

Full Circle of Innovation – from Surgical Suite Invention to a Surgical Product

Surgical History

Originally presented March 5, 2008

Foley Hoag, Enterprise Center, Waltham, MA

Surgical History

1585, Aranzi was the first to use a light source for an endoscopic procedure, focusing sunlight through a flask of water and projecting the light into the nasal cavity

<u>1706</u> The term "trocar," was coined in 1706, and is thought to be derived from trochartor troise-quarts, a three-faced instrument consisting of a perforator enclosed in a metal cannula.

<u>1752</u> Benjamin Franklin invented the first flexible, silver coil catheter for a urology application to help his ill brother and he likely used it later himself.

1806, Philip Bozzini, built an instrument that could be introduced in the human body to visualize the internal organs. He called this instrument "LICHTLEITER"

1853, Antoine Jean Desormeaux, a French surgeon first introduced the 'Lichtleiter' of Bozzini to a patient. For many surgeons he is considered as the "Father of Endoscopy".

1868, Kussmaul performed the first esophagogastroscopy on a professional sword swallower

1869, Commander Pantaleoni used a modified cystoscope to cauterize a hemorrhagic uterine growth. Pantaleoni performed the first diagnostic and therapeutic hysteroscopy





Surgical History

<u>1901</u>, Dimitri Ott, a Petrograd gynecologist wore head mirrors to reflect light and augment visualization

1901, The first experimental laparoscopy was performed in Berlin in 1901 by German surgeon Georg Kelling, also Creating the first pneumoperitoneum using filtered air.

<u>1911,</u> Bertram M. Bernheim, from Johns Hopkins Hospital introduced first laparoscopic surgery in the United States



1920, Zollikofer of Switzerland discovered the benefit of CO2 gas to use for insufflation

1929, Heinz Kalk, a German physician, introduced the forward oblique (135 degree) view lens systems. He used laparoscopy as a diagnostic method for liver and gallbladder disease

1938, Janos Veress of Hungary developed a specially designed spring-loaded needle. Interestingly, he did not promote the use of his Veress needle for laparoscopy purposes. He used veress needle for the induction of pneumothorax. Veress needle is the most important instrument today to create pneumo-peritoneum.

Surgical History

- **1944,** Raoul Palmer, of Paris performed **gynaecological examinations using laparoscopy** and placing the patients in the Trendelenberg position, so air could fill the pelvis.
- 1953, Professor Hopkins discovered the rigid rod lens system and he was credited with the concept of of videoscopic surgery as a result.
- **1960**, Kurt Semm, a German gynaecologist **invented the automatic insufflator** and in 1966 He added the capability to **monitoring intra-abdominal pressures**
- 1970, Gynecologists embraced and incorporated laparoscopy into their practice.
- **1977**, First Laparoscopic assisted appendicectomy was performed by Dekok
- **1980**, In United Kingdom Patrick Steptoe, started to perform laparoscopic procedures
- **1985**, The first documented laparoscopic cholecystectomy was performed by Erich Mühe in Germany
- **1987,** Phillipe Mouret, got the credit for performing the first video assisted laparoscopic cholecystectomy in Lyons, France.

MDG NOTES Forum

Medical Development Group March 5, 2008

Randal Chinnock
Founder/CEO
Optimum Technologies, Inc.



Evolution of Surgery



MDG March 5, 2008

Tech



Definitions

Minimally Invasive Surgery (MIS) or Laparoscopy

The term coined in the 1980s to describe surgical procedures performed through "keyholes" instead of major incisions. Was enabled by laparoscopes and instruments-on-sticks.

Single Portal Laparoscopy (SPL), or Single Portal Surgery (SPS)

- MIS procedures performed through a single "keyhole", typically the umbilicus
- Endoluminal Surgery, or Natural Orifice Surgery (NOS)
- Procedures performed inside body orifices (mouth, anus, vagina, urethra, bile duct), including polypectomies, mucosal resection, ERCP's, Barretts, GERD, etc.
- Natural Orifice Transluminal Endoscopic Surgery (NOTES)
- "Scarless" abdominal operations are performed with an endoscope passed through a natural orifice and through an internal incision in the stomach, colon, esophagus, bladder or uterus thus avoiding any external incisions or scars.
- Hybrid/Bridge Procedures
- A combination of both endoluminal and adjunct surgical procedures (i.e.: laparoscopic assisted, PEG, etc.) are utilized in order to mitigate surgical risks.
- Robotic Surgery
- The use of robots in performing surgery. May or may not be human-controlled.



Minimally Invasive Surgery

The first big wave of MIS: the lap-choly revolution starting in 1987. Many more abdominal and cardiothoracic procedures followed:

- Appendectomy (removal of appendix)
- MIDCAB (Minimal Invasive Direct Coronary Artery Bypass Dr. Valavanur Subramanian - India
- Coronary artery bypass grafting, heart valve repair and replacement, and congenital heart disease.
- Partial/radical nephrectomy (removal of kidney)
- Hysterectomy (removal of uterus)
- Colostomy (removal of part of colon or large intestine)
- Bariatric surgeries (control/reduction of obesity)



Minimally Invasive Surgery

<u>Advantages</u>

- Laparoscopy requires a few punctures instead of 2-12" long incisions, sternotomies
- Less blood loss / decreased need for blood transfusions
- Shorter hospital stays
- Decreased pain and need for postoperative pain medications
- Earlier resumption of regular diet
- Quicker recovery and return to normal activities
- Less scarring

MDG March 5, 2008

<u>Disadvantages</u>

- Requires special equipment
- Specialist training required
- Equipment is more expensive
- Some procedures, especially latest ones, may take longer
- Some complications can be masked, e.g., biliary peritonitis



Minimally Invasive Surgery

What enabled it?

- Easier regulatory environment than today
- Emergence of solid state video camera technology
- Hot investment environment
- Early clinical successes
- Historic adoption rate



Single Portal Laparoscopy

- Uni-X(TM) System
- Claimed to be first Single-Port Laparoscopic System consisting of a single multi-cannula laparoscopic port and a variety of curved laparoscopic instruments.
- Eliminates need for >1 abdominal wall incisions and laparoscopic ports
- Invented by Dr. Gregory Piskun
- Manufactured by Pnavel Systems, Inc.

-- http://markets.kiplinger.com/kiplinger?ChannelID=3191&GUID=4033737&Page=MediaViewer



Robotic Surgery - Intuitive Surgical





- Prostatectomy (prostate removal)
- Hysterectomy (removal of the uterus)
 - Thoracic procedures (lungs)
 - Some general surgeries







Nebraska Surgical Solutions

- Dmitry Oleynikov from the University of Nebraska Medical Centers
- Natural-orifice miniature robots cylindrical in shape during insertion
- Two opposable arms unfurl to create self-assembling, remote-controlled surgical robots inside the body
- Modules for grasping and cauterizing, and two cameras to provide 3D vision.
- Wired and wireless versions
- Place up to two robots into a patient at the same time.
- Multiple patents filed for devices which are inserted in the mouth and through the stomach
- Now in porcine trials, including gall-bladder removals, liver biopsies and the ablation of tumours.
- IDE filed for investigational use in humans.

-- 6/11/2007 http://www.economist.com/printedition/PrinterFriendly.cfm?story_id=9249290



Big Award in Boston

- \$2.1M CIMIT award to NOTES group led by David Rattner, MD
- Largest award yet for NOTES
- CIMIT's stated goal:

"CIMIT seeks to facilitate the delivery of better medical care to patients more quickly. The goal of the CSP is to select one project where a concentrated effort and commitment of funds can help accelerate and advance progress. We want to bring better technology and systems to the bedside within a relatively short window of time." -- CIMIT web site



Benefits of NOTES

- No visible scars (NOSCAR)
- Less pain
- Lower risk of wound infection
- Shorter recovery time
- Fewer re-ops due to adhesions & hernia
- Possibly perform under sedation, not general anaesthesia



Potenial Applications/Clinical Needs

- Cholycystectomy (removal of gall bladder)
- Appendectomy (removal of appendix)
- Liver biopsy (tissue sampling)
- Colectomy (removal of part of the colon)
- Bladder sling (incontinence treatment)
- Salpingectomy (removal of Fallopian tube[s])
- Oophorectomy (removal of one or both ovaries)
- Adrenalectomy (removal of adrenal gland[s] or lesions)
- Gastro-jejunostomy (surgical formation of a direct communication between the stomach and the jejunum [middle portion of small intestine])
- Tubal ligation (surgical sealing of the fallopian tubes)
- Barrett's ablation (cancer treatment in the esophagus)
- Gastric plication (obesity treatment)
- Nissen fundoplication (tightening of esophagus to treat reflux disease)
- Iliac lymphadenectomy (surgery for rectal cancer)



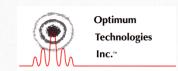
Obstacles to NOTES Procedure

- Access
- Stability
- Visualization
- Infection/inflammation control
- Closure largest hurdle, according to Mark Talamini, UCSD



Access Options

- Use existing flexible endoscopes
- Modify existing scope technology (e.g., Olympus R-scope)
- Develop novel platforms (e.g., USGI Medical EOS)

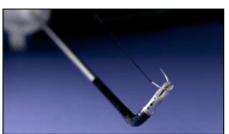


Recent Innovations



Articulated Instruments - Cambridge Endo









Cambridge Endo, Autonomy and Laparo-Angle are trademarks of Cambridge Endoscopic Devices, Inc. ⊚ 2006 Cambridge Endoscopic Devices. Inc. All rights reserved.





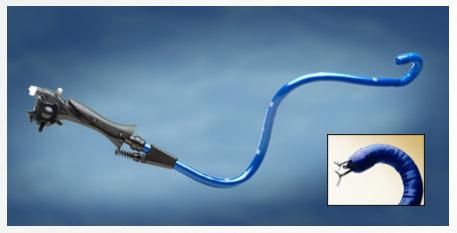
USGI Medical - EndoSurgical Operating System™

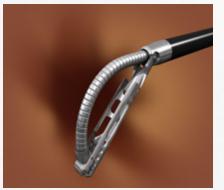
 The TransPort™ Multi-lumen Operating Platform has four large operating channels, two 6mm and two 4mm channels. An endoscope is advanced through one channel to illuminate and visualize the operative site. The other channels are used for instruments, insufflation, and irrigation.



g-Cath™ Suture Anchors

The g-Prox® Tissue Grasper/ Approximation Device is a multifunction, flexible endoscopic instrument that can be used to grasp, manipulate and suture tissue.











gi Dynamics

EndoBarrier product for obesity management Delivered and removed endoluminally

The EndoBarrier™ gastrointestinal liner



Food bypasses the duodenum and proximal jejunum as it does in a Roux-en-Y Gastric Bypass



MDG March 5, 2008



Olympus

 "R" Scope with multiple bending sections - modification of 12.9mm diameter gastroscope





Ethicon Endo-Surgery, Inc.

 "We expect to be the leader [in NOTES]," said Kevin Lobo, who took over as president at the Johnson & Johnson subsidiary in July, 2006. "The mix of surgery types will change. We'll let the patient outcomes determine that."

-- http://sanfrancisco.bizjournals.com/cincinnati/stories/2007/02/05/story3.html





Intellectual Property

There has been a heightened focus in recent years by academic/research institutions and medical device companies on patenting basic methodologies and devices for use in NOTES. Devices include those for access, visualization, instruments, and closure. New entrants to the field are likely to face hurdles in bringing technologies to market for certain surgical applications, particularly in the United States where surgical methods are patentable.

-- Jason M. Honeyman Wolf, Greenfield & Sacks, P.C.



Will NOS/NOTES be the Next Big Wave?

"In three years, we've gone from conceiving concepts and barriers to this field to applying the techniques in the operating room".

-- Dr. Santiago Horgan, Director of Minimally Invasive Surgery and Director of the Center for Treatment of Obesity at the University of California, San Diego Medical School (USGI web site)

"Natural orifice surgery represents the future of minimally invasive surgery. . . "

-- Bruce Robertson, H.I.G. Ventures

