Recent Advances in Medical Robotics
Applications, systems and legislation

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Óbuda University, Antal Bejczy Center for Intelligent Robotics;
Austrian Center for Medical Innovation and Technology (ACMIT)

Seoul National University seminar
Background

- Budapest University of Technology and Economics (BME)
  - Third biggest university in Hungary (25,000 students)
  - 8 faculties (all branches of engineering, econom., natural sci.)
  - Dept. of Control Engineering and IT
    - Laboratory of Biomedical Engineering
Research background

Junior faculty at BME

• Image-guided skull base drilling
• Electromagnetic tracker assessment
• Surgical skill analysis
• Classical and modern control algorithms for telesurgery
Background

Óbuda University
John von Neumann Faculty of IT

Antal Bejczy Center for Intelligent Robotics

- Establishing an ERC based on applied research
- Focusing on human-centered studies
- Building on international relations
Background

Austrian Center for Medical Innovation and Technology

Research area manager
• Surgical workflow analysis
• Patient immobilization in radiosurgery
• Laparoscopic skill training
• Gynecological robotic brachytherapy

Seoul National University seminar  Korea, 10.25.2012.
Background

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

Digital camera  UV-reflective antiseptic  Raw and processed image

Case w/ UV

Hardware and software solution combined  Image processing
Volunteering


- TC 184: Technical Comm. on Automation Systems & Integration
- SC 2: Sub-Committee on Robots and Robotic Devices
- JWG 9: Joint Work Group on Standard for Medical Robot Safety

- Delegate of the Hungarian Standards Institution (MSZT)
- Governor: Gurvinder S. Virk (UK)
- National POC: Dr. Seungbin Moon <sbmoon@sejong.ac.kr>

IEEE RAS standing committee for standardization

- Member of the ORA workgroup—Ontologies for Robots
- Leaders: Craig I. Schlenoff (USA), Edson Prestes (BR)
Rational for standards

- Following the mainstream development
- Facilitating interoperation
- Clarifying legal issues
- Ensuring user safety
State of the art in service robotics

Hitachi: EMIEW 2
(Excellent Mobility and Interactive Existence as Workmate 2)
Honda: ASIMO
Willow Garage: PR2
Medical robotics

- Visiting robots
- Patient carriers
- Medical delivery
- Rehabilitation robotics
- Surgical robotics

Credit: TUG, RP-1

iRobot
SoA in rehabilitation robotics

- Rehabilitation devices
- Assistive robots
- Exoskeletons
- Prosthetics
- Physiology ther.

DARPA/DEKA Arm

Credit: CYBERDYNE Hybrid Assistive Limb

Credit: REHAROB cons.
SoA in surgical application
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)
- CASPAR: ~93 (discontinued in 2003)
- MAKO RIO: 113 systems sold (12.2011)
- SpineAssist: 3 in the USA (07.2010)
  - Renaissance: 2 in the USA (12.2011.)
- CyberKnife: 220 (2010)
- Hansen Sensei: 130 (Q3 2012)
- da Vinci: ~2400 robots (Q2 2012)
Current trends in robotic surgery
Robotic approaches in CIS

- Human-in-the-loop control
  - Leave the mapping to the surgeon

- Registration (image) based
  - Human oversight

- Cooperative control
Intuitive’s da Vinci

master ↔ slave
Penetration of da Vinci Surgery

Share of ISRG Target Market

- Procedures
- dVH - Cancer
- dVH - Benign
- Sacralcolpopaxy
- Myomectomy
- dVP
- Nephrectomy (Prtl & Full)
- Mitral Valve Repair
- Lobectomy
- Low Anterior Resection
- TORS
- 150K Annual Procedures

Time

Intuitive Surgical, 2012
## da Vinci® Procedures

<table>
<thead>
<tr>
<th>Urology</th>
<th>Gynecology</th>
<th>Cardiothoracic</th>
<th>General</th>
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<tr>
<td>Prostatectomy</td>
<td>Hysterectomy</td>
<td>Mitral Valve Repair &amp; Replacement</td>
<td>Gastric Bypass</td>
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<td>Nephrectomy</td>
<td>Myomectomy</td>
<td>Single Vessel Beating Heart Bypass</td>
<td>Nissen Fundoplication</td>
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<td>Partial Nephrectomy</td>
<td>Sacral Colpopexy</td>
<td>Multi-Vessel Beating Heart Bypass</td>
<td>Heller Myotomy</td>
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<td>Pyeloplasty</td>
<td>Pelvic Lymphadenectomy</td>
<td>Single Vessel Arrested Heart Bypass</td>
<td>Gastrectomy</td>
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<td>Cystectomy</td>
<td>Tubal Reanastomosis</td>
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<td>Colon Resection</td>
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<td>Donor Nephrectomy</td>
<td>Vaginal Prolapse Repair</td>
<td>IMA Harvesting</td>
<td>Thyroidectomy</td>
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<td>Ureterolithotomy</td>
<td>Dermoid Cyst</td>
<td>Coronary Anastomosis</td>
<td>Arteriovenous Fistula</td>
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<td>Pelvic Lymphadenectomy</td>
<td>Endometrial Ablation</td>
<td>Atrial Septum Aneurysm</td>
<td>Toupet</td>
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<td>Adrenalectomy</td>
<td>Oophorocystectomy</td>
<td>Atrial Septal Defect Repair</td>
<td>Pancreatectomy</td>
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<td>Cystocele Repair</td>
<td>Oophoroectomy</td>
<td>Tricuspid Valve Repair</td>
<td>Adrenalectomy</td>
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<td>Ovarian Cystectomy</td>
<td>Thrombectomy</td>
<td>Hemi-Colectomy</td>
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<tr>
<td>Lymphadenectomy</td>
<td>Ovarian Transposition</td>
<td>Thymectomy</td>
<td>Sigmoidectomy</td>
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<td>Testicular Resection</td>
<td>Salpingectomy</td>
<td>Esophagectomy</td>
<td>Splenectomy</td>
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<td>Lobectomy</td>
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<td>Vaso-vasostomy</td>
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<td>Hernia Repair</td>
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IGS development

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

Credit: SRI International
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
Titan Medical Inc. (CA)
- KUKA’s 7 DOF lightweight arm/new, custom arms
- FDA submission in late 2014
- PI: Dr. Rayman
- IPO + grants
- 2008–
ALF-X

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

Credit: Sofar S.a.P.
• **Surgica Robotica & University of Verona**
  • 5 years of development, 2 generations
  • Based on NASA JPL’s RAMS (1994–98)
  • EU grant support
  • 6 +3 DOF
  • euRobotics Technology Transfer Award 2011
  • CE mark by end 2011

• **First tests (with 2-3 robots)**
  • pancreatic resection (cryoablation at U. Padova)
  • aortic aneurism treatment
Eye surgery robot prototype
• Tremor filtering, 1:10 motion scaling
• Haptic feedback, RCM mechanism
• Tools of a diameter of 0.5 millimeter
• Fast instrument changing

SOFIE: Surgeons Operating Force-feedback Interface Eindhoven

Credit: Tech. University of Eindhoven
• Deutsches Zentrum für Luft- und Raumfahrt (DLR)
• KineMedic (discontinued)
• MIROsurge
  • 10 kg weight, 3 kg payload
  • 3 robot, 1 animal trial
Huato/Vesalius Platform (HVP)

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
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
Tokyo Women’s Medical University
• Workspace Securing Manipulator
• In vivo surgery on porcine

University of Tokyo
• MM1 robot for neurosurgery
South Korea

**Lapabot**
National Cancer Center, Goyang

- 5 DOF slave arms
- 5 mm conventional lapar tools

Credit: National Cancer Center
Simris (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
• Looking for FDA clearance in 2012
  • Treating up to 120 patients

Credit: Univ. of Calgary, www.neuroarm.org
Future trends

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

SRI Tool

Gill et al. (2008)

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
Deployment of telemedicine

Telehealth

Telemedicine

Offline
- Archiving
- Store-and-forward telemedicine
  - Telediagnositics
  - Teleconsultancy
  - Pre referral screening
  - Tele follow up
  - Remote treatment planning

Online / real time
- Remote monitoring
  - Telementoring, teleproctoring
  - Passive telepresence
  - Teleconferencing
- Telepresence
  - Hands-on telementoring
  - Telepresence surgery, telesurgery, remote surgery
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)
Need for standards et al.

To ensure patient safety

- Minimize risk
- Resolve liability
“Robots for medical intended use”

EC Machinery Directive:
• Non-medical personal care robots -> machines for performing “aiding actions, and actions contributing directly towards improvement in the quality of life of humans, except medical application”

EC Medical Device Directive:
• Medical robots are classified and will be regulated as *medical electrical equipment and systems* which are to be used to diagnose, treat or rehabilitate patients from medical conditions
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)
Regulatory bodies

**European Economic Community (EU)**
- CE mark (Conformité Européenne) managed by independent Notified Bodies
  - more clinical data required

**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>
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</thead>
<tbody>
<tr>
<td>Preoperative planning</td>
<td>II</td>
<td></td>
<td></td>
<td>X</td>
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<tr>
<td>Stereotactic frames</td>
<td>II</td>
<td>X</td>
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<tr>
<td>Computer-assisted or navigation device</td>
<td>II</td>
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<tr>
<td>- Computer-assisted intraoperative planning and surgical guidance</td>
<td>II</td>
<td>X</td>
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<tr>
<td>Robotic operating assistants</td>
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<td>X</td>
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<tr>
<td>- Computer-assisted intraoperative planning and surgical guidance or action</td>
<td>II or III</td>
<td>X</td>
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<tr>
<td>Fly-by-wire</td>
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<td>Robots</td>
<td>Unclassified</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
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
Building from scratch
Categorization of robots

Robotic systems in accordance with ISO 8373, based on application

Robots and robot systems

Industrial robots
- Fixed base
- Mobile

Service robots
- Personal
- Professional

Other applications, e.g., Military

Gurvinder et al. 2012
Seoul National University seminar, Korea, 10.25.2012.
Personal service robots

Medical robots

- Nursing robots in hospitals
- Rehabilitation exoskeleton robots
- Diagnostic robots
- Training robots (phantoms)

Surgical robots

Passive
- Tool holders
- Patient positioner

Active
- Open surgery assist
- Minimally Invasive procedures
- Radiosurgery

Social robots
- Home care servant robots, butlers
- Assistive exoskeletons
- Medical service delivery robot
- Person carrier robot

Intelligent robot companions

Gurvinder et al. 2012
Ambiguous issues

VS.

Credit: DARPA, RIBA
Ambiguous issues

VS.

Credit: DARPA, HAL
Ambiguous issues

VS.

Credit: TUG, Amazon—Kiwa

Seoul National University seminar  Korea, 10.25.2012.
Ambiguous issues

VS.

Credit: AIBO, Paro
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]
<table>
<thead>
<tr>
<th>Robot</th>
<th>Company</th>
<th>Intrinsic accuracy</th>
<th>Repeat.</th>
<th>Application accuracy</th>
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<tbody>
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<td>Puma 200</td>
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<td>NeuroMate</td>
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<td>0.75 / 0.6, 0.36 ± 0.17</td>
<td>0.15</td>
<td>0.86 ± 0.32, 1.95 ± 0.44</td>
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<td>da Vinci</td>
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<td>B-Rob II</td>
<td>ACMIT (ARC GmbH)</td>
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<td>1.1 ± 0.8</td>
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<tr>
<td>SpineAssist</td>
<td>Mazor Surgical Technologies</td>
<td>0.87 ± 0.63</td>
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</tr>
</tbody>
</table>

All values are in mm.
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
Degree of Autonomy

DoA: the only missing piece

- Risks and hazards originating from DoA
  - In current and future medical electronic equipment

- ALFUS approach
  - IEEE workgroup for Autonomy Levels for Unmanned Systems

- DoA levels identified
Thank you for your attention!
Post script

For more information:

SurgRob
a blog on CIS and medical robotics

http://surgrob.blogspot.com
Takeaway

“Get smarter people than you are, and make them excited about your problem!”
/R.H. Taylor/

“If you enjoy your job, you will never have to work for your entire life.”
/Teik Seng Tan/