Future Trends and Opportunities in Robot-Assisted Minimally Invasive Surgery

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Introduction

Research faculty at BME

- Image-guided skull base drilling
- Electromagnetic tracker assessment
- Surgical skill analysis
- Classical and modern control algorithms for telesurgery
  - to handle large latencies
Introduction II

Research area manager at ACMIT

- Surgical workflow analysis
- Patient immobilization in radiosurgery
- Laparoscopic skill training (CASSET)
- Gynecological robotic brachytherapy (ROBOGYN)
Introduction III

- CEO/CTO Clariton Ltd.
  - Hand-in-Scan solution

Digital camera
Case with UV lighting
UV-reflective antiseptic
Raw and processed image
Image processing
Hardware and software solution combined

Raw and processed image
Market for Computer-Integrated Surgery

$20 B estimated market for IGS and medical imaging

$20 B estimated market for MIS by 2015

$5 B estimated for robotic surgery
Forecasted to grow $14 B by 2014

Source: Frost & Sullivan, TMD, Piribo
Surgical robotic sales

- NeuroMate: ~30 (16 by ISS)
- ROBODOC: ~50 (37 before 2000)
- MAKO: 86 systems sold (09.2011)
- SpineAssist: 3 in the USA (07.2010)
- CyberKnife: 220 (2010)
- Hansen Sensei: 120 (Q3 2011)
- da Vinci: ~2100 robots (11.2011)
  - Taiwan has 9 systems
Intuitive’s da Vinci
Financial results

• Q3 2011 results
  – 133 da Vinci sold in Q3
  – total revenue: $447 million, up 30%
  – net income: $122 million, up 41%
  – operating profit: $214 million, up 32%
  – total recurring revenue: $248 million, up 34%
  – revenue from instrument and accessories: $176 million, up 38%
  – 1845 employees, up 30%
  – RLRP penetration in the USA: ~90%

• Projections, potentials
  – No. of procedures world-wide: 1.8M
  – Annual recurring revenues: $2.6B
  – Annual system revenues: $1.4B
    up to 10,000 systems
  – Annual service revenue: $1B
Intuitive’s financial performance

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$1,413.0</td>
<td>$1,052.2</td>
<td>$874.9</td>
<td>$600.8</td>
<td>$372.7</td>
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<tr>
<td>Gross profit</td>
<td>$1,030.0</td>
<td>$751.1</td>
<td>$620.8</td>
<td>$414.3</td>
<td>$247.8</td>
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<tr>
<td>Net income (1)</td>
<td>$381.8</td>
<td>$232.6</td>
<td>$204.3</td>
<td>$144.5</td>
<td>$72.0</td>
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<tr>
<td>Net income per common share:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>$9.74</td>
<td>$6.07</td>
<td>$5.26</td>
<td>$3.82</td>
<td>$1.96</td>
</tr>
<tr>
<td>Diluted</td>
<td>$9.47</td>
<td>$5.93</td>
<td>$5.12</td>
<td>$3.70</td>
<td>$1.89</td>
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<tr>
<td>Shares used in computing net income per share:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>39.2</td>
<td>38.3</td>
<td>38.9</td>
<td>37.8</td>
<td>36.7</td>
</tr>
<tr>
<td>Diluted</td>
<td>40.3</td>
<td>39.2</td>
<td>39.9</td>
<td>39.0</td>
<td>38.1</td>
</tr>
<tr>
<td>Cash, cash equivalents and investments</td>
<td>$1,608.9</td>
<td>$1,172.0</td>
<td>$901.9</td>
<td>$635.4</td>
<td>$330.3</td>
</tr>
<tr>
<td>Total assets</td>
<td>$2,390.4</td>
<td>$1,809.7</td>
<td>$1,474.6</td>
<td>$1,040.0</td>
<td>$671.8</td>
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<tr>
<td>Long-term liabilities</td>
<td>$79.2</td>
<td>$69.6</td>
<td>$43.3</td>
<td>$19.6</td>
<td>$1.4</td>
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<tr>
<td>Shareholders’ equity</td>
<td>$2,037.4</td>
<td>$1,537.3</td>
<td>$1,266.8</td>
<td>$888.7</td>
<td>$589.7</td>
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<tr>
<td>Total headcount</td>
<td>1,660</td>
<td>1,263</td>
<td>1,049</td>
<td>764</td>
<td>563</td>
</tr>
</tbody>
</table>
• Technical problems (requiring laparoscopy or conversion)
  – [Patel 2007]: 4.7% complications (900 cases)
  – [Bodnera 2005]: 2% lapar., 3% conversion (128 cases)
  – [Olthof 2007]: 2.27% conversion (400 cases)
  – [Borden 2007]: 2.6% technical problems (350 RLRP)
  – [Zorn 2007]: 0.4% lapar., 0.5% conversion (850 RLRP)
  – [Koliakos 2008]: 0.9% software errors (520 cases), 1 broken EW
  – [Kim 2009]: 2.4% mech. failure, 0.17% conversion (1797 cases)
  – [Murphy 2009]: device failure 0.2 – 2.6% (survey paper)
  – [Kaushik 2010]: 56.8% of surgeons (176) have experienced malfunction
  – [Magrina2011]: 2.9% conversion (67 patients)

• [Borden 2007]: Hardware errors
  – wrist mechanical failure
  – arm mechanical failure
  – power supply system
  – loss of 2D screen
  – camera error
  – Master/slave device break
  – software errors
Complications II

- Not just the best of the best

- 2002 Tampabay Hospital
- 2009 Boca Raton Hospital
  - 42-y patient died after prostatectomy
- 2010 collective lawsuit in the USA
  - Wentworth-Douglass Hospital
  - 4 surgical errors with robot
- Cleveland Clinic sued by retired colonel in 2010

- J. URUology [Barocas2010]: no real advantage over open RLPR
- J. for Healthcare Quality [Lin 2011]: Robotic surgery is presented biased
Complications III

- [Hermsen2010]: Increased SSI with certain procedures
  - 6–8x increase with hernia, prostate, colon, gynecology
  - Nebraska Medical Center

Learning curve

- Skill Simulator (MIMIC), ROSS
  - 1 week initial training, while 200 procedures are needed app.
  - “Language of surgery” project
Current trends in robotic surgery
IGS development

ROBODOC (Curexo Tech. Co.)
NeuroMate (Renishaw plc.)
MAKOplasty (MAKO)
Magellan (Hansen Medical)
ROSA (MedTech co.)

Credit: MAKO, Rosa, Curexo, Renishaw
EU FP6–7 projects

• ACTIVE
  – Awake epilepsy surgery with soft robots and motion compensation
  – www.active-fp7.eu

• ROBOCAST
  – Keyhole neurosurgery with micro-macro robot
  – www.robocast.eu
Cooperative control

• “Hands-on” technique
  – The master and the slave devices are identical
  – Real-time force/torque measurement
  – Provides haptic feedback

Application examples

• Acrobot (Imperial College, London)
  – Total knee replacement [Jakopec 2003]
• PathFinder (Armstrong HealthCare, UK)
  – IG neurosurgery [Finlay 2006]
• Steady-Hand Robot (JHU, USA)
  – Sinus surgery [Li 2007]
  – Skull base surgery [Matinfar 2007]
  – Eye robot: retinal vein cannulation [Balicki 2009]
JHU neurosurgery robot system

CISST ERC Johns Hopkins University

- Cooperative skull base drilling
- NeuroMate robot (5DOF, FDA cleared)
- StealthStation surgical navigator
- 6DOF force sensor (hands-on surgery)
- Surgical bone drill (classical device)
- Slicer 3D (open source)
Da Vinci competitors—M7

- SRI International, 1998
- Light weight—15 kg
- 7 DOF arms
- 1:10 scale down
- tremor filtering
Raven

- University of Washington
- DARPA, OR of the Future
- 22 kg overall mass
- Field trials in 2007
- NASA trials in 2009
- 2nd generation: 8 devices

Credit: University of Washington
Titan Medical Inc. (CA)
- KUKA’s 7 DOF lightweight arm
- FDA submission in late 2014
- PI: Dr. Rayman
- IPO + grants

Credit: Titan Medical Inc.
- Advanced Laparoscopy through Force-RefleCT(X)ion
- **Sofar S.a.P.** (Milan, IT)
- NES Academy, EU grant support
- 2006–
Sofie

- Surgeons Operating Force-feedback Interface Eindhoven
  - Tech. University of Eindhoven (NL)

Credit: Tech. University of Eindhoven
Eye surgery robot

- Tech. University of Eindhoven (NL) and K. U. Leuven
- Tremor filtering, 1:10 motion scaling
- Haptic feedback
- RCM mechanism
- Tools of a diameter of 0.5 millimeter (forceps, scissors and drains)
- Fast instrument changing
The DLR robots

- Deutsches Zentrum für Luft- und Raumfahrt
- KineMedic (discont.)
- MIROsurge
  - 10 kg weight, 3 kg pl
  - 3 robot, 1 animal trial

Credit: DLR
ICEMR, IRCAD Taiwan
- Began at K.U. Leuven
- Modular design
- Laparoscopic CO2 laser ablation
- PI: Dr. Tang
China

**Micro Hand A (妙手A)**
Tianjin University and Nankai University
- Tested at the Tianjin Medical University General Hospital (June 2010–)
- And also Southern Medical University

**Orthopedic robot**
Xinqiao hospital in Chongqing
- 2010, first trial
Japan

University of Waseda
• Beating heart surgery robot
• MRI-compatible robot

NAVIOT (Hitachi Co.)
• First commercialized robot in Japan
• 5-bar linkage mechanism for safety design to restrict moving area

Credit: U. Waseda
Credit: Hitachi
Credit: U. Waseda & Hitachi
Tokyo Women’s Medical University
• Workspace Securing Manipulator
• In vivo surgery on porcine

University of Tokyo
• MM1 robot for neurosurgery

Credit: U. Tokyo
South Korea

Lapabot
National Cancer Center, Goyang
• 5 DOF slave arms
• 5 mm conventional lapar tools

Credit: National Cancer Center
neuroArm

IMRIS (2010–)
Developed by Univ. Calgary and MD Robotics
• With experience gained at the Space Station SPDM
• 1 systems, MR compatibly up to 3 T
• First brain tumor patient: 2008
• Few dozen human surgeries
• Looking for FDA clearance in 2012
  • Treating up to 120 patients

Credit: Univ. of Calgary, www.neuroarm.org
Basic alternatives

PandaRobotics
Robarts Research Institute, University of Western Ontario, University of Waterloo
- Student project (2009–)
- 5 DOF gripper for conventional laparoscopic tools
- Haptics-enabled controller (Novint Falcon)
- Image-guidance through 3D Slicer
- Development cost: $1800

Credit: PandaRobotics
Future of robotic surgery
Bottom line: better clinical outcome

- Augmenting accuracy and/or efficacy
- Increasing the added-value
- Providing smarter tools

• Task specificity
  • e.g. prostate biopsy robots
• Reduced size
  • micro/nanorobot
• Increased safety
  • MR compatibility
Single-port devices

Similar to NOTES

• Nanyang Technological University, Singapore
• CardioArm (Carnagie Melon)
• Suturing machines

CardioArm - CMU

Gill et al. (2008)

SRI Tool

Phee et al. (2008)
Swallow-able devices

Prior only for imaging

- PillCAM

Now with actuators

- Scuola Sup. St. Anna:
  - Capsule robot
Tethered robots

- ARAKNES project
  - EU FP7 consortium
  - Scuola Superior Sant’ Anna, Pisa (coordinator)
  - www.araknes.org
Small-scale MIS robotics

University of Nebraska
D. Oleynikov et al.

[McCormick, 2011]
In-vivo imaging

- MR compatibility
  - JHU/Queens brachy robots
  - WPI AIM lab robots
  - Harvard/AIST open bore MR robot

Credit: CISST ERC, Harvard Medical School, WPI
Telesurgery—far-fetched
Telesurgical experiments

Long range procedures around the world

*The Lindbergh operation*
- 7th Sept, 2001
- New York --- Strasbourg
- Hour-long gallbladder removal
- Master setup in France Telecom office
- Average latency: 150 ms

*CMAS*
- 1st regular telemedicine network (in Canada)

*PlugFest 2009*
- Telesurgery experiment w/ 14 systems world wide

Many intercontinental trials
Surgery in space

On board & in simulated environments

**NASA zero G experiments**
- On board of a DC-9 hyperbolic aircraft
- Simulated surgery (2007)
- Suturing with M7 robot
- Human control / automated task execution

**NASA NEEMO program**
- 14 missions in an underwater habitat in Florida
- Robotic surgery mission objectives
  - Telesurgery with AESOP (2004)
  - Simulated procedures with the M7 (2006)
  - Telesurgery with Raven and M7 (2007)

**Zero G surgeries**
- First surgery in weightlessness on a rat (2003)
- Removal of a cyst from the arm of a human (2006)
- Parabolic flights: 20-25 s of microgravity
- ESA Zero-G plane (modified Airbus A-300)
OR of the Future

Credit: SRI, DARPA
On the way towards standards
Accuracy metrics

Originating from the industry

Inherent accuracy of system components

- Accuracy vs. repeatability

Use of phantoms (artifacts) for testing

- Trying to replicate clinical conditions as much as possible

Problems with measurements

Accuracy of treatment delivery is important

- Difficult to measure routinely
- Single numbers are not meaningful

Ultimate goal is

task specific measurement of uncertainty

[Simon et al. 1995]
### Accuracy numbers

<table>
<thead>
<tr>
<th>Robot</th>
<th>Company</th>
<th>Intrinsic accuracy</th>
<th>Repeat.</th>
<th>Application accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puma 200</td>
<td>Memorial Medical Center</td>
<td></td>
<td>0.05</td>
<td>2</td>
</tr>
<tr>
<td>ROBODOC</td>
<td>Int. Surgical Systems Inc. Curexo Tech. Corporation</td>
<td>0.5–1.0</td>
<td></td>
<td>1.0–2.0</td>
</tr>
<tr>
<td>NeuroMate</td>
<td>Inn. Medical Machines Int. Int. Surgical Systems Inc. Renishaw plc</td>
<td>0.75 / 0.6 0.36 ± 0.17</td>
<td>0.15</td>
<td>0.86 ± 0.32 1.95 ± 0.44</td>
</tr>
<tr>
<td>da Vinci</td>
<td>Intuitive Surgical Inc.</td>
<td>1.35</td>
<td></td>
<td>1.02 ± 0.58</td>
</tr>
<tr>
<td>da Vinci S</td>
<td>Intuitive Surgical Inc.</td>
<td>1.05 ± 0.24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CyberKnife</td>
<td>Accuray Inc.</td>
<td></td>
<td></td>
<td>0.42 ± 0.4 0.93 ± 0.29</td>
</tr>
<tr>
<td>B-Rob I</td>
<td>ARC GmbH, Seibersdorf</td>
<td></td>
<td></td>
<td>1.48 ± 0.62</td>
</tr>
<tr>
<td>B-Rob II</td>
<td>ACMIT (ARC GmbH)</td>
<td></td>
<td></td>
<td>0.66 ± 0.27 1.1 ± 0.8</td>
</tr>
<tr>
<td>SpineAssist</td>
<td>Mazor Surgical Technologies</td>
<td></td>
<td></td>
<td>0.87 ± 0.63</td>
</tr>
</tbody>
</table>

All values are in mm.
"Regulatory bodies are to prevent failures and safety issues originating from bad design."

**European Economic Community (EU)**

- CE mark (Conformité Européenne) managed by independent Notified Bodies
  - possibility of self-certification
- ISO 13485:2003 “Medical devices—Quality management systems”
  - more clinical data required
Regulatory bodies

**Food and Drug Administration (USA)**
- Pre-Market Approval (PMA): long, thorough, expensive
- Premarket notification, 510(k):
  - doctrine of “substantially equivalency”
- FDA Quality System Regulations (QSR)
- All surgical robots went down 510(k)

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Regulatory Class</th>
<th>Bench Testing</th>
<th>Animal Testing</th>
<th>Software Validation</th>
<th>Clinical Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative planning</td>
<td>II</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Stereotactic frames</td>
<td>II</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Computer-assisted or navigation device</td>
<td>II</td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Computer-assisted intraoperative planning and surgical guidance</td>
<td>II</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Robotic operating assistants</td>
<td>II or III</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Computer-assisted intraoperative planning and surgical guidance</td>
<td>II or III</td>
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<tr>
<td>Fly-by-wire</td>
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<td>Robots</td>
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Current standards

Standards and regulations

- European Norm (EN) 1441 on risk management (1997)
- IEC 61025 Fault Tree Analysis (Ed. 2.0, 2006)
- ISO 14971 Application of Risk Management to Medical Devices (2007)
- IEC 60601 international standard on Medical Electrical Equipment (Ed. 3.0, 2010)
- IEC 1508 draft standard on Functional Safety for software developers

Risk management (from industrial robotics)

- risk analysis (system definition, hazard identification and risk estimation)
- risk evaluation (determine risk tolerance levels)
- risk control (implementing the right action for maximum safety)
Standardization efforts

Need of objective, comparable assessment

- Standards for procedures
  - cutting, drilling, milling, reaming

- Distinct applications
  - joint replacement, implant nailing, osteotomy, etc.

- Certain imaging modalities
  - fluoroscopy, CT, MRI, ultrasound

ASTM working group F04.05 (2004—)


NIST Phantom (2007)

- Computer-Assisted Orthopaedic Hip Surgery (CAOHS) Artifact
- Designed to mimic hip joint

Courtesy of N. Dagalakis, NIST, U. Nebraska
New standardization efforts

ANSI/AAMI ES60601-1:2005  *Medical electrical equipment*

New amendment for medical robots (due August 2013)
- defining technical requirements
- streamlining the application of risk management
- clarifying the definition of essential performance
- identifying essential performance and mitigating the risk

IEC 60601-1 updates
- supportive medical data as evidence for the safety and performance
- risk assessment and analysis even for OEMs
- from June 2012 in the EU, planned from 2013 in the USA

Joint ISO–IEC workgroup on Medical Robot standards
- ISO/TC 184/SC 2 (Robots and Robotic Devices)
- IEC/SC 62A (Common Aspects of Electrical Eq. used in Medical Practice)

510(k) is under fire
- 510(k) Working Group
- Task Force on the Utilization of Science in Regulatory Decision Making
Cost and efficiency

• High R&D costs
  – da Vinci was created with $0.5B
• Long development time
  – From idea to product: 8-10 years
• Universality vs. added value
• Low selling numbers
• National differences in regulations
• Surgeons’ compliance
Innovation in MIS free course (not only for students):
www.ircad.fr/student
Thank you for your attention!
Post script

This presentation is available at http://tinyurl.com/MIS-and-MR-Haidegger

SurgRob
a blog on CIS and medical robotics

http://surgrob.blogspot.com