OMNIBOT

University of Washington

Health Innovation Challenge 2016

Business Plan

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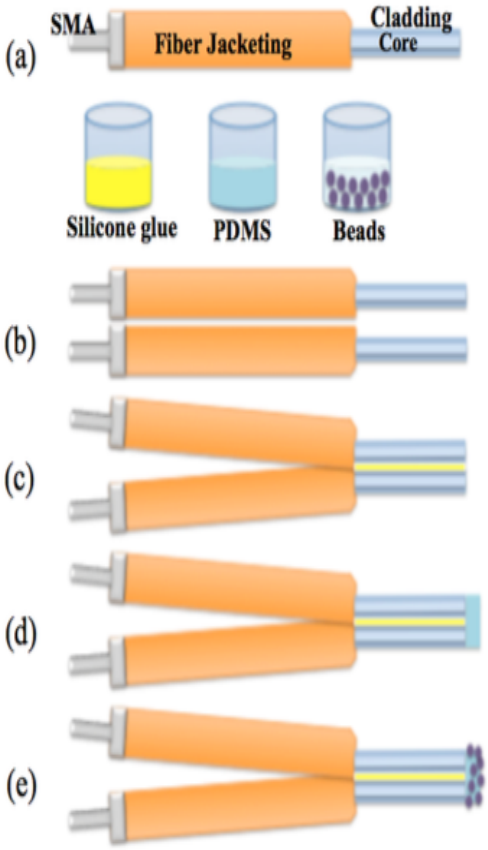
Danger of Stomach Atrophy

- Pernicious Anemia
- Peptic Ulcer Disease
- Gastric Cancer
- Heartburn (GERD)

"An easy to use, mass-screening endoscope that can be operated by medical technicians would be a useful tool as a preventative measure against stomach atrophy."

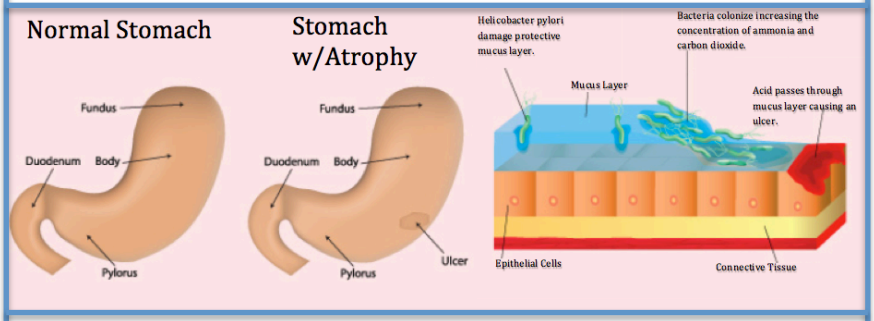
Gas Sensor Process:



Summary

Smart Medical Devices Lab is a medical device development research lab that has designed medical devices which it plans to produce and market. A flexible gastric gas sensor that is incorporated onto a capsule endoscope utilizing soft robotic control has been designed with the participation of leading medical research personnel at Tufts University in Medford, MA, University of Washington on both Seattle and Bothell campuses, and Qatar University in Doha, Qatar. One patent is initially incorporated.

Problem



- The leading causes of stomach atrophy are H. pylori infection and NSAID use (Aspirin, Ibuprophen, etc.)
- An estimated 50% of the world's population is infected with *H pylori,* and, therefore, stomach atrophy is extremely common.
- Most patients are diagnosed with diseases related to stomach atrophy after mucus layer and epithelial cells have been damaged.
- There is a need for a preventative, cost-effective

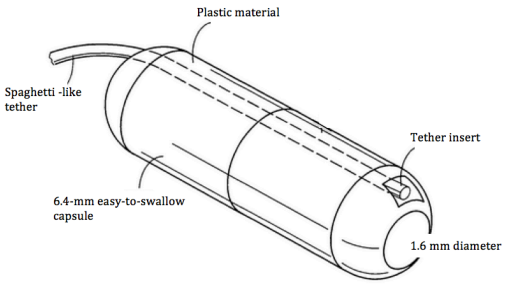
Solution

Smart Medical Devices Lab has designed and manufactured a prototype, called OmniBot. We plan to market the OmniBot system to the atrophy prevention/diagnosis clinical market. The OmniBot consists of a capsule endoscope attached to a flexible steering mechanism to omnidirectionally manipulate the capsule to effectively survey the stomach lining. Within the capsule is a camera, to image the lining, as well as a gas sensor, to quantify the gas concentration within the stomach environment.

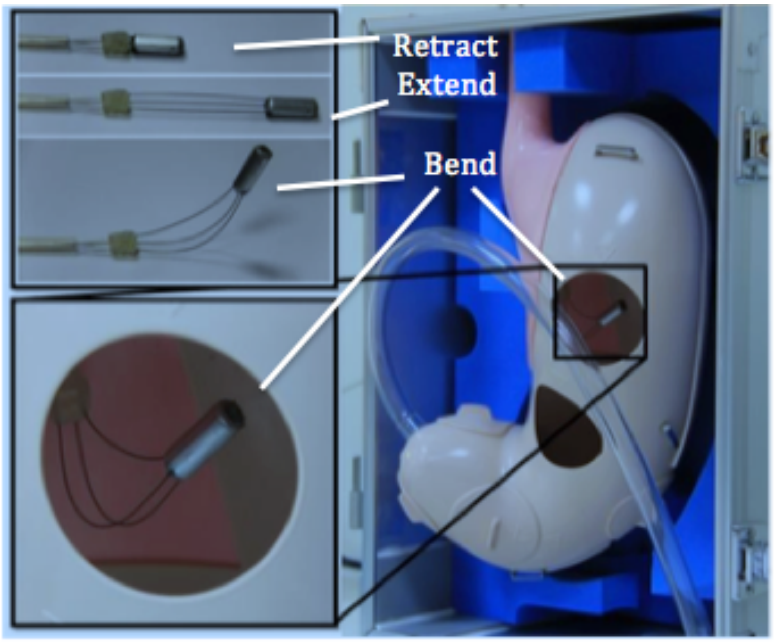
Technology

"The Omnibot could be to gastroenterology what the blood pressure monitor has been for cardiology."

Swallowable Capsule

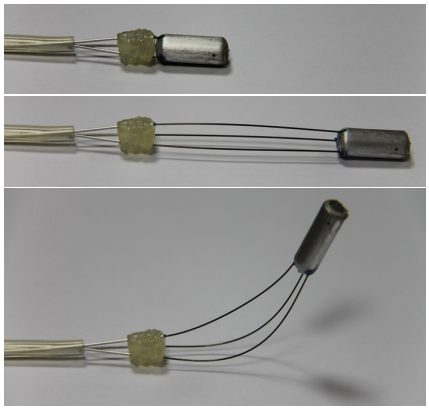


No Anesthesia Needed

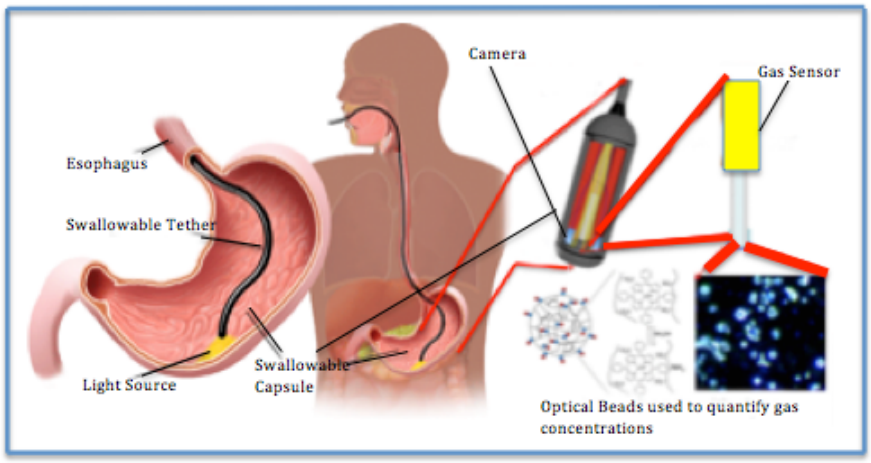


Navigation system capable to retract, extend, and bend to gain complete surveillance of the stomach environment.

160-degree field of view



Design will see 10% more mucosa than other capsule endoscopy



H. pylori infected stomach can have an ammonia concentration increase as high as 200 ppm and a carbon dioxide concentration increase as a high as 100 ppm. Our gastric gas sensor based with a functionalized optical fiber with optic dyes is sensitive to, and can reliably detect, carbon dioxide and ammonia concentrations.

Cost of Materials for an Omnibot System

Competitor Pricing:

Company	Name	Price
Olympus	Endoscope 10	~$3000
Ethicon	PillCam ESO2	~$2500
Boston Scientific	Capsule Endoscope	~$3000

Cost of Endoscopy Procedure:

~$1500 per patient

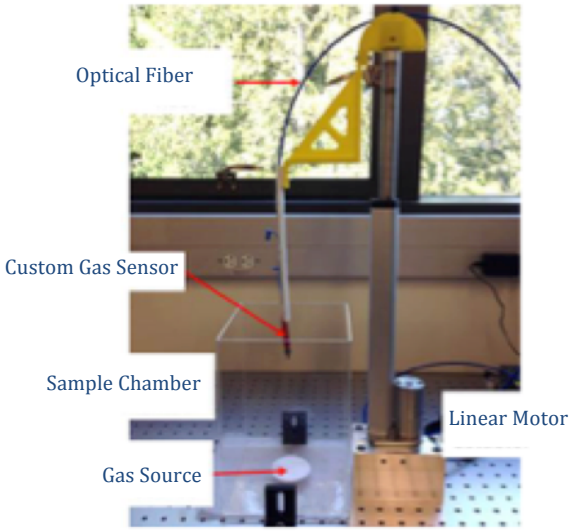
Cost of Anesthesia Services:

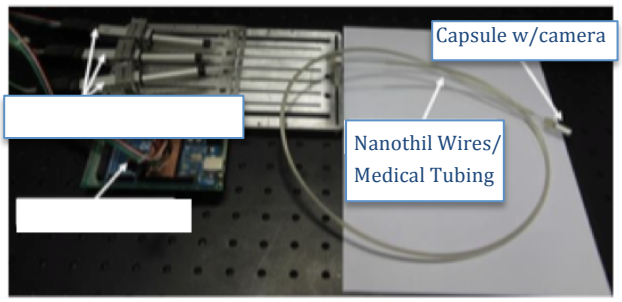
~$1000 per patient

Cost of Total Endoscopy Procedure:

w/Competitor: ~$2500 per patient

w/OmniBot: ~$1500





Gas Sensor/Imaging:

Optical Fiber: $7

Custom Sensor: $10

Camera: $420

Capsule: <$1

Navigation System:

3 Motors: $ 100

3 Nanothil Wires: $15

Medical Tubing: $3

Microcontroller: $15

Total = $571

"There is a void in the market, for an endoscope that can be easily used for preventative measures."

"The clinical benefits of imaging, gas sensing, and navigation are the resourceful health innovations that could lead the OmniBot to be successful endoscope for the future."

Market Need/ Opportunity

The market for mass screening soft robotic endoscopy in gastrointestinal medicine is existent, but in the embryonic stages and subject to explosive growth once the technology proves cost-effective. Currently a capsule endoscope equipped with gas sensing and navigating abilities does not exist. This potential market has reached an estimated 4.2 million patients in the United States annually.

Regulatory Issues

Through obtaining an Investigational Device Exemption and clearly labeling the product "For Investigational Use Only," FDA regulations will be satisfied and market entrance will be expedited. Acceptance of these products based on successful research results will drastically increase demand and allow for expansion to foreign

Lab Summary

Smart Medical Devices Lab will continue research and develop biomedical devices, including the OmniBot systems, to aid in the treatment of a variety of diseases. Its customers are patients afflicted with any condition resulting in gastrointestinal atrophy, as well as those patients interested in physician recommended screening as a preventative measure. Our lab is seeking to establish its corporate identity in the medical products field. Our growth strategy involves the following objectives:

- Complete the patent process.
- Establish corporate identity, brand names, and trademarks.
- Set a clear business direction and both long-term & short-term goals to be achieved.
- Build staff and company infrastructure.
- Complete clinical trials and obtain FDA approval.
- Continue R&D and product development.

"The product is the basic element of marketing. In medicine, the product is service."

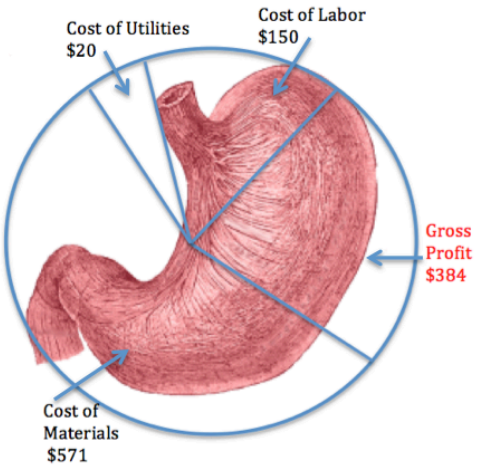
Additional Products Include in OmniBot System:	Price
Disposable Capsules	$15
Training DVD'S	$250
Training Seminars	$50 per technician

"The potential easy-to-use user interface that will be created for the OmniBot system, can lead it to become an everyday diagnostic tool."

Customer Description

The OmniBot will allow physicians at family and specialty clinics to monitor the stomach environment in order to prevent atrophic events. Essentially the clinic, or physician, is the customer. Practice management and the healthcare marketplace are changing rapidly. Competition for patients requires practices to market their expertise to patients. Marketing a medical practice requires the technology that will allow a practice to distinguish it from its competitors. The OmniBot can be that distinguishing technology that can boost a clinic to the highest echelon of patient service. The physician owners have the greatest financial, emotional and personal investment in the practice. The goal is to create a unique service, allowing the practice to gain an advantage over its competitors. The OmniBot is that advantage.

Cost of an OmniBot System



In the non-healthcare business world, price is typically the most important part of the strategic marketing plan. In the healthcare market, price has traditionally been less important, although it is gaining ground. Our product will be sold at a price where clinics can offer its service at a reasonable price.

Cost of 1 unit: $1,125

Five-Year Plan

This plan is considering research and Development underway, early Year One.

- Extend patent coverage to Australia, Japan and Canada, middle Year One
- Human clinical trials underway, middle Year Two.
- Research studies published, end of Year Two.
- OmniBot for beta-sale, end of Year Three.
- OmniBot for sale, labeled as 'For Investigational Use Only', end of Year Four.

Based on detailed financial projections, if Smart Medical Devices Lab receives the $1,250,000 in funding, it will operate profitably by Year 5. The lab projects $14 million in sales with a formidable profit in Year 3, with projections based on penetration of less than 5% in any market segment. The following shows financial predictions until 2020:

Year	Goal	Operating Cost	Projected Sales
2016	Begin R&D	$300,000	$0
2017	Complete Product	$700,000	$0
2018	Beta-Sale to Local Market	$1,150,000	$1,500,000
2019	Capture %5 of National Market	$3,900,000	$6,000,000
2020	Capture %5 of International Market	$9,850,000	$14,000,000

About the Team

Michael Yacoub is biochemistry major at the University of Washington-Bothell. He is also pursuing a minor in entrepreneurship. He is in charge of the gas sensing research and design for the OmniBot system.

Megan Hewitt is a mechanical engineering major at the University of Washington-Bothell. She is in charge of the navigation and user interface research and design for the OmniBot system.

Jong Yoon is an assistant professor at the University of Washington-Bothell and leads the Smart Medical Devices Lab. He is an advisor for the OmniBot system. Dr. Yoon served as an Assistant Professor in the Department of Mechanical and Industrial Engineering, Qatar University, Doha, Qatar before joining UW Bothell. He received the B.E. degree from Hong Ik University, Seoul, and the M.S. and Ph.D. degrees from the University of Washington, Seattle, in 2004 and 2009, respectively, all in mechanical engineering.

David Shaw is a lecturer at the University of Washington-Bothell. He is an advisor for the OmniBot System. Dr. Shaw has ten years experience teaching entrepreneurship and international business in USA as well as nine years experience teaching business in China (BBA, MBA programs). In 1994 Dr. Shaw received his PhD in Agricultural Economics from Purdue University.

What We Ask

Smart Medical Devices Lab needs $1.25 million of capital for the research and design phase, which will last until the end of 2018. During this phase we will create an automated surveillance sequence to be preformed by the OmniBot system as well as a user-friendly interface designed to be operated by a medical technician. Below is a breakdown of the cost for the research and design phase.

R&D for first 2 years	
Equipment/Materials Costs	
Capsule Mold	$5,000
Comprehensive Materials	$200,000
FDA Verification/ Labor and Administrative Costs	
Clinical Trials	$200,000
Publish Papers /Patents	$10,000
Employees	$300,000
Administrative Fees	140,000
Facilities	
Construction Costs/ Building Space	$195,000
Miscellaneous	
Lab and Office Supplies	$200,000
Total	$1.25 million