da Vinci and Beyond...

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Intuitive Surgical

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Medical Robots as Products

- Tele-Robots
- Radio-Therapy Robots
- Robotic Assistants
- Image-Guided Robots
- Imaging Robots
- MEDICAL ROBOTICS
The Anatomy of a TeleRobotic System

**Surgeon Console**

**Control System**

**Patient-Side Manipulator**
The Anatomy of a TeleRobotic System
(Sensei, Hansen Medical)

Surgeon Console  Control System  Patient-Side Manipulator
Manual Laparoscopy (1980’s)

Dr. Philippe Mouret ~ 1987
Credited with first lap chole procedure in France in 1987

Laparoscopic oophorectomy (removal of the ovaries) ~ early 1990’s
1980’s – Advancements in Robotics

- 1980’s offered tremendous advancements in microelectronics and computing.
- Robotic telepresence technology began to reach new heights (and depths).

- Nuclear material robotic arm ~ 1981
- Deep Sea Robotics ~ 1985
- Robot “Jason Jr.” Titanic wreck ~ 1986
- NASA Robotic Arm ~ 1981
Robotics meets Surgery

• In the 1990’s, several groups recognized the opportunity to use tele-robotic technology to overcome laparoscopic challenges:
First Surgical Console and Patient-side Manipulators (1996)
The *da Vinci Si* Surgical System

- Surgeon Console
- Patient Side Cart
- Vision Cart
- EndoWrist Instruments
The *da Vinci Xi* (April 2014)
What value can MIS offer to the Patient?

- Reduced pain.
- Reduced scarring.
- Reduced blood loss.
- Fewer complications.
- Faster return home, to work, and to normal activity.
- Fewer side effects (incontinence, impotence, infertility).
- Better cancer diagnosis and control (sometimes).
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Focus Procedure Areas

>500,000 da Vinci procedures performed in 2013

<table>
<thead>
<tr>
<th>Cardiothoracic</th>
<th>Urology</th>
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<tbody>
<tr>
<td>➢ Mitral Valve Repair</td>
<td>➢ Prostatectomy – prostate cancer</td>
</tr>
<tr>
<td>➢ Coronary Revascularization</td>
<td>➢ Nephrectomy – kidney cancer</td>
</tr>
<tr>
<td>➢ Lobectomy – lung cancer</td>
<td>➢ Cystectomy – bladder cancer</td>
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<td>➢ Pyeloplasty – kidney reconstruction</td>
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<table>
<thead>
<tr>
<th>Gynecology</th>
<th>General Surgery</th>
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<tbody>
<tr>
<td>➢ Hysterectomy – benign and endometrial cancer</td>
<td>➢ Lower Anterior Resection – colorectal cancer</td>
</tr>
<tr>
<td>➢ Sacral Colpopexy – pelvic floor reconstruction</td>
<td></td>
</tr>
<tr>
<td>➢ Myomectomy – removal of debilitating fibroids</td>
<td></td>
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| Head and Neck Surgery                   |                                      |
|-----------------------------------------|                                      |
| ➢ Trans-oral Robotic Surgery (TORS) – throat and base-of-tongue cancer |                                      |
Open vs MIS trends in the US: Malignant Hysterectomy

- **da Vinci** primarily displaces open surgery
- Prevalence of lap hysterectomy for cancer less than 15% at its peak
- Open surgery is now used in only about 20% of surgeries for cancer

**U.S. MALIGNANT HYSTERECTOMY MARKET BY MODALITY**

Estimated Adoption of Minimally Invasive Surgery (MIS)

- Percentage of all procedures
- FDA clearance of da Vinci® Surgery GYN, 2005
- Laparoscopy
- Vaginal

1. Inpatient data: Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality
2. Outpatient data: Solucient® Database - Truven Health Analytics (Formerly Thomson Reuters)
3. da Vinci data: ISI Internal Estimates
Open vs MIS trends in the US: Benign Hysterectomy

- *da Vinci* primarily displaces open surgery
- After the introduction of *da Vinci*, the prevalence of MIS (lap, vaginal and *da Vinci*) grew.
- Open surgery is now used in only about 20% of benign hysterectomies
da Vinci Platform Evolution

1999
- da Vinci
  - Robot-assisted MIS

2006
- da Vinci S
  - 3D HD Vision

2009
- da Vinci Si
  - Dual Console option

2014
- da Vinci Xi
  - Multi-quadrant access
  - “Chip-on-tip” 3D HD vision

- SINGLE PORT SURGERY (FUTURE RELEASE)
- PATIENT-SIDE SKILLS
- INTEGRATED ENERGY
- TABLE INTEGRATION (FUTURE RELEASE)
- SINGLE-SITE
- ADVANCED INSTRUMENTATION
- SKILLS SIMULATOR
- FIREFLY
- SINGLE-SITE
- SYSTEM NETWORKING
Observations

• Platform iterations take a long time.

• “Add-on” technologies iterate faster.

• A shift to multiple-platforms is imminent.

• Question:

  What factors have driven evolution directions?
Design Drivers

• The OR environment.
• The team of users.
• Intended clinical indications.
• Some trade-offs:
  – Usability (surgeon vs assistant vs OR staff)
  – Versatility (procedures, indications, patients)
  – Surgical performance
  – Size
  – Cost
  – ...what else?
This is a media photograph!
This is reality: the OR environment
This is reality: the OR environment
This is reality: the OR environment
This is reality: the environment
A Team of Users

- There are several users.
- The work is highly collaborative.
- Different levels of familiarity with the system.
Back to basics: Components of Surgery

- **Preparation**
  - operating room, patient, equipment

- **Access**
  - incision, insufflation, cannulation, (re)docking

- **Exposure**
  - manipulation, retraction, dissection

- **Assess**
  - visualization, palpation

- **Resection**
  - transection, clamping/sealing, cutting, hemostasis

- **Removal**
  - suction, morcellation

- **Reconstruction**
  - suturing, stapling, fusing, anchoring

- **Closure**
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**Impact on the OR:**
- Patient positioning
- Size and mobility
- Impact on workflow
- Procedure flexibility
Impact on the OR

- Design philosophy: one cart...multiple procedure applications.
- Trade-offs: Size, Versatility, Modularity, Ease of setup
Impact on the OR

• Design philosophy: one cart...multiple procedure applications.

• Trade-offs:
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Architecture of the Xi Cart and Gantry

- Column
- Boom
- Helm
- Arms
- Base
- Casters
- Fixed drive wheels
Architecture of the Xi Arms

- Column
- Helm
- Base
- Boom
- Arms

- Shallow angle
- Steep angle
Impact on the workflow: Guided Set Up
Impact on the workflow: Guided Set Up
Impact on workflow: Avoiding Buttons
Bringing it all together: Rapid Setup

Video (3x, 90 seconds actual)
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**Surgical field:**
- Multiple ports
- Single port
- Natural orifice
- Number of quadrants
- Range of motion
Workspace Flexibility

• Trade-offs:
  - multi- vs. single-incision
  - range of motion vs. rapid multi-quadrant
Multi- vs Single-port Access

Not available for sale. In development.
SingleSite Access with Multiport Platform
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**Surgical capability:**
- Dexterity and precision
- Range of motion
- Stiffness and force
- Number of instruments
Surgical Capability

• Trade-offs:
  – Rigid versus flexible
  – Wristed versus non-wristed
  – Surgeon autonomy (how many hands?)
Surgical Capability: Not just instruments...

* Product feature not yet available. In development.
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- **Surgical guidance:**
  - Sensing/Feedback
  - Decision support
  - Navigation
Surgical Guidance & Decision-making

- Fluorescence imaging
- Open opportunities:
  - Image guidance?
  - Haptics, Palpation?
Advanced Imaging: Fluorescence Imaging
Augmented Vision:
The Image-Guided Surgical Cockpit
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**Tissue interaction:**
- Specialized instruments
- Interchangeable instruments
Tissue Interaction

• Trade-offs
  – Diameter versus functionality & performance
  – Ability to exchange instruments quickly
  – Single versus multi-use
  – Cost
Advanced Instruments

*EndoWrist® One™* Vessel Sealer

*EndoWrist One*
Vessel Sealer System

Arteries
5-7 mm
Advanced Instruments

**Endowrist Stapler**
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Platform Trade-offs

**da Vinci Si**
Support for *Single-Site®* & Some Complex Cases

**da Vinci Si-e**
Designed for *Single-Site*® & Simple Cases

**da Vinci Xi and Sp**
Optimized for Complex Cases
Opportunities: Ideals in Surgery

1. See disease perfectly.
2. Resect diseased tissue, spare healthy tissue.
3. Reconstruct with precision.
4. Leave as if no surgery was required.
Opportunities: How is technology taking us closer to the Ideal?

**Surgeon Console**

**Control System**

**Patient-Side Manipulator**
The “Software in the Middle”

- Surgeon Console
- Control System
- Patient-Side Manipulator

- Stabilize
- Augment
- Scale
- Extend
- Navigate
- Warn
- Automate
- Anticipate
- Guide
Our Technology Development Focus

- Advanced Imaging
- Advanced Instrumentation
- Surgeon Training
- New Platforms
The Role of Simulation

- Pre-product visualization.
- Product preview.
- Console training.
- Patient-side training.
The Role of Simulation

- Pre-product visualization.
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Simulator Impact: Morristown Study

Console Operative Times*

<table>
<thead>
<tr>
<th></th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced Group</td>
<td>20.2</td>
</tr>
<tr>
<td>Study Group</td>
<td>21.7</td>
</tr>
<tr>
<td>Control Group</td>
<td>30.9</td>
</tr>
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</table>

*All operative times were measured during a supracervical hysterectomy on patients with a 50 gm-or-less uterus

Accepted for publication in Female Pelvic Medicine & Reconstructive Surgery; Dr. Patrick Culligan.

(P = 0.12)  (P < 0.0001)
Some Challenges

- Complexity
- Regulation
- Litigation
- Cost
Product Development Cost and Complexity

- It took ~9 years and >$250M for Intuitive to reach profitability.
- 2013 R&D investment totaled $167 million, or ~$320 per patient.
- A *da Vinci* system is composed of >35,000 individual components (counting down to resistors) from >300 suppliers (direct).
- There are >2 million lines of embedded run-time code. Almost half of this code is related to safety and redundancy.
- A typical software verification will consist of ~40,000 test cases.
- The formally-maintained design history file is >10,000 pages of documentation.
Complexity: The Product Ecosystem

- da Vinci
- da Vinci S
- da Vinci Si
- da Vinci Si-e
- da Vinci Xi
- da Vinci Firefly
- da Vinci Single-Site
- da Vinci Skills Simulator
- Instruments
  (8mm: 44; 5mm: 12; 12mm: 1)
- Endoscopes
  (12mm & 8.5mm: 18)
- Accessories
  Cannulas, obturators, seals, drapes, sterile adapters, energy cables, sterilization trays, light guides, etc.
Challenges: Economic Cost vs. Value

- **Direct Costs**
  - System capital expense, service contracts, and training.
  - Instruments and accessories.

- **Direct Savings**
  - Avoided supply costs and operating expenses (e.g., length of hospital stay).
  - Reduced re-admissions costs (due to complications & recurrence).

- **Overall health & quality of life outcomes, including...**
  - Cancer control (effect on positive margin rates)
  - Cancer diagnosis, improved lymph removal (malignant gynecology)
  - Continence, potency (prostatectomy)
  - Fertility (myomectomy)
  - Avoided sternotomy (cardiac procedures)
  - Reduced rate of dialysis (partial nephrectomy vs. full nephrectomy)
  - Reduced pain during recovery (feeding tube for throat cancer surgery).
  - Faster return to work and other normal activities.

- **Avoided costs of expensive non-surgical therapies (e.g., radiation therapy).**

- **Reduced long-term capital investment (fewer beds built/maintained).**

- **Surgeon focus and productivity.**
Minimally invasive procedures increased from 17% to 98% in 2 years

Historic cohort n=160; Robotic cohort n=143

Robotic cohort:
- Longer OR time (233 vs 206 minutes)
- Fewer adverse events (13% vs 42%)
- Less blood loss (50 ml vs 200 ml)
- Reduced median hospital stay (1 vs 5 days)
- Lower overall hospital costs ($7644 vs $10,368)
  - with amortization/maintenance, ($8,370 vs $10,368)
- Reduced recurrence rates (11 cases vs 19)
Economic Analyses – Same subject, same journal*, different conclusions

**Wright, et al**
- Laparoscopic population
- Excludes open surgery
- Cost-to-charge and direct costs: “Lap < robotic”
- Conclusion: Lap less expensive than robotics for this subset of patients

**Leitao, et al**
- Total population approach
- Includes open surgery
- 6-month direct costs: “Lap < robotic < open”
- Conclusion: By reducing open surgery, robotics yields savings on a population basis

Direct, comprehensive cost analysis—on a population basis—yields a more accurate assessment of the cost-to-treat impacts for hospitals and the healthcare system overall.

*Both studies published in May 2014 edition of Obstetrics & Gynecology evaluating uterine cancer.*
What might the future hold?

This was the Automobile roughly 15 years in...
The Future Through the Lens of Research
The Future Through the Lens of Research
The Future Through the Lens of Research

Stoianovici et al, JHU

Desai et al, U. Maryland
The Future Through the Lens of Research

Abbeel, Goldberg et al, UC Berkeley
The Future Through the Lens of Research
Concluding Thoughts

• Robots are just one part of a complex system.
• The overall goal is to enable greater shift to MIS.
• There are many system design trade-offs.
• User-centric design tries to balance the needs of a team of users.
• Different system architectures for different clinical needs.
• There are many opportunities, particularly in surgical guidance and decision support.
INTUITIVE
SURGICAL