Printing Medical Robots: Current Research
From Application Specific Robots to Disposable Robots in Surgery

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Autonomous Robotics (1990-1996)
Surgical Robotics (1997-2005)
A Standard Operating Room
Surgical Tasks

- **Neuro surgery**
  Tumor, Biopsy, Spine, Skull base
- **Orthopedics / Trauma**
  Hip, Knee, Osteotomies
- **ENT/CMF**
  Skull base, FESS
- **Soft Tissue Navigation** (Liver, Kidney)
- **Dental**
  Implantology
- **Interventional radiology**
- **Interstitial radiation therapy**

Soft Tissue Surgery in 2007 (believed in 2004)
Soft Tissue Surgery in 2016 (believed in 2010)
A High-End ENT/Skull Base OR

[IRDC KARL STORZ, Leipzig, Germany]
Contents of Surgical Robotics Research

• Surgery is not an application for advanced automation and robotics concepts.
• Surgery is an important, common, and risky step of human patient treatment.
• Any automation of manual performed surgical procedures require a good medical literature/reference base.
• THE TASK IS NOT TO REPLACE THE HUMAN DOCTOR BUT TO IMPROVE THE PATIENT OUTCOME SIGNIFICANTLY.
Contents

I. WHAT KIND OF AUTOMATION IS REQUIRED AND ACCEPTED IN THE OPERATING ROOM?

II. WHAT IS REQUIRED TO BRING AUTOMATION IN THE OPERATING ROOM?

III. WHAT IS THE MAIN PROBLEM IN CREATING SUCCESSFUL SURGICAL ROBOT SYSTEMS?
I. What Kind of Automation is Required?

Patient diagnosis and therapy are successful and efficient without automation since decades: There are still some challenges (most do not need robots)

• Improved standardized procedures
• Improved efficient work flows to safe time/costs
• Improved quality measurement & management

• *Treatment of difficult cases as simple, risk-free, and quick procedures with less experienced surgeons achieving a predictable patient outcome.*

➔ Improve intraoperative Imaging and Use of Instruments
Different Levels of Automation Exist!

1. Rapid manufacturing of patient individual anatomical models for training a standard or individual case
2. Drilling and cutting templates to guide the surgical instruments
3. Surgical Navigation of manual guided instruments
4. Surgical Distance Control of instruments
5. Navigated Control of active instruments
6. Tele-manipulation of imaging systems and instruments
7. Hands-On Robotics for guiding active instruments
8. Fully automatic robots (Image, Instrument, Task)
1. Patient Individual Anatomical Models
1. Patient Individual Anatomical Models
1. Patient Individual Anatomical Models
2. Drilling and Cutting Templates

CT Imaging → DICOM Reading

SURFACE Segmentation → Marching-Cube Algorithm

Planning of Cavities and Cuts → Generate a form fitting template

STL-Export → 3D-Printing (SLS / 3DP)

3D-Printing (SLS / 3DP) → Surgical Treatment

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3. Surgical Instrument Navigation

- CT Imaging
- Orthogonal Slicing
- Realtime Measurement of Patient and Instrument
- DICOM Reading
- Marching-Cube Algorithm
- Registration of Virtual Model & Real Patient
- Realtime Measurement of Patient and Instrument
- 3D Visualization of Model and Instrument
- Surgical Treatment
3. Surgical Instrument Navigation
3. Surgical Instrument Navigation

Soft tissue [2007]
Using Homogenous Transformation

\[ A_{TB} = \begin{pmatrix} e_x & e_y & e_z & t \\ 0 & 0 & 0 & 1 \end{pmatrix} = \begin{pmatrix} x e_x & x e_y & x e_z & x t \\ y e_x & y e_y & y e_z & y t \\ z e_x & z e_y & z e_z & z t \\ 0 & 0 & 0 & 1 \end{pmatrix} \]
Spanning Coordinate Systems by 3 P

\[
  A_{T_{3P}} = \begin{pmatrix} e_x & e_y & e_z & t \\ 0 & 0 & 0 & 1 \end{pmatrix}; \quad t = p_1; \quad e_x = \frac{p_2 - p_1}{|p_2 - p_1|}; \quad e_z = \frac{e_x \times (p_3 - p_1)}{|e_x \times (p_3 - p_1)|}; \quad e_y = e_z \times e_x
\]

(8.4)
Registering Coordinate System by 3 P

\[
\text{mod } T_{\text{pat}} \quad = \quad \text{mod } T_{3\text{P}} \quad \cdot \quad \left( \text{pat } T_{3\text{P}} \right)^{-1}
\]

Registration of the coordinate systems
3 Points selected at the virtual model
3 Points measured at the Patient in the OR

\[
\text{mod } T_{\text{tool}} = \quad \text{mod } T_{\text{pat}} \quad \cdot \quad \left( \text{cam } T_{\text{pat}} \right)^{-1} \cdot \text{cam } T_{\text{tool}}
\]

Registration of the coordinate systems
Real-time position measurement of patient and instrument
4. Surgical Distance Control
5. Navigated Control of Instruments

- CT Imaging
- Orthogonal Slicing
- Planning of Cavities and Cuts
- Registration of Virtual Model & Real Patient
- 3D Visualization of Model and Instrument
- Surgical Treatment
- DICOM Reading
- Marching-Cube Algorithm
- Realtime Measurement of Patient and Instrument
- Realtime Distance Measurement & Visual & Acoustic Warning
- Power Control of the Active Instrument

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5. Navigated Control of Instruments
5. Navigated Control (outside Clinic)
Power Control by Risk Distance

\[
\begin{align*}
u_{\text{tool}} &= \begin{cases} 
    u_{\text{ped}} & \text{risk}(\text{tool}) = 0 \\
    u_{\text{ped}} - (u_{\text{ped}} - u_{\text{min}}) \cdot \text{risk}(\text{tool}) & 1 > \text{risk}(\text{tool}) > 0 \\
    u_{\text{min}} & \text{risk}(\text{tool}) \geq 1
\end{cases}
\end{align*}
\]

\[
\text{risk}(\text{mod} p_{\text{tool}}) = \begin{cases} 
    0 & \text{mod} p_{\text{tool}} - \text{mod} p_s > d_{\text{max}} \\
    \frac{\text{mod} p_{\text{tool}} - \text{mod} p_s}{d_{\text{max}} - d_{\text{min}}} & d_{\text{max}} > \text{mod} p_{\text{tool}} - \text{mod} p_s > d_{\text{min}} \\
    1 & \text{mod} p_{\text{tool}} - \text{mod} p_s < d_{\text{min}}
\end{cases}
\]
5. Navigated Control & Nerve-Monitoring

- CT Imaging
- Orthogonal Slicing
- Planning of Cavities and Cuts
- Registration of Virtual Model & Real Patient
- 3D Visualization of Model and Instrument
- Surgical Treatment
- DICOM Reading
- Marching-Cube Algorithm
- Realtime Measurement of Patient and Instrument
- Realtime Distance Measurement & Visual & Acoustic Warning
- Power Control of the Active Instrument

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6. Tele-Manipulation of Instruments

Mount Robot near OR-Table

Mount Input Console near OR-Table

Mount Instrument at Robot

Recording Surgeons Hand Movement

Move Robot with Instrument
6. Tele-Manipulation of Instruments
Robot Control Concepts

Tele-Manipulation:

\[
\begin{align*}
  base^{T_{tcp[k+1]}} &= base^{T_{tcp[k]}} \cdot usr^{T_{mm}} \cdot mm^{T_{usr[k+1]}} \\
  \text{New Pose} &\quad \text{Current Pose} &\quad \text{Relative Move of Mastermanipulator}
\end{align*}
\]

Hands-On:

\[
\begin{align*}
  base^{T_{tcp[k+1]}} &= base^{T_{tcp[k+1]}} \cdot tcp^{T_{kms[k]}} \\
  \text{New Pose} &\quad \text{Current Pose} &\quad \text{Current Measured Force/Torque}
\end{align*}
\]

Off-line programmed:

\[
\begin{align*}
  base^{T_{tcp[k]}} &= base^{T_{rob}} \cdot rob^{T_{cam}} \cdot cam^{T_{pat}} \cdot pat^{T_{mod}} \cdot mod^{T_{dest[k]}} \\
  \text{Known from CAD} &\quad \text{Realtime Measured Positions} &\quad \text{Registration} &\quad \text{Planned goal}
\end{align*}
\]

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7. Hands-on Robotics with Instruments

- Mount Robot near OR-Table
- Mount FT-Sensor near Robot’s TCP
- Mount Instrument at Robot
- Apply Forces to the Surgical Instrument
- Apply Virtual Forces to the Surgical Instrument
- Robot moves with Instrument in Compliant Motion

2001
7. Hands-on Robotics with Instruments
8. Full Automation using Robots

- Mount Robot near OR-Table
- Mount FT-Sensor near Robot’s TCP
- Mount Instrument at Robot
- Planning based Offline Program
- Sensor based Virtual Forces
- Robot moves with Instrument in Compliant Motion

2003
8. Full Automation using Robots

2008

2010

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I. Summary: Gradual Automation

- **Goal is the treatment of difficult cases as simple, risk-free, and quick procedures with less experienced surgeons achieving a predictable patient outcome**
- **Gradual automation is well accepted as long as the surgeon feels assisted doing the job in a professional manner**

- Using a robot is a huge step for a trained doctor and competing with a trained doctor is a huge challenge for a robot development team.
- Promise and expect not to much. Nevertheless, surgery and elderly care it is the future market for robot system
- **Market = Value: Facebook ~ 80 Billion, Intuitive Surgical ~ 25 Billion**
II. WHAT IS REQUIRED TO BRING AUTOMATION IN THE OR?

• Working under Quality Management ISO 13485
• Administrate a product file for the device
• Applying for and receiving a medical approval
• Performing ISO conform safety measurements
• Performing verification, validation and clinical studies with significant results
• Publication of significant results in medical Journals

Since 2009 even simple medical software is a medical device

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Quality Management ISO 13485

All steps to generate a medical device are managed and fully documented

• New ideas and changes
• Documentation
• Development process
• Production process
• Service process
Product File of the Medical Device

- Medical Demand and Function
- Quantitative Parameters
- System Description (Components and Processes)
- User Manual & Work flow
- Risk Analysis (Parameter, Workflow, Components, Life cycle)
- Testing & Verification Plan
- Testing & Verification Protocol
- Measurement Protocols
- Clinical trails

- Production Manual
Medical Approval (FDA) or CE

- Creation of Application
- Submission of Documentation including Publications
- DIMDI – IQWIK - Databases

Two different concepts
- Europe CE – Safety
- USA FDA – Outcome
ISO 60601 and other Obligations

For some safety aspects, there exist well defined testing procedures:

- Electrical safety
- Electromagnetic compatibility (EMC)
- Microbiological Proof of instrument sterilization
Verification, Validation & Clinical Studies

**Verification** = Measuring against defined quantitative limits (phantoms)

**Validation** = Testing results in clinical environment against expectations (animal, patient)

**Clinical studies** = Controlled multi-centric validation to measure patient outcome (insured patients)

(ex vivo / in vitro / in vivo / proband / patient)

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Significance and PubMed-Publication

For describing results arithmetic mean and standard deviation are not sufficient.

The required scientific procedure is:

1. Motivate a quantitative parameter limit by the medical need
2. Explain exactly the mathematic relation between measured value and relevant medical parameter
3. Use f-test and t-test and significance to calculate the number of required experiments
4. Conclude with a clear statement about the medical effect
5. Publish the results in a medical referenced journal (PubMed)
Marketing, Production, Distribution

Product marketing and product distribution is the task of companies

- At least in Europe you are not allowed to announce any medical advantage if there is no scientific publication with significant proof of it’s outcome.
II. Summary: Scientific Proof

• Automation can be an important and valuable improvement of surgical tasks
• Strict guidelines for research, development and testing have to be observed
• Results without significance are useless
• Significant scientific publications are precondition for marketing and distribution
III. WHAT IS THE CHALLENGE IN CREATING SUCCESSFUL SURGICAL ROBOT SYSTEMS IN FUTURE?

• An appropriate robot for the required task
• Gradual automation with clinical experience
• Reducing the cost by separation of parts
• Adjust the robot structure quickly to demands
Robot Design for Surgical Cases

The robot has to be designed for the
• medical requirements
• carried instrument
• expected work space
• required power
• user interface
• chance to get approved

➢ finite pose kinematic syntheses

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Gradual Automation over Time

As less automation as possible => maximum reliability and robustness

Required steps:

• Passive instrument holder
• Control of instrument function
• Motorized movement of the instruments’ DoF
• Tele-Manipulation
• Hands-On (Compliance)
• Automatic movement
Gradual Automation over Time

Telemanipulation mode

Instrument tracking mode
Gradual Automation over Time
Reducing the Robot’s Cost

The creation costs of a robot system are defined by

• motors
• manufacturing,
• assembly

of precision engineering parts.

Since motors and controllers are reusable, we use rapid manufacturing for the robot structure by Selective-Laser-Sintering (Polyamide) or Selective-Laser-Melting (Titanium, Steel)
Adjust the Robot Structure on Demand

For one-of-a-kind robot systems, the main problem is that the device does not fit mechanically to the demand. Since many parts can be reused, we start to use Matlab instead of classical CAD-Systems. The robot becomes a parameterized STL-File that can be printed within 24 h for a change.
3D Printing (SLS) of Tissue (E-Modulus)

[DFG FOR 102 (together with H. Feussner, S. Gillen)]
Calculated Bionic Structures
New class of light weight robots

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[ergoSURG • Ismaning • 2012]
3D Printing (SLS) of Robots
Cheap Robots for Surgical Tasks
Some features of automatic construction of robots using Matlab
Robot Description Language

• Instead of using CATIA/SolidWorks/ProEngineer, convert mathematical formulas of space, materials, drives, structures, kinematics, and ‘colors’ plus new construction operators to create a

  Robot and Mechatronics Description Language

• Elementary Construction Operators
  Main difference: a) Grow and adhere structures instead of use Boolean operators on CSG (Constructed solid geometry). Geometry is a result of kinematic function not of manually programmed operators
Some problems have to be solved by yourself (Delaunay is not enough....)
Snake like instrument guiding robots

Daniel Roppenecker, 2012
Automatic Integration of Motors/Drives
(RC-Servo, Fischertechnik, Harmonic Drive)
Side effect for my two daughters: Extension of Fischertechnik Kit

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[ergoSURG • Ismaning • 2012]
III. Summary: Parametric Design and Rapid Manufacturing of Robots

- Neither human anatomy, not operating rooms, nor surgical procedures are standardized. A designed robot will not fit potentially to many cases.
- Robot structures have to be cheap and disposable.
- Robots have to be designed parameterized and should be printable/changeable within 24 h.
Thank you for the invitation to JHU

I’d like to thank especially
Greg Hager & Russ Taylor
being model researcher for me!

I’d like to thank both and the faculty at CISST for
inviting and educating our students from TUM

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There is great team that supports me!

I have to thank my team:
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Administration of MIMED in Munich

My medical colleagues (Gero Strauß, Leipzig, and others) who cooperate since 15 years!

DFG (Andreas Engelke) and BMBF for funding

Dr. h. c. Sybill Storz and Karl Christian Storz
(Owner of KARL STORZ)
Example of Student Exchange JHU-TUM

PROF. DR. TIM LÜTH
20.06.2007 10:07 UHR

How to integrate into the MIMED Team as visiting researcher?

Tim Lueth for Tian Xia and Marcin Balicki

This short paper should help to understand how research at the MIMED’s Institute is done at the TU Munich.

Dear Tian, dear Marcin,

Currently, you are here as visiting researcher at MIMED with the idea to learn specific capabilities in addition to your education at Johns Hopkins. The basic idea for this exchange came some month ago, when Russ Taylor and Greg Hager visited MIMED.

The idea was that learning to make a medical product could be a good topic. As final goal it was planned to make a physical EndoWrist interface including motors, housing, electrics and a simple interface and documentation.
Example of Student Exchange JHU-TUM