad or worse that the acuity present with the primary cataract."[3] In essence, cataract surgery without the use of an intraocular lens is only half an operation, because there is not adequate visual rehabilitation. For example, one study in the Transvaal, South Africa, found that 39

Aurolab's Technology Transfer Process

1) Identify prospective technologies through feedback with AECS.

2) Verify that the prospective technology has the potential to satisfy Aurolab's mission of producing critical eye care technologies that are affordable and sustainable.

3) Receive approval from the board to pursue further research and development on the potential technology.

4) Discovery phase—learn about the existing marketplace for the technology.

5) Identify potential partners for technology transfer, with the help of existing relationships such as Project Impact and Seva Foundation.

6) Make a deal with a partner to transfer expertise and equipment necessary to produce technology.

percent (13 out of 33 cataract patients) were functionally blind because they no longer had their aphakic glasses; a similar result was found in KwaZulu, where 113 cataract extractions resulted in an effective reduction of 16 blind patients; the rest remained functionally blind because of problems with the aphakic glasses.[4] Because of the drawbacks of aphakic glasses, health care providers would only operate on mature cataracts.

By 1984, the ICCE operation was considered unacceptable in the West because post-operative outcomes were considered substandard. In contrast, ECCE surgery allows for exceptional post-operative visual outcomes, so that it is practical to intervene in younger patients whose cataracts are not mature. Yet there were significant barriers to the accessibility of this procedure in developing regions such as India. State-of-the-art ECCE technology required:

- Clinical training in the micro-surgical techniques necessary to perform ECCE. Aravind had to provide and develop clinical training for this procedure because such training was not available elsewhere;
- Expensive equipment needed to perform the surgery and deal with any complications (such as microscopes and a YAG laser); and
- Expensive consumables for each surgery (such as the lenses, methylcellulose, and nylon sutures).[5]

In the early 1990s, ECCE surgery cost three to four times more than the ICCE procedure, even without the cost of consumables. Aravind's challenge was to make the surgery affordable enough to provide it to all its patients. Aravind tried to convince the multinational producers of intraocular lenses to sell this critical eye care technology to the developing world at an affordable price, but as has been shown numerous times, health care markets in developing countries are not foremost in the mind of multinational medical technology corporations (see inset text box "Medical Technologies and Developing Regions"). This is reflected in the prices, research focus, and design choices of these companies.

Table 1. Global costs of providing cataract surgery

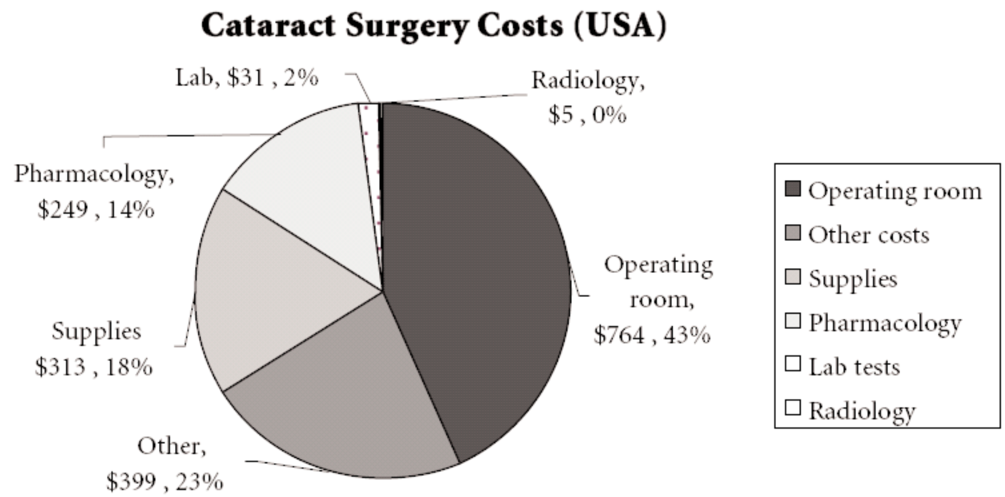
Country/Region	Cost of Surgery (US$)	Acquisition price of IOL*
India, Bangladesh Nepal	$15-$20	less than $5
Africa	$80-$100	-
Latin America	$150-$200	-
United Kingdom	$1740	-
Germany	$1560	-
New Zealand	$1980	-
Australia		$130
United States	$1600-$2500	$105
Japan -		$315

* These represent estimates based on interviews or other sources of information of the cost to a hospital or surgeon. The cost of the IOL to the patient is often considerably higher.

Thus, the idea of Aurolab was born—an Indian, non-profit organization to provide Aravind with affordable, high-quality lenses and supplies for cataract surgery. In fact, despite Aravind's successful track record, few international agencies were willing to support its mission to bring ECCE surgery to India. The prevailing attitude was that ECCE was inappropriate for the developing context: in regions with a dearth of health care capacity, why introduce a procedure that requires the additional investment of significant physical and human capital? However, Aravind had solved many of the health care delivery problems for eye care.[6] AECS was able to push ahead, because, as Mr. R.D. Thulasiraj, Executive Director of LAICO (Lions-Aravind Institute for Community Ophthalmology), stated, "Having monetary success has given AECS the freedom to chart their own direction, otherwise we would have had to rely on donor agencies."

INNOVATION 1: MANUFACTURING THE LENS

The creation of Aurolab was a three-year project that started as collaboration between Aravind, the Seva Foundation, and Sight Savers International. Similar to the formation of many medical device companies, Aurolab had to demonstrate need, form partnerships, engage in technology development, and raise venture capital. Dr. P. Balakrishnan, an Aravind collaborator, who was working as an engineering research scientist in the United States in 1989, worked with David Green of the Seva Foundation to solve the greatest challenge to local IOL production—access to the production technology. From its beginning, Aurolab has been defined by technology transfer (see inset text box "Aurolab's Technology Transfer Process"). Aurolab had sufficient production space and resources to hire quality



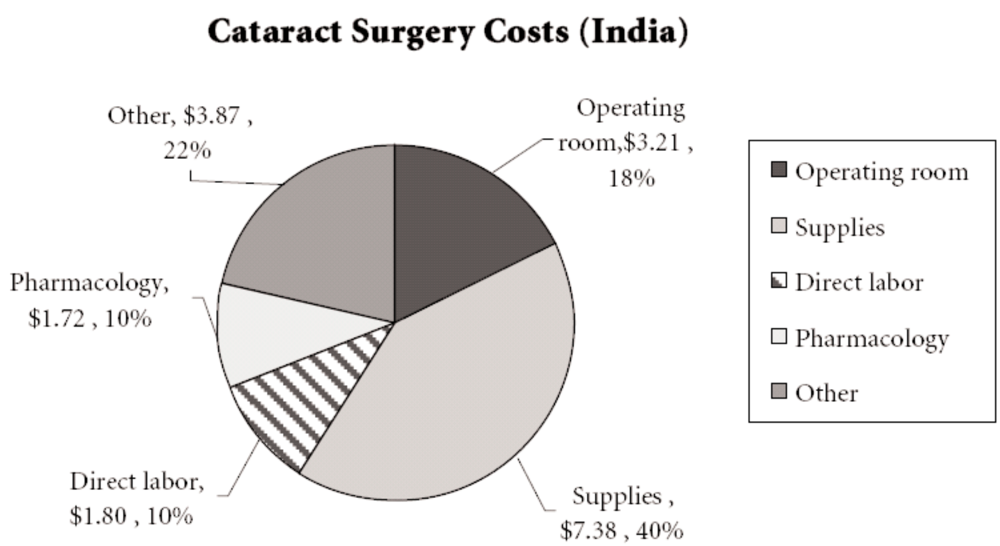


Figure 2. Comparison of Costs (U.S. and India)

Sources: Naeim A. 2002. Healthcare Cost-Effectiveness Analysis for Older Patients: Using Cataract Surgery and Breast Cancer Treatment Data. RAND publication RGSD-168 [top]. Aurolab. 2004 [bottom].

engineering and production staff and purchase manufacturing equipment, but it did not have access to the lens-making technology. The technology used to produce the intraocular lenses and other consumables were guarded closely by major medical equipment manufacturers. The process of obtaining the technical know-how to manufacture the lenses was arduous, but Aravind and Aurolab were ultimately successful.

With the support of Seva Foundation, a systematic search was conducted to

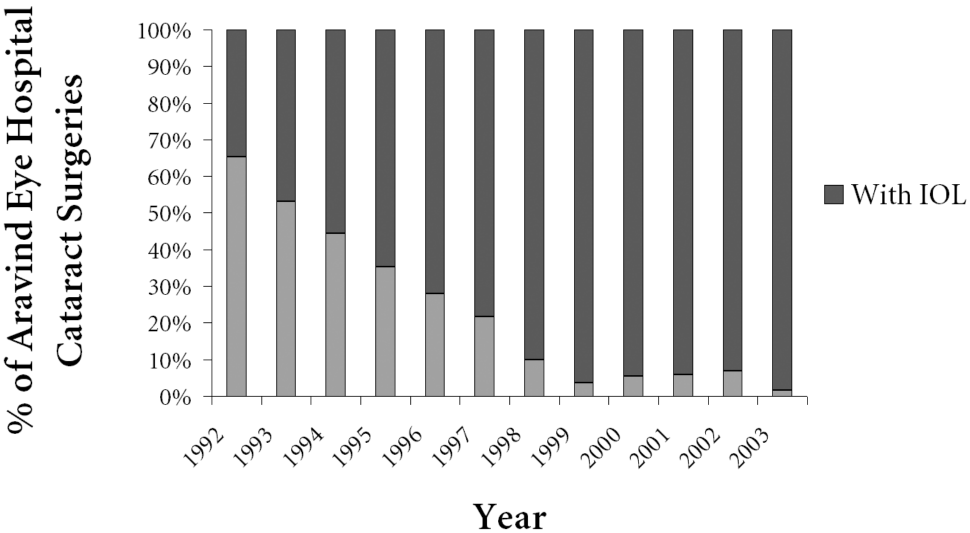


Figure 3. Increase in the fraction of cataract surgeries at Aravind Eye Hospitals involving use of intraocular lenses (IOLs) since the inception of Aurolab in 1992.

Source: Aurolab 2004

identify small companies or individuals willing to provide the know-how needed to produce the lenses since initial efforts to obtain this expertise from established companies were unsuccessful. Fortunately, a small IOL manufacturer in Florida looking to expand its business agreed to work with Aurolab to provide the expertise and equipment for IOL production, in other words, to act as a technology transfer agent for the lens-making technology. Given the unique physical and organizational context of Aurolab, the requirements for the equipment and processes were tailored to minimize capital investment and instead to maximize use of the labor cost advantage in India. The production equipment was constructed for Aurolab by the Florida IOL manufacturer to meet these unique requirements, and trial run of the production system was set up in Florida to certify the system's capability, but also to offer Aurolab engineers the chance to familiarize themselves with the equipment and production process under the experienced eyes of the IOL manufacturer. However, this exercise in technology transfer did not end in Florida; for two weeks staff members of the IOL manufacturer made the journey to India along with the equipment to ensure smooth installation and provide further training to the broader Aurolab organization. Aurolab recruited experienced nurses (also known as Sisters) from the hospital to serve as production staff and trained them in a local contact lens manufacturing facility before the arrival of the IOL production equipment. Through this careful planning and training, Aurolab staff managed to quickly absorb the intricacies of IOL production. Through the application of continuous improvement methods and procedures the rejection rate improved gradually over a period of time. The technology provider assisted Aurolab in monitoring and improving the production system through onsite visits and regular interaction over the course of the initial endeavor to manufacture the lenses.

Aurolab officially began operation in 1992. At this stage, Aurolab produced about 100-150 three-piece lenses daily.[7] In 1992 it produced nearly 35,000 PMMA (polymethyl methacrylate) lenses; today Aurolab manufactures over 600,000 intraocular lenses, sold in over 120 countries, and has reduced the manufacturing cost to under US$4. In the same period, for-profit multinational ophthalmic companies reduced lens prices to US$100-$150 in developed markets.[8] According to David Green, the price differential between the lenses produced in Madurai and those manufactured in developed countries is largely a result of the difference in organizational orientation:

> Basically, we use the same equipment and manufacturing process and we fulfill the same regulatory requirements for quality as other companies do, whether they are in America or Europe or elsewhere … but Aurolab sells the lenses for less, not only because their costs are lower but because they choose to price them lower—because our goal is maximizing service rather than maximizing profit.[9]

These first production runs were sold to Aravind for INR (Indian rupees) 300 (US$11.60)[10] per unit, as compared to the best discounted price of INR 2000 (US$77.50) for lenses from multinational companies. Over time, Aurolab further reduced the lens cost to a price of INR 200 (US$7.75). This cost reduction has dramatically increased the number of ECCE procedures at AECS, from 35 percent of all cataract-related procedures in 1992 to 98 percent in 2004. Table 1 shows the cost of cataract surgery in various geographic regions, as well as the cost of intraocular lenses; Aurolab's impact on the costs in India are very clear. Figure 2 shows a detailed comparison of cataract surgery costs between the United States and India. Figure 3 shows Aravind's growth in ECCE procedures since the inception of Aurolab.

The introduction of IOLs at the low end of the market by Aurolab created millions of new customers and increased substantially the overall IOL market size in India. Multinational companies had minimal interest in serving this market segment due to lower margins and other marketing difficulties. The considerable growth in IOL surgery volume in many developing countries can be attributed to the availability of quality IOLs at affordable prices.

INNOVATION 2: KEEPING UP WITH THE TIMES—FOLDABLE LENSES

The IOL market is constantly evolving as new types of intraocular lenses are developed and diffuse into the marketplace; innovation is thus a necessary part of Aurolab's ability to continue to provide technologies that allow doctors to deliver the best standard of care. The single piece IOL that was state-of-the-art five years ago is now simply a commodity. The current state-of-the-art is the foldable lens. Of the three types of IOLs that Aurolab produces today, two are of hard polymer and the other is a soft, foldable lens. The primary advantage of the foldable lens is that it enables a surgeon to use a smaller incision during surgery—the folded IOL is inserted through this incision and unfolds into its proper form and position after the insertion. The smaller incision has many direct clinical benefits, including no need for sutures, faster recovery, less astigmatism, and fewer post-operative complications. However, the use of foldable lenses requires special equipment and additional microsurgical training. The foldable IOL is typically used with phacoemulsification, a procedure that utilizes ultrasound to liquefy the clouded lens before suction is used to remove it through a small incision.

For Western manufacturers, hard lenses represent a dead market; in developing countries, however, there is still a large market for hard lenses because the expertise, equipment, and funds to support the surgery are often lacking. Foldable lenses are produced almost exclusively by large U.S. lens producers, such as Alcon and AMO. Sales of foldable lenses in the United States represent over 90 percent of IOL sales, compared to just 8 percent in India. Aurolab began selling these lenses in 2003. The trend in India is for middle-class patients to prefer foldable lenses, and for non-paying or low-income patients to select hard lenses because of their affordability. The result is a shrinking market for quality hard lenses.

Advancements in polymeric materials led to the development of new foldable IOLs. That is, it is the material itself that represents the core technology of the lens. Aurolab developed this technology through close cooperation with David Green's NGO Project Impact.[11] In order to prove the lens safety, Aurolab conducted an 18-month study with 100 patients; after this period Aravind adopted these lenses. From initial technology development to lens sales took two years.

Aurolab's price for these foldable lenses is INR 1000 (US$22), compared to the price of US$80-$100 for foldable lenses from multinational companies in India. Notably, Aurolab managed to produce foldable lenses with minimum capital investment. Aurolab selected suitable foldable lens material and processes that could be produced with existing machinery. The lens' flexibility is imparted at the end of the process by hydrating and packing the lens in saline solution.

INNOVATIONS BEYOND THE LENS

In addition to the intraocular lens, each cataract surgery requires the use of other consumables that can also present cost barriers. One expensive item is a product known as viscoelastic. Sold under the brand name Aurovisc™, viscoelastic is a high molecular weight solution of hydroxypropyl methylcellulose (HPMC) that is essential to cataract surgery. After the initial incision is made, viscoelastic is injected into the eye to maintain its shape and protect interior surfaces from damage.

With technical support from Moorsfield Hospital (UK), Aurolab started production of viscoelastic in 1997. At that time there were only three other manufacturers of viscoelastic worldwide, and the solution was available at a high unit cost—8-10 percent of the total cost of consumables used in cataract surgery. In addition, the packaging was not appropriate for the Indian context. Pre-filled vials were needed, to ease both the logistical inconvenience to surgeons in the field and the cost burden for those performing fewer procedures.

Aurolab's cost structure for viscoelastic and other products is not significantly different from that of its international competitors. Particularly for raw material acquisition, Aurolab's costs are actually higher than its international competitors—because of the shipping costs and lower-volume purchases from Western suppliers. Overall, 80 percent of Aurolab's raw materials come from Germany and the United States. Most of the remaining 20 percent are purchased locally.`

Although pharmaceutical companies including Aurolab buy the main viscoelastic ingredient (HPMC) from the United States, Aurolab was able to reduce the price by 50 percent, largely because of the shift to local production and selective pricing. Today Aurolab sells a 2 ml pre-filled syringe for INR 45 (US$1), and is one of 10 viscoelastic manufacturers in India selling it for this price. Much as it did for intraocular lenses, Aurolab assisted in the creation of a market and paved the way for a collection of low-cost manufacturers.

There are two grades of viscoelastic—Aurolab produces the less expensive one. Aurolab's attempts to produce the higher-grade viscoelastic (sodium hyaluronate) highlight the failure of Western manufacturers (see inset text box "Medical Technologies and Developing Regions") to adequately address developing world markets. Most of the developed markets use the high-grade viscoelastic due its benefits in the surgery. This beneficial product is not affordably available in many markets because the knowledge needed to manufacture this high-grade viscoelastic is closely guarded and controlled. Aurolab is looking at the possibility of locally formulating and producing this high-grade viscoelastic using imported raw materials, but the option of purchasing the finished product at an affordable cost from existing manufacturers was also explored, albeit without success. In 1995, Aurolab was offered a price of INR 700 per ml by a U.S. company. This sourcing price was more than 20 times the *retail* price of the less expensive viscoelastic Aurolab is currently producing. Very recently, Aurolab visited another U.S. company that produces the high-grade viscoelastic, but the quoted price was US$10 per vial, equivalent to the current total cost for all surgical consumables used in cataract surgery. Aurolab asked the firm to reduce the price to US$3-4, but the firm required a guarantee to purchase several hundred thousand vials. Aurolab could not possibly guarantee such a high volume purchase without incurring significant risk. Given the large number of blind eyes worldwide and the ongoing incidence of cataract blindness, there is potentially a huge market for high-grade viscoelastic —but only at the right price.

CONTEXT MATTERS: ANTIFUNGALS & BUNDLED SURGERY KITS

Aurolab has focused on technologies where cost was the primary barrier, but has also addressed other needs that multinational producers of essential medical technologies have failed to meet. Two particular concerns are problems in the supply of technologies for diseases or conditions no longer common in the West, and a mismatch between the design of certain technologies and the realities of health care infrastructure and practice in developing country settings.

For example, corneal scarring due to untreated fungal and bacterial infections is a major cause of blindness across the world, second only to cataracts in the developing world.[12] Antifungal drugs, a major part of the required response, are often in short supply in the developing world. In 2000, when Aurolab first considered development of a new antifungal drug, there was only one widely available in the Indian marketplace. It sold for INR 100 (US$2.20) and was considered toxic. Aurolab developed a drug with much lower toxicity and sold it for INR 50 (US$1.10). To better suit the conditions of many hospitals and clinics across the developing world, Aurolab later offered a formulation with an improved shelf life. These local pharmaceutical innovations provided a cost-effective way to prevent blindness due to fungal infections across the developing world.

To address a poor health care supply chain infrastructure in India and across the developing world, Aurolab created a bundled surgery kit with all the supplies needed to perform five cataract surgeries. By purchasing some supplies from other manufacturers and drawing on its own diverse line of products (some manufacturers only produce lenses while Aurolab also produces microsurgical sutures and ophthalmic pharmaceuticals), Aurolab provided a simple innovation that has had a significant impact. If one lacks a single supply, those on-hand are useless. The bundle allows surgeons to buy their cataract-related products from a single supplier, eliminating much of the uncertainty of the supply chain. This approach has been successful partly because of the prevalence of the disease. In the developing world cataract surgeries are performed in batches, rarely in isolation; in contrast, this is a relatively low-volume surgery in industrialized regions.

Reuse of single-use devices and drugs is common in emerging nations to cut costs. Aurolab has designed products whose reuse does not reduce performance, safety, or efficacy. For example, Aurolab pursued rigorous testing to ensure that reuse of suture needles for additional cases would not cause any performance degradation of the product under normal use. Another example is the packaging of some single-use drugs; a small quantity of the drug may be extracted more than once through a rubber enclosure using sterile syringe needles without compromising sterility.

THE PARADOX OF PRIMARY CARE INNOVATION IN DEVELOPING COUNTRIES: MANY TECHNOLOGIES, FEW OPPORTUNITIES

While Aurolab's first task was to reduce the cost of the IOL, the management of Aurolab and Aravind quickly realized that there were many essential ophthalmic technologies that are prohibitively expensive or at least costly enough to severely impact the bottom line of socially focused organizations in developing countries. However, not all these technologies represent an opportunity for Aurolab. As a social enterprise, Aurolab must meet the dual mission of being self-sustaining and reducing the cost of essential ophthalmic technologies. The prime opportunities for Aurolab are low-cost/high-volume products, where small margins can be offset with a high volume of sales. Cataract surgery in India fits this profile perfectly, because of India's high prevalence and incidence of cataracts. Aurolab has focused primarily on the consumables used in cataract surgeries, developing a full line of IOL products, sutures, and viscoelastic solution.

Aravind and Aurolab's success in developing a market for eye care technologies in India has dramatically altered the landscape of available technology and innovation in this arena. In addition to Aurolab, today India has roughly 150 ophthalmological companies, of which 10-12 make intraocular lenses and four have CE certification for their lenses.[13] (The CE mark is a quality certification required for marketing products in European Union countries. Aurolab was one of the first companies in India to pursue the CE mark for IOLs and other ophthalmic medical products.[14])

Today rising demand for new products is undermining demand for some of Aurolab's core products. For example, Aurolab's development of foldable IOLs and sutureless cataract surgeries using phacoemulsification has begun to erode sales of hard lenses and sutures. The troubles of the suture division present a paradox of mission versus business logic. It is clear that the market for ophthalmic sutures will dwindle and may eventually become obsolete with greater adoption of the sutureless surgeries. The existing manufacturing equipment and process could be adapted to manufacture other types of sutures; in particular, Aurolab has investigated the market for sutures in cardiac surgery. This is a growing market because of the rising incidence of heart disease in India and worldwide. Yet going beyond its core competency to enter other markets such as cardiac sutures would be a significant departure from Aurolab's focus on the ophthalmic market, which would create challenges because the Aurolab brand, as well as its sales and marketing, are tied heavily to its Aravind connection.

Are there other opportunities within the ophthalmic market that would allow Aurolab to make up for the declining revenue of the suture division? The answer is complicated. There are clearly ophthalmic technologies that are expensive and essential, but does Aurolab have the expertise and capacity to develop and produce these technologies? Furthermore, would developing these technologies satisfy the business logic of Aurolab? For example, diabetes is growing problem worldwide, and India has seen a significant growth in the prevalence of this disease. If not properly managed and controlled, diabetes can lead to a number of complications including vision loss and blindness due to a damaged retina or diabetic retinopathy. Diabetic retinopathy cannot be cured but progression of vision loss can be halted using special green laser technology. This laser is currently very expensive, costing about INR 2 million (approximately US$45,000). If Aurolab could produce this laser at a cost far below the current price it would have a tremendous impact on the treatment of diabetic retinopathy, but lasers differ from consumables both in the complexity of the technology design and production, and the market. The market for durable equipment such as the laser is typically low volume and high cost because hospitals and other organizations will only make a purchase every five to ten years. Further, ongoing maintenance and spare parts become critical pieces of the value chain for these products, reducing the impact of a lower initial purchase price; in addition, these areas are not within Aurolab's current core competencies. Rather than sitting still, Aurolab is continuing to investigate various technologies and innovations in the eye care arena. Thankfully, Aurolab is not alone in its mission to fill the gap in the production of affordable medical technologies.

The global failure to address the lack of available and affordable medical technologies (such as pharmaceuticals and medical devices) has spawned many efforts by the non-profit sector, of which Aurolab is one. For example, the Bill and Melinda Gates Foundation has provided funding for the Institute for OneWorld Health, the first non-profit pharmaceutical company in the United States, which has developed a drug for visceral leishmaniasis,[15] and has provided US$43 million in funding to Amyris Biotechnologies for developing a synthetic malaria drug.[16] A host of other public-private partnerships are dedicated to neglected diseases.[17] What differentiates Aurolab is that, while it has received critical help from Western partnerships, it is driven from the ground up by the local community.

In filling critical gaps in the health care infrastructure for eye care in India, Aurolab has proved a model for the *indigenous* development of medical technologies in developing countries. Not only has Aurolab managed to produce affordable medical technologies, it has also, in partnership with Aravind Eye Care System, created a solid supply chain and delivery system—often a critical deficit in resource-poor settings. In 14 years in operation, Aurolab has established and maintained a position of leadership in the production of affordable ophthalmic technologies because of its commitment to excellence and to delivering state-of-the-art care to the underserved. There are several foreseeable challenges in the near future for Aurolab; continued success will require renewed innovation, infused by the spiritual commitment and entrepreneurial vision of Dr. Venkataswamy.

We invite reader comments. Email <editors@innovationsjournal.net>.

Authors' Dedication

We dedicate this article to Dr. Govindappa Venkataswamy, the founder of Aravind, who passed away on July 7, 2006, at the age of 87. Though Dr. Venkataswamy, or Dr. V as he is more fondly known, is no longer with us, his mission was so powerful, his personality so strong, and his faith so pure that he lives on in the organization he founded and shaped until his last days—Aravind. Dr. V, who worked tirelessly to give sight to millions, began his medical career as an obstetrician. In the prime of his life, he developed rheumatoid arthritis that eventually disfigured his extremities so severely that he could no longer deliver babies. Dr.V has always possessed a singular focus and determination to his cause. He turned to ophthalmology, creating specialized tools that allowed him to operate with unparalleled precision. He was legendary in the Indian Medical Service for his stamina, routinely performing 100 cataract surgeries a day, but this was only the beginning of his legacy. Upon retirement from the government medical service, Dr. V enlisted the help of his family to start the Aravind Eye Care System. Mixed with the philosophy of Gandhi and Sri Aurobindo, Dr. V encountered more than a few raised eyebrows with his insistence that if McDonald's and Coca-Cola can bring consumer goods to the masses, the same can be done with delivering eye care and eradicating blindness. The soul of Aravind is the deep commitment to service that permeates all levels of the organization from the housekeeping staff to the surgeons, and is an outgrowth of the spiritual commitment of Dr. V; but what astonishes many is that Aravind is also a superbly managed business with a focus on efficiency, frugality, and innovation.

1. In the realm of ophthalmic technologies, the Fred Hollows Foundation has also been very active in setting up IOL production facilities in Nepal and Eritrea. In addition, Jaipur Foot is a non-profit manufacturer and developer of affordable prosthetics with a particular emphasis on the design of prosthetics for the physical environment of developing regions. One important distinction between these examples of non-profit medical technology organizations is the business model. Aurolab is a self-sustaining and self-financing organization; these other organizations rely on the donor model.

2. Medennium news release. 2003. Medennium Announces Sale of PRL to CIBA Vision. http://www.medennium.com/PRL_sale.htm.

3. Apple, D. 2000. Organizations Supporting Developing-World Cataract Surgery and Present Surgical Initiatives, S*urvey of Ophthalmology*, 45 (Suppl. 1), 191-196.

4. Yorston, D. 1998. Are intraocular lenses the solution to cataract blindness in Africa?, *British Journal of Ophthalmology*, 82, 469-471.

5. Perkins, A. 2001. Letter to the Editor, *Community Eye Health* 14(38), 51.

6. The standard of care for cataract treatment in developing regions is still Intracapsular Cataract Extraction (ICCE) surgery with aphakic glasses. While the vast majority of cataract procedures in India use implant intraocular lenses, in much of the developing world ICCE with aphakic glasses remains the only choice. The cost of the lenses and other consumables is not the only barrier. For example, it is estimated that there is an ophthalmologist for every million Africans.

7. A three-piece IOL separates the two haptic ends from the main portion of the IOL.

8. Combat Blindness Foundation 2004, Project Impact 2004.

9. Herbst, K. 2004. Doing Business with Humanitarian Goals. India Together, http://www.indiatogether.org/2003/feb/hlt-lwcstman.htm.

10. The conversions are based on historical (1992) exchange rates from the U.S. Federal Reserve.

11. Project Impact is a non-profit organization founded by David Green to bridge the medical technology gap between the West and developing regions. They have been heavily involved with Aurolab on the foldable lens and affordable Hearing Aid projects.

12. Bharathi MJ, Ramakrishnan R, Vasu S, Meenakshi. 2002. Palaniappan R. Aetiological diagnosis of microbial keratitis in South India - A study of 1618 cases. I*ndian Journal of Medical Microbiology*, 20, 19-24.

13. Personal Communication , R.D. Sriram, IOL Division Manager, Aurolab.

14. Ibid.

15. Visceral leishmaniasis, also known as black fever, is a parasitic disease endemic to tropical and temperate regions. After malaria, it is the second most deadly parasitic disease in the world.

16. Amyris Biotechnologies Press Release Dec 2004.

17. Buse K, Walt G. 2000. Global public-private partnerships: Part I—A new development in health? *Bulletin of the World Health Organization*, 78(4), 549-561.