Flexible endoscopy in a robotic world – Challenges?
Objectives

1. Provide definitions and applications of robotic surgery

2. Discuss advancements and designs with flexible endoscope robotic surgery

3. Review reprocessing instructions and challenges
Janet Prust - Disclosure

Employee of 3M Health Care
Infection Prevention Division

Association for Advancement of Medical Instrumentation (AAMI)
Positions held:

AAMI Board of Directors – Director representing industry since 2015

Member:

- AAMI Finance committee
- Sterilization Standards Committee
- WG 61: Chemical sterilants hospital practices – co-chair
- WG 84: Endoscope reprocessing
- WG 40: Steam sterilization hospital practices
- WG 13: Washer disinfectors; TAG to ISO TC 198 WG 13
- WG 93: Cleaning of reusable devices
- Sterilization of endoscopes stakeholders group
- Task group – HVAC conditions in OR
Robotic Endoscopy = Minimally Invasive Techniques

Technology incorporating automation, microsurgery, engineering, imagery, electronics for minimally invasive surgery that offers better precision, flexibility and control compared to conventional techniques.

Types:

**Laparoscopy**
- Urology
- Gyn
- Prostate
- Kidney
- Gallbladder
- Cardiothoracic
- Orthopedic

**Flexible endoscopy**
- Colorectal
- Oncology
- Esophageal

Key innovation: wrist like movement
What is robotic flexible endoscopy?

New MIS technology to allow advanced procedures in natural-orifice transluminal endoscopic surgery (NOTES), with a robotic endoluminal platform, e.g. flexible endoscope enabled by robotics used for:

1. Tissue triangulation – two or three forceps
2. Used for advanced resection techniques, e.g. endoscopic submucosal dissection (ESD)
3. May provide better assessment of resection rate for early cancers
4. Better staging of disease treatment
5. Better access of hard to reach structures
6. Most system require two operators

Common types of procedures: esophageal and colonic are ESD most common application

Applications in gastric plication and many others.

Source: Baldwin, 2016
Two mechanical arms attached to a head or conventional endoscope.

Allows endoscopic manipulations
- Grasping
- Traction
- Incision
- Excision
- Hemostasis

Source: Baldwin, 2016
(a) The system of the ENDOSAMURAI™ (by courtesy of Olympus Medical Systems, Tokyo, Japan). (b) The insertion part of the ENDOSAMURAI™ (by courtesy of Olympus Medical Systems, Tokyo, Japan).

Source: Olympus Japan
How do the systems work today?

1. Endoscope connected to mechanically to actuation equipment with mechanically driven cables or levers to move the instrument’s arms.
2. Precise movements controlled by endoscopist by joystick or similar control to improve tissue handling in the confined endoluminal space.
3. System allows forward/backward, rotational, up/down, left/right movement of a conventional endoscope.
4. Surgeon views surgical site through microscope and often controls the system from the surgical console.
5. Goal is to improve the procedural performance efficiency.

- New technology with many designs still in trials
- Requires learning curve
- Reported complications:
  - Hemorrhage and perforation
  - May be more of issue with low volume centers
  - System requires expertise
- Multiple designs in trials or use.

Source: Baldwin, 2016
<table>
<thead>
<tr>
<th>Platforms</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic driven locomotion</td>
<td></td>
</tr>
<tr>
<td>Electromechanical control of a conventional endoscope</td>
<td>FDA Y</td>
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<tr>
<td>Robotic steering and automated lumen centralization (RS-ALC) (Netherlands)</td>
<td>N</td>
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<tr>
<td>Endoscopic operating robot (EOR) (Kyushu Institute of Technology, Japan)</td>
<td>Y</td>
</tr>
<tr>
<td>Invendoscope (Invendo Medical GmbH, Germany)</td>
<td>Y</td>
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<tr>
<td>Systems with elements of autonomous locomotion</td>
<td>Y</td>
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<tr>
<td>Neoguide (Intuitive Surgical, United States)</td>
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<tr>
<td>AER-O-scope (GL View Ltd, Israel)</td>
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<tr>
<td>Endotex (ERA Endoscopy SRL, Italy)</td>
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<tr>
<td>CUHK double-balloon endoscope (Chinese University of Hong Kong, China)</td>
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<tr>
<td>Robotic driven instrumentation</td>
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<td>MASTER (EndoMASTER Pte, Singapore)</td>
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<tr>
<td>ISIS-Scope/STARS system (Karl Storz/IRCAD, Europe)</td>
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<td>Endorna (EndoTools Therapeutics, Belgium)</td>
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<td>Scorpion shaped endoscopic robot (Kyushu University, Japan)</td>
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<td>Viscath (Hansen Medical, United States)</td>
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<tr>
<td>CUHK robotic gripper (Chinese University of Hong Kong, China)</td>
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<tr>
<td>Imperial College robotic flexible endoscope (Imperial College, United Kingdom)</td>
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</tbody>
</table>

Source: Baldwin, 2016
Aeroscope.

Figure 5

The Aeroscope relies on a balloon at the tip of the endoscope to form a seal with surrounding colonic wall. A computerized pump system generates a pressure gradient proximal and distal to the balloon. This pressure gradient propels the device. Courtesy of Glyview Ltd.

- Pump system pressure propels the device.
- FDA cleared

Source: Baldwin, 2016
Invendoscope

Scope pushed forward with actunating wheels.

Has sheath that unfurls.

FDA cleared, CE marked

Same company has produced a disposable colonoscope.

Recently acquired by Ambu.

Source: Baldwin, 2016
Endomima System

Figure 10

The Endomima system can be mounted onto a conventional endoscope. The arms allow passage of conventional flexible instruments. Each arm has up to 3 DOF of movement (Endotools Therapeutics).

- FDA cleared
- Available for sale.

Source: Baldwin, 2016
Viacath System

- Fits over a conventional endoscope
- FDA cleared, CE marked
- Available for sale

On the left, the endoscope and the viacath robotic arms are integrated using an overtube. Abbott et al [75], 2007.

Source: Baldwin, 2016
Inspection Before Use

CAUTION: Inspect the instruments for broken, cracked, chipped, or worn parts. Do not use an instrument if it is damaged.

Before use, all instruments should be visually inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include:

- Broken cables or wires
- Scratches, cracks or broken parts on the instrument shaft
- Cracks or missing pieces where the grips attach to the shaft
- Broken, bent, misaligned or gouged instrument tips
- Cracked or broken pulleys near the instrument tips
- Cracks or missing pieces on the outer components surrounding the pulleys
- Loose tip or grips
- Broken lever guards (if applicable)

Source: Intuitive – Da vinci User Manual
Additional Types of Instruments in Robotic Systems

- Graspers, dissectors, needle drivers, scissors
- Clip applicators
- Suction irrigators

Electrocautery and accessories

- Cannulas
- Obturators
- Seals
- Connectors
Reprocessing Robotic Instruments

1. Invasive surgical procedures = Terminal Sterilization

2. Da vinci Endowrists limited reuse – steam or low temperature sterilization

3. Accessories typically steam sterilized

3. Complex precleaning, manual cleaning, ultrasonic followed by automated washer/disinfector cycle. Special attachments for WD.

4. Easily damaged – inspection is important process step.
### Types of surgical instruments for Da vinci system

**Source:** Intuitive – Da vinci User Manual
### Compatible sterilization process types

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Steris®</th>
<th>Sterrad®</th>
<th>Eto®</th>
<th>Autoclave (Pre-vacuum)</th>
<th>Enzymatic Cleaner</th>
<th>Ultrasonic Bath</th>
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<tbody>
<tr>
<td>Type 1 Endoscopes (Straight and angled)</td>
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<td>Sterile Camera Adapter</td>
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<td>Sterile Instrument Arm Adapter</td>
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<td>Scope Alignment Targets</td>
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<td>Camera Cannula Mount</td>
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<td>Endowrist Instruments</td>
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Compatible Process Types and Cycle Parameters

User Manuals provide validated processing instructions

- Types of detergents
- Automated cleaning systems and parameters
  - Ultrasonic
  - Washing
  - Disinfection
- Packaging and technique
- Sterilization process types and parameters
  - Ensure these parameters are available on system in the facility

Source: Intuitive – Da vinci User Manual
Summary

1. Advancements in MIS techniques and instrumentation has brought a new wave of technology that will continue to rapidly evolve

2. Robotics incorporated for both rigid, semi-rigid and flexible endoscopy

3. Consolues, carts, instruments and accessories have specific reprocessing instructions

4. Point of use pre-cleaning, manual cleaning and automated cleaning must be effectively performed.

5. Remember – these are invasive surgical techniques using CRITICAL medical devices representing a high risk the patient and the instruments must be terminally sterilized.
References


4. Intuitive Surgical Inc. Da vinci® Surgical System User Manuals. Series Xi, X, S.