Disinfection of Surgical Procedures
Undertaken with the
NOTES Technique
(Natural Orifice Translumenal Endoscopic Surgery)

11th World Sterilization Congress
and the
7th International Symposium of Sterilization and Hospital Infection Control

Georg Spaun MD
Salzburg
Austria
Surgery  ➡️  Endoscopy

- Large colon polyps
- Common bile duct explorations
- Bile duct and foregut/hindgut palliative surgery
- GI bleeding
- Esophageal varyx surgery
- Open Zenkers excision

- Pancreatic necrosectomy
- Pancreatic pseudocyst drainage
- Iatrogenic perforation repair
- Esophagectomy for HGD Barrett
- Early gastric cancers

Swanstrom, Supercourse Portland 2009
Evolution of GI Surgery

Open Surgery

Flexible Endoscopy

Laparoscopic Surgery

Single Port Surgery

Transluminal Endoscopic Surgery

Invasiveness

Therapeutic Endoscopy

Mucosectomy/Mucosal resection

Stents Ablations

Swanstrom, NOSCAR Meeting 2007
NOSCAR White Paper

- Natural Orifice Surgery Consortium for Assessment and Research
- 14 leaders from the American Society of Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) met in New York City on July 2005
- Potential barriers to clinical practice:
NOSCAR White Paper

• **Potential barriers to clinical practice:**
  
  • Access to peritoneal cavity
  
  • Gastric (intestinal) closure
  
  • Prevention of infection
  
  • Development of suturing and anastomotic device
  
  • Spatial orientation
  
  • Development of a multitasking device to accomplish procedures
  
  • Management of iatrogenic intraperitoneal complications and hemorrhage
  
  • Physiologic untoward events and compression syndroms
  
  • Training
NOSCAR White Paper

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Access to the peritoneal cavity
Access to the peritoneal cavity
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Gastric (intestinal) closure

Tissue Apposition System, Ethicon
Gastric (intestinal) closure

- Tissue anchors
- Endoclips
- Endoloops
- Over the scope clips (OTSC)
- Cardiac septal occluder
- Endoscopic stapler
- NDO plicator
- Eagle claw I-VIII
- Endoscopic suture
- Tissue glue
NOSCAR White Paper

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Prevention of infection

- Single shot antibiotics
- Acid suppression medication paused 4 weeks ahead of surgery
- Lavage optional (stomach), mandatory in rectum und vagina
- Sterile instruments (ETO, sterilant)

- Glutaraldehyde 10h at 10-15°C
- Hydrogen peroxide 6h at 20°C
- Isopropanol + Glutarald. 10h at 20°C
- Peracetic acid 12min at 50°C
- Ethylene oxide 20h
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Development of suturing device

Eagle Claw II Prototype

Flexible EndoStitch, Covidien

Anubis, Storz

Tissue Apposition System, Ethicon

G-Prox, USGI Medical
Development of suturing device

Endosamurai, Olympus
Development of suturing device

- Animal survival study (7 pigs)
- Endoscopic placement of the magnets: 34.3 ± 14.8 min

Development of suturing device

**EsophyX**

- Attempts mimic effects of antireflux surgery by elongating angle of His

- Feasibility study N=13
  - 81% demonstrated anatomical integrity of the GE valve at 12 months
  - 82% remained completely off PPIs
  - 63% had normal pH (defined as less than or equal to 5.3% of time with pH<4); however, no pre-procedure pH measurements are provided
Development of suturing device

Weight loss surgery:

- TOGA system (Satiety Inc., Palo Alto, CA)
  21 patients, 6 mo f/u:
  - no adverse events;
  - % excess weight loss 1, 3, 6 mo: 16.2, 22.6, 24.4
Development of suturing device

- **Endoluminal Vertical Gastroplasty (EVG)**
  - 64 patients, 12 mo f/u
  - Procedural time 45 min
  - % excess weight loss at 1, 3, 12 mo
    - 21.1, 39.6, 58.1
  - BMI >40, 35-40, <35
    - %EWL 48.9, 56.5, 85.1
  - No complications

NOSCAR White Paper

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  • Development of a multitasking device to accomplish procedures
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  • Training
Spatial orientation
Spatial orientation

Development and testing of a tethered, independent camera for NOTES and single-site laparoscopic procedures

Paul Swain · Ralph Austin · Kurt Bally · Robert Trusty

Received: 4 May 2008/ Accepted: 10 January 2010
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NOSCAR White Paper

- **Potential barriers to clinical practice:**
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- **Development of a multitasking device to accomplish procedures**
  - Management of iatrogenic intraperitoneal complications and hemorrhage
  - Physiologic untoward events and compression syndroms
  - Training
Development of a multitasking platform to accomplish procedures

USGI Medical
Development of a multitasking platform to accomplish procedures

Endosamurai, R-Scope, DCS, Olympus
Development of a multitasking platform to accomplish procedures

Direct Drive Endoscopic System (DDES), Boston Scientific
Development of a multitasking platform to accomplish procedures
Rigid Instruments

- Zornig et al.: german NOTES registry: 1000 procedures transvaginal, 5 flexibel, all others rigid
Transvaginal (pure) NOTES

Pure natural orifice transhuminal endoscopic surgery (NOTES) cholecystectomy

Marc Roussel · Andrew A. Gumbs · Luca Milone · John C. Evans · Peter Struwe · Dennis Fowler

Received: 28 April 2009 / Accepted: 12 November 2009 © Springer Science+Business Media, LLC 2010

Totally NOTES (T-NOTES) transvaginal cholecystectomy using two endoscopes: preliminary report

Luís Henrique de Sousa · José Adriano Gomes de Sousa · Luís Henrique de Sousa Filho · Martín Miranda de Sousa · Vânia Miranda de Sousa · Ana Patrícia Miranda de Sousa · Ricardo Zerron

Received: 22 November 2009 / Accepted: 27 February 2010 © Springer Science+Business Media, LLC 2010
Transanal Endoscopic Microsurgical (TEM) Platform for Natural Orifice Surgery

Gastrointest Endosc 2008 Nov;68(5):954-9
Transanal Endoscopic Microsurgical (TEM) Platform for Natural Orifice Surgery
Development of a multitasking platform to accomplish procedures
NOSCAR White Paper

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- Training
Management of iatrogenic intraperitoneal complications and control of intraperitoneal hemorrhage

- Isolated electrodes + ERBE VIO 300D generator, 3.7mm shaft
- 7 pigs, 65 vessels
- As effective as laparoscopic control in sealing vessels 2.0-6.0mm

The NOTES Toolbox

- **Dissection**
  - Articulating Hook
  - Articulating Needle Knife

- **Manipulation**
  - Articulating Grasper

- **Ligation**
  - Flex Clip Applier

- **Tissue Sampling**
  - Articulating Bx Forcep

- **Hemostasis**
  - Bela Bipolar Forceps

- **ACCESS**
  - NOTES Trocar and Rotary Veress Needle

- **Specimen Retrieval**
  - Articulating Specimen Bag

- **Cutting**
  - Flexible Scissors

- **Dissection**
  - Oscar Marylands

- **Closure/Suturing**
  - TAS

**Ethicon**

- Adaptation of laparoscopic tools to a smaller, flexible, platform
NOSCAR White Paper

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  - Training
Physiologic untoward events

Airseal, Surgiquest
Physiologic untoward events

- 300 women using a 12-point questionnaire
- 32% unhappy or very unhappy to undergo a transvaginal procedure,
- 18% happy or very happy
- 50% felt neutral
- Younger nulliparous women were most concerned about the potential negative effect of NOTES on sexual function
NOSCAR White Paper

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• **Training**
Training

A comparison of early learning curves for complex bimanual coordination with open, laparoscopic, and flexible endoscopic instrumentation

Gero B. Spurz · Ren Zheng · Daniel Y. Martinez ·
Brittany N. Arnold · Lee L. Swanson

Received: 4 May 2009 / Accepted: 7 October 2009
© Springer Science+Business Media, LLC 2010
Clinical Results

- German NOTES registry: >1000 transvaginal procedures, only 5 flexibel, others rigid

- Transgastric NOTES cholecystectomy
  Portland, OR
  - 2007-2009: N=10, mean operative time 240 min

- International Multicenter Trial on NOTES—
  NOTES IMTN Study: Preliminary results of 362 patients.
  - Mean operative time: transvaginal: 96 min; transgastric 111 min
  - General complication rate of 8.84% (minor 5.8%, maior 3.04%)
Background

• Standard endoscope-reprocessing is a three stage process

Standard dual channel endoscope
Background

- Standard endoscope-reprocessing is a three stage process
  - *Pre-processing* or cleaning the endoscope and its detachable components using a detergent solution and brushes
  - *Processing* or high level disinfection of the endoscope using an liquid chemical germicide followed by water rinsing to remove chemicals
  - *Post-processing* includes proper handling, drying and storage of the endoscope
Background

• Additional stage (sterilization) necessary to provide truly sterile endoscopes
Methods

- A comprehensive review of the available relevant literature was performed.

- We evaluated options that are currently available (2007-2009) for endoscope sterilization in the United States and analyzed them for:
  - Potential for re-contamination
  - Cost (depreciation of machinery, regulatory fees, maintenance, labor, disposables, and chemicals used for sterilization)
  - Available validation
  - A score was developed to rank the available options for use in our facility.
Methods

• Based on the score, a protocol for the sterilization of flexible endoscopes for NOTES procedures was created

• The protocol involved mechanical cleaning and high level disinfection per multi-society guidelines with subsequent terminal sterilization

• Methods for transportation and handling of the sterile endoscope were created
Results

- Literature survey reveals controversy around the absolute necessity for sterilization of surgical instruments
- Standard of practice seems to call for sterile instrumentation for surgical procedures and high level disinfection for flexible intraluminal endoscopy
- It is possible to sterilize flexible endoscopes
Results

- **Prolonged soak in high-level disinfectant/sterilant:**
  - The cost for the sterilant was found to be <1% of the total cost for the prolonged soaking sterilization method in our institution.
  - The sterilization process is lengthy and therefore not practical.
  - In our evaluation the risk of re-contamination was found to be the highest for this sterilization method.
  - The cost for the soak-sterilization was ranked second.

<table>
<thead>
<tr>
<th></th>
<th>Cost</th>
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<tbody>
<tr>
<td>Sterile gloves</td>
<td>$ 5.82</td>
</tr>
<tr>
<td>Sterile gown</td>
<td>$ 15.12</td>
</tr>
<tr>
<td>Sterile container</td>
<td>$ 1.00</td>
</tr>
<tr>
<td>Mask /Shield</td>
<td>$ 3.66</td>
</tr>
<tr>
<td>Syringe</td>
<td>$ 1.86</td>
</tr>
<tr>
<td>Cidex (example)</td>
<td>$ 0.52</td>
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<tr>
<td>Sterile water</td>
<td>$ 6.78</td>
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<tr>
<td>Labor</td>
<td>$ 24.41</td>
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<tr>
<td><strong>Total Cost</strong></td>
<td><strong>$ 59.17</strong></td>
</tr>
</tbody>
</table>

Results

- **Ethylene oxide (ETO) gas sterilization:**
  - All flexible endoscopes are compatible with ETO, which provides true sterilization
  - Endoscopes sterilized with this method are dry and therefore easily packaged and transported to the sterile field as a sterile instrument
  - Therefore, the risk of re-contamination was found lowest for ETO sterilization, but cost was found to be the highest

* Costs calculated for using ETO sterilization (100% ETO). “Other costs” include depreciation, regulatory standards and maintenance.
As the Company previously announced, its new liquid chemical sterilant processing system, SYSTEM 1E™, was cleared by the FDA on April 5, 2010

Results

- **Steris System 1 (Steris Inc., Mentor, OH):**
  - The automated System 1 claims sterilization capability using a liquid chemical sterilization method (peracetic acid)
  - It uses a just-in-time method much like flash-steam sterilization with the advantages of permanent endoscope availability in the endoscopy suite and short sterilization time
  - The cost for this sterilization method was ranked lowest in our evaluation and the risk for re-contamination second

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<td>Mask</td>
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<td>Single use gloves</td>
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<td>Container sterilization</td>
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<td>Sterilant</td>
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<td>Indicator</td>
<td>$0.88</td>
</tr>
<tr>
<td>Maintenance</td>
<td>$8.00</td>
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<tr>
<td>Labor</td>
<td>$1.25</td>
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<tr>
<td><strong>Total Cost</strong></td>
<td><strong>$23.47</strong></td>
</tr>
</tbody>
</table>
Results

- **Hydrogen peroxide gas vapor sterilization (e.g., STERRAD®, Ethicon Inc., Somerville, NJ, USA):**
  - Not available for clinical use for flexible endoscopes 2009 in the USA
  - Future?
Results

- **Ozone sterilization (TSO3 Inc., Dalton, Quebec, Canada):**
  - Not available for clinical use for flexible endoscopes 2009 in the USA
  - Future?
Results

Portland protocol

- Endoscopy Services provides standard three-stage endoscope processing (high level disinfection)
- Endoscopes are stored afterwards in closed cabinets
- Two hours before a scheduled NOTES, a flexible endoscope is delivered to the central sterilization unit (Surgical Services), where sterilization is performed using the Steris ‘System 1’
Results

Portland protocol

- The sterile endoscope has to be removed from the sterilization container under sterile precautions, is placed in a sterile container with lid and delivered through the sterile core to the operating room
Results

Portland protocol

- Circulating nurse assists scrub nurse to unpack the sterile endoscope when the operator is in the room
- Accessories like water bottle, lid and tubing are autoclaved and delivered sterile to the operating room
Conclusion

• Natural Orifice Surgery (flexible endoscopy) is evolving

• Significant industry activity
  • Obesity, GERD, EMR-ESD, Anastomosis, EUS based therapies, NOTES

• New devices and new treatment algorithms are on the way

• We recommend sterile instrumentation for clinical NOTES until well-designed, randomized clinical trials are available and guidelines are published