

MDG NOTES Forum

Medical Development Group

March 5, 2008

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Optimum Technologies, Inc.

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Evolution of Surgery

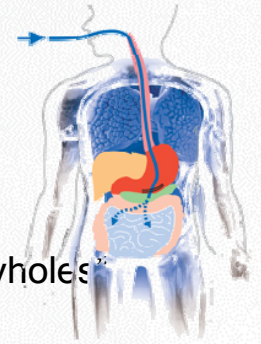


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Slide courtesy of Covidien



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

Advantages

- 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

Disadvantages

- 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

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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



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Nebraska Surgical Solutions

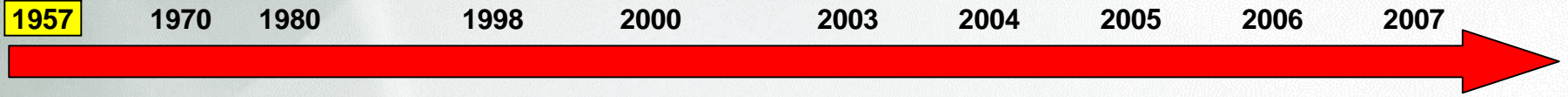
- Dmitry Oleynikov from the University of Nebraska Medical Centers
- Natural-orifice miniature robots - cylindrical in shape during insertion
- Two opposable arms unfurl to create self-assembling, remote-controlled surgical robots inside the body
- Modules for grasping and cauterizing, and two cameras 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

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Endolumenal/NOTES History



1957	1970	1980	1998	2000	2003	2004	2005	2006	2007
Flexible Fiberscope invented			Apollo Group Formed			Drs. Rau and Reddy present on first X-Oral Appendectomy			
	Contemporary Endoscope		Dr Seifert first documents NOTES – Pancreatic Necrosectomy			Dr. Kalloo publishes 1 st X-Gastric Peritonoscopy			Growth Initiative Addtl Funding Dedicated Organization Addtl Resources
	Advanced Endoscopic Procedures			Bard EndoCinch FDA approved Curon's Stretta FDA approved		1 st NOSCART Meeting		2nd NOSCART Meeting	
				BSCI Enteryx approved for GERD NDO receives FDA approval Plicator				Multiple US IRB's approved for NOTES InScope \$1mm NOSCART Grant Olympus \$500K NOSCART Grant Covidien \$500K NOSCART Grant EGS Stomaphyx FDA approval	
								Press Release on 1 st X-Vaginal Cholecystecomy	
								IRCAD Intl. NOTES Training Course	

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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

Potential Applications/Clinical Needs

- Cholecystectomy (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

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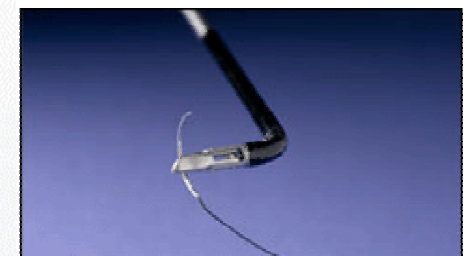
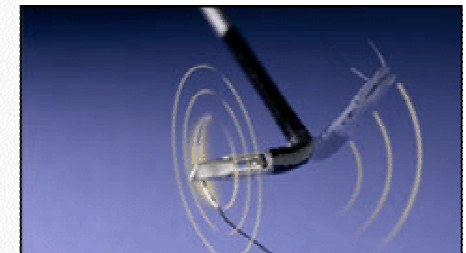
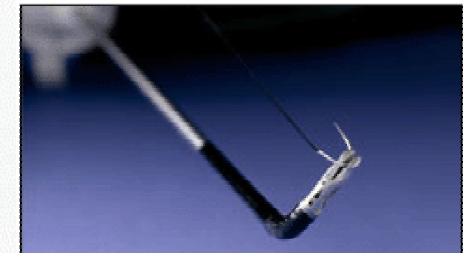
Articulated Instruments – Cambridge Endo

Introducing Autonomy™ Laparo-Angle™ Instrumentation.
a full line of fully articulating handheld instruments for pure laparoscopy

NOW AVAILABLE

Autonomy
Achieve Pure Laparoscopic Performance
LAPARO-ANGLE. INSTRUMENTS

See Autonomy in surgery >



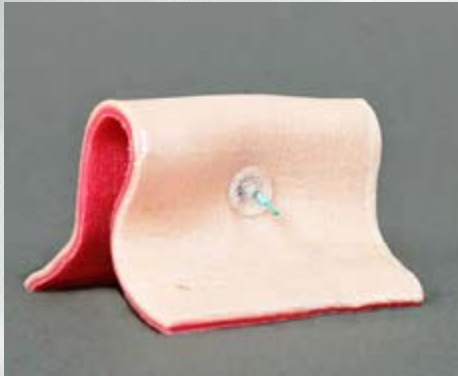
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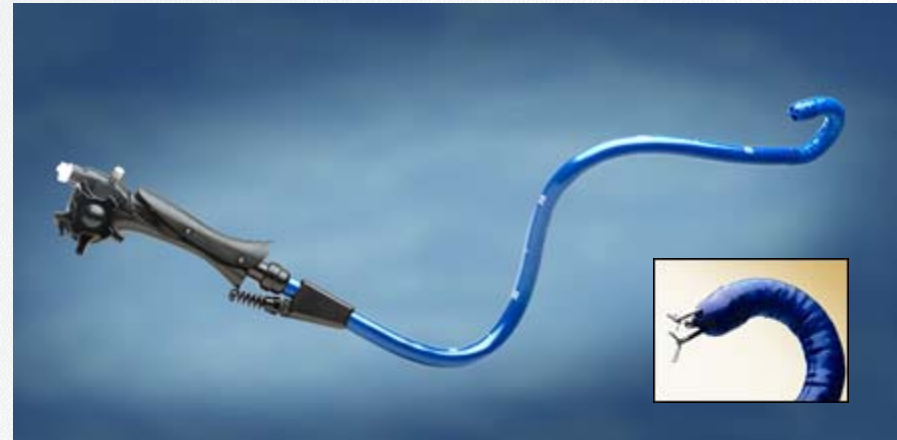
USGI Medical - EndoSurgical Operating System™

- 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 multi-function, 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



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Olympus

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



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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>



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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

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