R&D for Sustainable Development

Amitava Gupta

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Summary

- State of public Health (especially children’s health) is a key variable that controls the pace of sustainable development
- Healthy vision is a key component of good public health: in children it promotes learning, in adults it promotes higher productivity
- Uncorrected refractive errors, cataracts and aphakia are the three most prevalent causes of loss of vision in developing countries
- I will present two case studies that show how products developed to serve the same basic need, acquire completely different designs when they are designed to meet the needs of different communities
- In both cases, innovative products derived from cutting edge science were developed through collaboration among multinational teams, but they are only part of the story
- These products disrupted existing supply chains in these countries (Africa, China and India), and put consumers and community workers in control
- Results were:
  1. An explosive growth in number of treatments
  2. Transfer of pricing control to local caregivers, allowing them to pursue their growth model
- A multistage sustainable product development model can be developed from these initial results
Success Requirements in Building a Sustainable Health Care Product Development Program

- Excellence in science as well as technology. This is because only science can enable us to change the path of technology development and develop transformative solutions.
- Adoption of local health needs as a strategic driver of development.
- Collaboration with and learning from local caregivers and local industry.
- Achieve scale by increasing the level of community involvement across the country (many parallel starts), rather than by vertical integration followed by automation.
Total factor productivity (TFP) was estimated for a wide range of developed and developing countries. The impact of several quality of life parameters on TFP were analyzed, pooling all countries together. It was found that health had the strongest correlation with TFP, among several other positive predictors, such as Education, Openness and GDP.

Sustainable R&D Programs Should Start from Community Priorities


Note that this assessment does not take into account user needs and community priorities.
In this model, consumer needs and community interests come in indirectly, but the development is still being carried out in a vacuum, with no explicit involvement of the community leaders and consumers in creating innovation.
Vision correction, poor vision and blindness:

- **Over 3 billion people** (45% of the world’s population) need some form of vision correction to see clearly\(^2\).
- Poor vision is a developmental issue affecting the everyday lives of these 3 billion people worldwide. Of these, two thirds live in the less developed world where the majority do not have ready access to an eye evaluation and affordable spectacles.
- Poor vision is an educational issue that can in the absence of adequate vision correction limit the ability of hundreds of millions of children to take full advantage of what may be their only opportunity to participate in school.
- Significant vision impairment due to uncorrected distance or near vision (at a level defined by the WHO as a disability) affects 284 million people globally\(^3\).
- **Blindness** affects the health, well being and quality of life of approximately 39 million people worldwide\(^4\); 8 million from uncorrected refractive error\(^5\).
Adspecs: How it works

- Adjustable Power Eyeglasses developed by Oxford Physics Professor, Joshua Silver
- Lenses in these eyeglasses consist of two membranes bonded to the frame
- The space between the membrane is filled with silicone oil (refractive index ~ 1.45 - 1.53)
- A syringe filled with more silicone oil is attached to the temples (one at each temple) of the adjustable power eyeglasses
- This syringe with extra oil enables the power of each lens to be adjusted from +3.00D to -7.50D.
- Once adjustment is complete, the syringes are removed, automatically sealing the lenses, and the eyeglass is ready to be used

What the wearer needs to do

- Upon wearing the eyeglasses, the wearer adjusts the syringe to either pump in more oil (providing more plus power) or drain oil away from the lenses (provide more minus power)
- The wearer looks at a target about 3 meters away, and brings the target to best focus
- Each eye is adjusted singly, keeping the other eye closed, then both eyes are opened, and the adjustment of each eye is refined
- The whole process takes a few minutes
Carlson, S, “Vision Correction in the Remote North of Ghana using the Self refraction Adspec”

The Adspec™
The top Figure shows the Adspec with the pumps on and ready for adjustment. The bottom Figure shows the Adspec with the pumps removed and ready for wear. Over 40,000 pairs have been distributed worldwide in more than 20 countries, and results show that self refraction is easy to learn, train and teach without direct support form professionals, and is safe and effective.
This was a study that involved 600 children from impoverished parts rural China.

The study demonstrated that self refraction using Adspecs could provide excellent vision correction without the need of a professional examination and cyclopegia in a refractive error range of +2.5D to -7.5D, covering over 90% of the population.
Introducing the first adjustable strength reading glasses. See more clearly in more situations.

Today much of our close-up viewing is on screen: our computer, iPod, cell phone, Blackberry and other electronic devices. Traditional reading glasses weren’t designed to cope with these situations. Now there’s a new and better kind of eyewear that adapts to today’s viewing needs. It’s called ModifEye.

Unlike ordinary readers, ModifEye glasses use adjustable lenses that change strengths with a simple, quick twist at each temple. The result: you get clear vision in each eye and in any close-up or medium-range situation.

So whether you’re looking at the Sunday paper or your latest email, it’s always clear and in focus. In fact, in a recent clinical study, the majority of people preferred ModifEye over their current readers.
Extensive New Product Pipeline Opportunities

- Technology Easily Applied to New Lens Shapes and Frame Styles
- Technology Can Cover Any Diopter Range, for Reading and Also Distance Vision
- Opportunity to Expand New Products Globally

Smaller, More Feminine Style

Wire Framed with New Actuation

Combination Frame
Clinical Testing Proves Superior Visual Acuity of ModifEye

VISUAL ACUITY OF MODIFEYE IS BETTER THAN LEADING BRAND BY ABOUT 0.5 LINE, OS AND OD

Source: Clinical Study, June 2010
Wire Framed Product With New Piezoelectric Actuation System

- Same Basic Liquid-Filled Lens, Contoured Membrane Design
- Now a Reservoir-Less System
- Piezoelectric Transducers Around Edge of Lens
  - Actuated via Small Rechargeable Battery in Temples
  - User Slides Button to Actuate, Signaling Transducers to Compress or Release, Changing Curvature of Back Membrane
## Two Products for Two Different User communities: Same Optical Principle

<table>
<thead>
<tr>
<th>Adspec</th>
<th>Modifeye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide vision correction to underserved populations in developing countries</td>
<td>Adjustable reading glasses: a high end product for emerging presbyopes in developed countries</td>
</tr>
<tr>
<td>Round shape: Membrane of uniform thickness provides best optics at lowest cost</td>
<td>Non-round optics: Membrane with built in anisotropy to correct for spherical aberration, astigmatism when optical power is altered</td>
</tr>
<tr>
<td>Single sku (stock keeping unit) to reduce cost of manufacture and inventory</td>
<td>Multiple skus: color, frame shape, multiple frame materials</td>
</tr>
<tr>
<td>Distribution: Direct, through government agencies and community organizations</td>
<td>Distribution: Utilizes the normal channel (optometrists and major optical outlets)</td>
</tr>
<tr>
<td>Cost of production: $1.00/pr</td>
<td>Cost of production: $13.00/pr</td>
</tr>
<tr>
<td>Target price: Cover cost of production, training and distribution (~$2.50/pr)</td>
<td>Target price to consumers: ~$80-$100/pr</td>
</tr>
<tr>
<td>Innovation: Empowers underserved consumers in developing countries, especially children, improves learning ability</td>
<td>Innovation: Superior to current products: Enhanced comfort while working at a computer, more natural vision without compromising cosmetics (“Looks”)</td>
</tr>
</tbody>
</table>
A Sustainable Product Design for a Developing Society

- Simple manufacturing and assembly process
- One product sku (round optics)
- Covers 90% of presbyopia, myopia or hyperopia
- Does not require training to learn how to use it: Subjects in Ghana, Kenya and China learned how to use it from brochures
- May be distributed directly, by passing optometrists

Both products deliver excellent visual acuity, and meet the needs of the intended users

Product Designed for High End Consumers

- Cosmetics (appearance), ease of use, and superior optical performance are key product requirements
- Requires precision optical injection molding and highly sophisticated fabrication of components and assembly
- Multiple skus (colors, frame shapes, IPD)
- Distributed through optometry shops to provide selection and superior customer service
Global Blindness

• 285 million people are visually impaired
  • Of these, 39 million are blind
  • 246 million have moderate to severe visual impairment

• Cataract is the main cause of blindness and visual disability followed by refractive errors
## Cataract Surgery and Intraocular Lens Implantation: Global needs

### GLOBAL IOL MARKET

<table>
<thead>
<tr>
<th>GLOBAL IOL MARKET</th>
<th>2010 Market Overview</th>
<th>CAGR: 2010-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Units (000)</td>
<td>Units</td>
</tr>
<tr>
<td>United States</td>
<td>3,385</td>
<td>3.3%</td>
</tr>
<tr>
<td>Western Europe</td>
<td>2,992</td>
<td>2.5%</td>
</tr>
<tr>
<td>Japan</td>
<td>1,133</td>
<td>2.7%</td>
</tr>
<tr>
<td>Other developed countries</td>
<td>1,180</td>
<td>4.7%</td>
</tr>
<tr>
<td>China</td>
<td>952</td>
<td>6.1%</td>
</tr>
<tr>
<td>India</td>
<td>4,137</td>
<td>4.3%</td>
</tr>
<tr>
<td>Latin America</td>
<td>1,065</td>
<td>5.2%</td>
</tr>
<tr>
<td>Rest of World</td>
<td>1,636</td>
<td>3.7%</td>
</tr>
<tr>
<td>TOTAL IOL Market</td>
<td>16,479</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

### USA

<table>
<thead>
<tr>
<th></th>
<th>Patients with diagnosed cataracts</th>
<th>Patients with Pseudophakia (IOLs) or Aphakia (no IOLs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEI Estimate (2000)</td>
<td>20.5 Million</td>
<td>6.1 Million</td>
</tr>
<tr>
<td>NEI Projection (2020)</td>
<td>30.1 Million</td>
<td>9.5 Million</td>
</tr>
<tr>
<td>Actual (2007)</td>
<td>~25 Million</td>
<td>10.5 Million</td>
</tr>
</tbody>
</table>


CAGR: Compound annual growth rate
Intraocular Lens design driven by two different user and community needs

Conventional IOL, excellent optic, restores vision following cataract surgery

- For Developing communities
  1. Excellent optic
  2. Assured excellent surgical outcome
  3. Minimize surgical trauma and postoperative complications
  4. Ultra low cost

Foldable IOL to reduce incision size, reduce surgical trauma and healing time

- For Enhanced patient satisfaction
  1. All of the above
  2. Dynamic change in optical power when patient uses near vision, providing accommodation
  3. Design and electronic settings are customized for each patient
  4. Regular monitoring and adjustment by ophthalmologist recommended
  5. Higher fabrication cost

Foldable IOL with embedded electronic module
300 Sustainable Eye Care Programs

There are over 300 examples of affordable and sustainable eye care programs around the world providing over a million surgeries annually where 33-83% of patients receive care for free, below cost and above cost.

<table>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
<th>Annual Surgeries</th>
<th>% Free / Low Pay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aravind Eye Hospital</td>
<td>India</td>
<td>401,000</td>
<td>51%</td>
</tr>
<tr>
<td>SadGuru Trust - Chitrakoot</td>
<td>India</td>
<td>128,000</td>
<td>80%</td>
</tr>
<tr>
<td>LV Prasad Eye Institute</td>
<td>India</td>
<td>100,000</td>
<td>50%</td>
</tr>
<tr>
<td>Lumbini Eye Hospital</td>
<td>Nepal</td>
<td>48,000</td>
<td>80%</td>
</tr>
<tr>
<td>He Eye System</td>
<td>China</td>
<td>40,000</td>
<td>33%</td>
</tr>
<tr>
<td>Eye Foundation Hospital</td>
<td>Nigeria</td>
<td>15,000</td>
<td>30%</td>
</tr>
<tr>
<td>Magrabi Eye Hospital</td>
<td>Egypt</td>
<td>10,000</td>
<td>43%</td>
</tr>
<tr>
<td>Visualiza</td>
<td>Guatemala</td>
<td>10,000</td>
<td>83%</td>
</tr>
</tbody>
</table>
Aurolab

The intersection of technology, disruptive pricing and compassion

20M eyes have regained sight through affordable Aurolab products
Changing the Competitive Landscape with Pricing as the Lever

- It's not just about reducing costs, it's about changing the entire business model in order to reduce price.
- Discover and analyze "non-value added margin", and create systems that eliminate non-value margin.
- Understand political environment in which the status quo of high pricing, lack of competition and transparency can live and thrive -- in order to formulate disruptive interventions.
- Use price as the weapon to change the competitive landscape in a given industry in favor of the consumer.
Total direct and indirect costs to Aravind Eye Hospital for each cataract surgery procedure in 2013 were $29.02.

Aurolab IOL Production
Making Sight Affording (Part I) Aurolab Pioneers
Production of Low-Cost Technology for Cataract Surgery

% of Aravind Eye Hospital

Year

mitpress.mit.edu/innovations innovations / summer 2006

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How Aurolab Changed the Competitive Landscape

India market growth in cataract surgery after creation of Aurolab, 1992-2002:

- Commercial companies competed with Aurolab on price and quality
- Market grew from 800,000 to 7 million cataract surgeries per year

Created price competition in favor of the consumer
Visual Accommodation without Movement™
Electronic IOL to provide dynamic power change

Autofocusing intraocular lens (AFIOL)

- Sensor to pick up physiological trigger
- On-board electronics (ASICS)
- On board Logic, firmware and embedded software to filter noise
- On board Power source, RFID, Memory
- External unit to recharge batteries, receive data
AFIOL Design and Electronics

- **KEY COMPONENTS**
  - Photovoltaic Cells
  - Sensor Algorithm
  - ASICs
  - Batteries
  - Optics
  - RF Microcoils
  - Insertion Tool

- **Process & Assembly**

- **Clinical/Reg. Strategy**

- **Gen II Developments**
Comparison of Two Products

**Aurolab IOL**
- Foldable, allows small incision
- Biocompatible, allows and enables latest surgical techniques
- Excellent visual outcome
- Far vision only, patient needs to wear spectacles for near vision
- Cost of manufacture ~$1-2.00/unit
- Cost to Patient ~$5-10

**Elenza IOL**
- Foldable, allows small incision
- Biocompatible
- Requires special IOL inserter
- Excellent visual outcome expected, aberration corrected optic design
- Accommodating, patient will not require spectacles for most tasks
- Cost of manufacture ~$80/unit
- Cost to patients ~$2000 for the implant and external unit
Product Development Model

- User Needs
- Community needs
- Community involvement
- Expert involvement

- Product Requirements
- Brainstorming
- Innovating
- Constraints

- Design concepts
- Design concepts
- Design concepts
- Design concepts

- Selected Design concept
- Preliminary design specifications

- Crude prototype fabrication and bench testing
- Refined prototype fabrication and field testing

- Design iteration
- Current
- Long term
- Constraints

- Final product specifications
- Final prototype
- Bench and field test
- Scale-up
- Launch

- Regulatory approval
- Manufacturing scale-up
I thank Mr. R.D. Sriram, Director of Operations, Aurolab, Mr. David Green, founder of Project Impact, and McArthur Prize winner, Professor Joshua Silver, Oxford, and Mr. Joel Segre, volunteer and currently at Google X, and colleagues at Helbling Technik (Bern, CH), Adlens Beacon and Elenza for their inputs and guidance.

I supported development of the Modifeye and Elenza products as well as the polymer used to fabricate foldable IOLs at Aravind.