Surgical Robots and Phantom (Artifact) Devices

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My Background

1989-1990 Postdoctoral research at IBM on ROBODOC

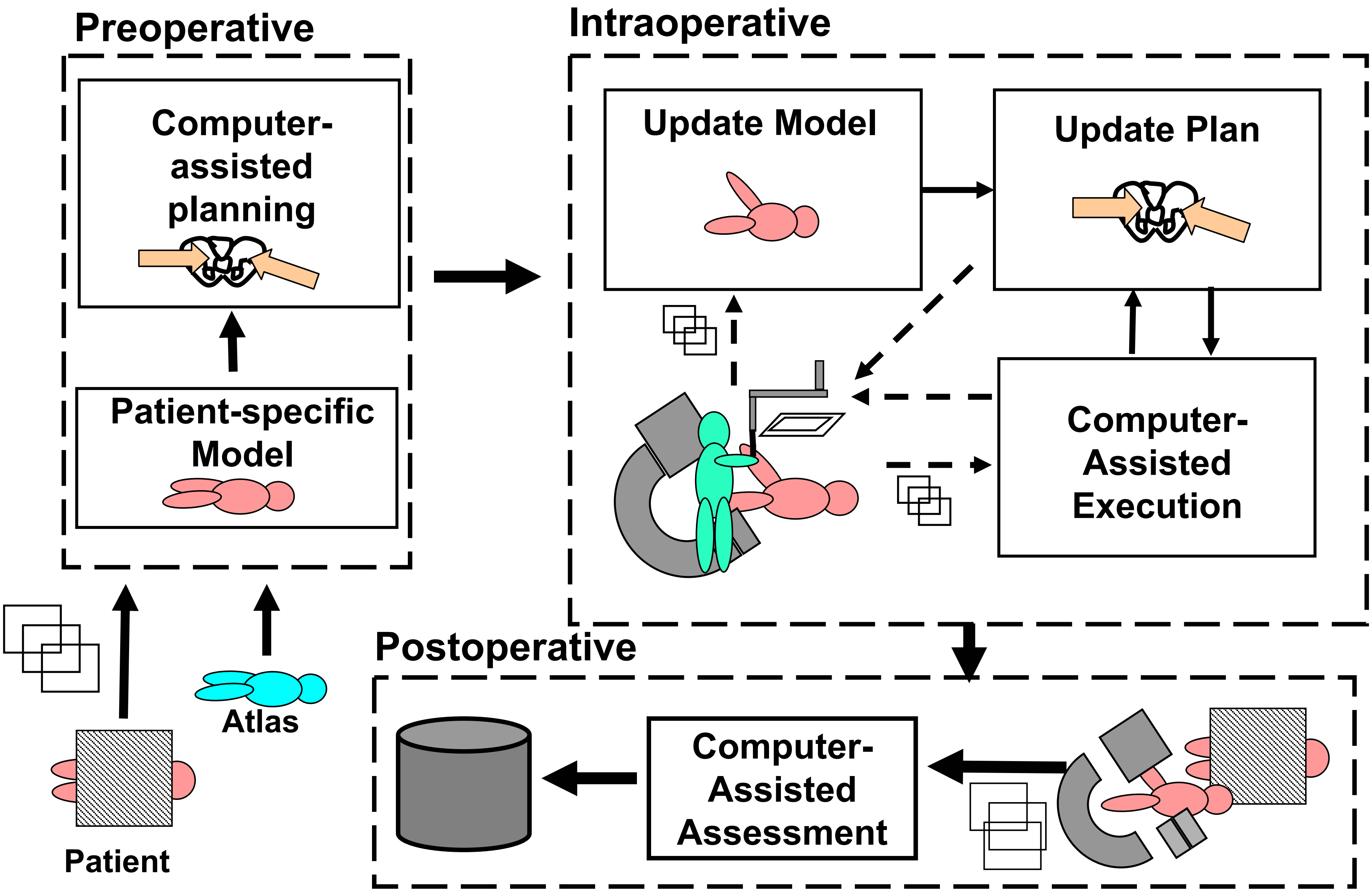
1990-2002 Co-Founder of Integrated Surgical Systems

- Commercial development of ROBODOC® System
- Commercial sales in Europe (CE Mark)
- Clinical trials in U.S. and Japan

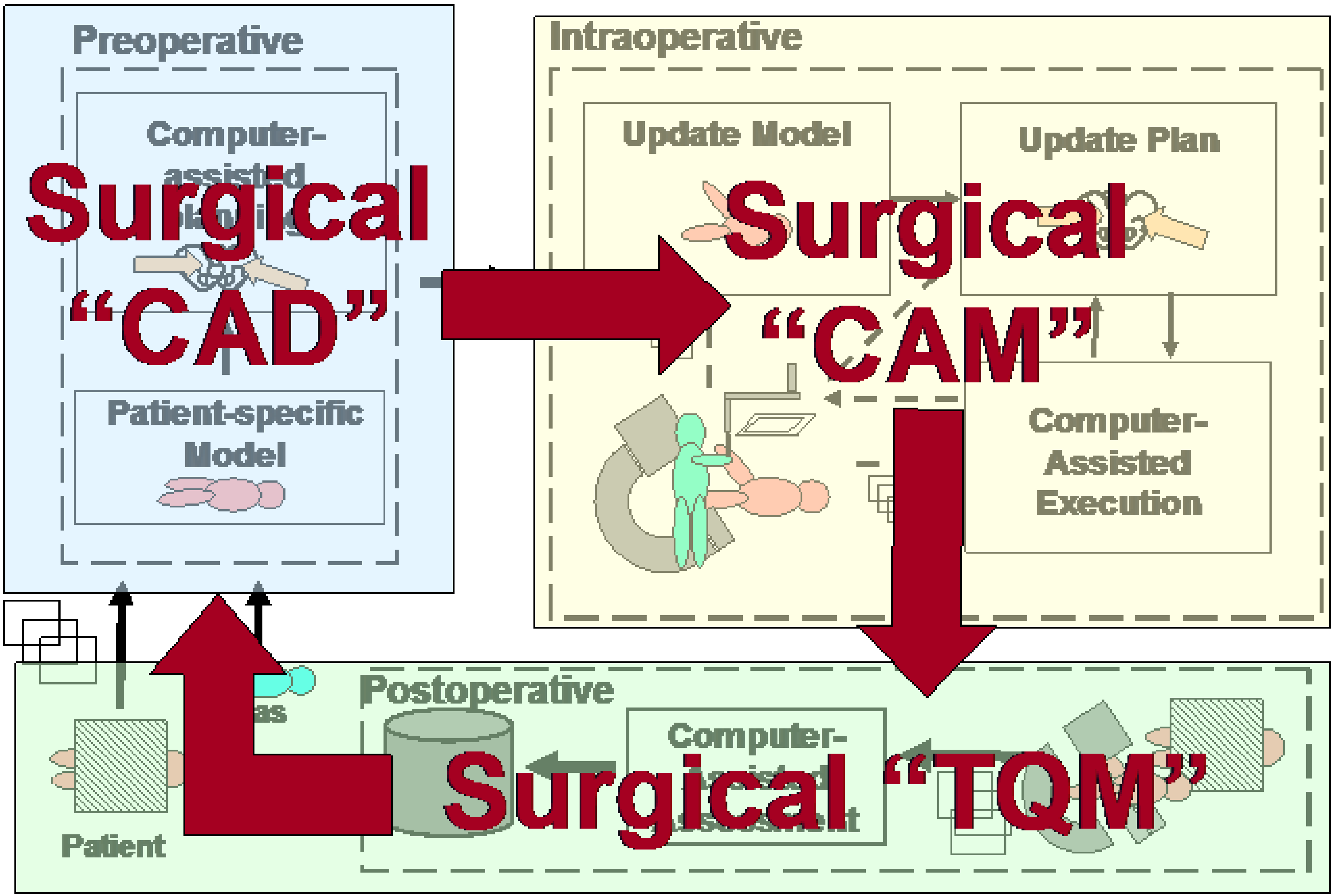
2002-present Research faculty at JHU ERC-CISST

Outline

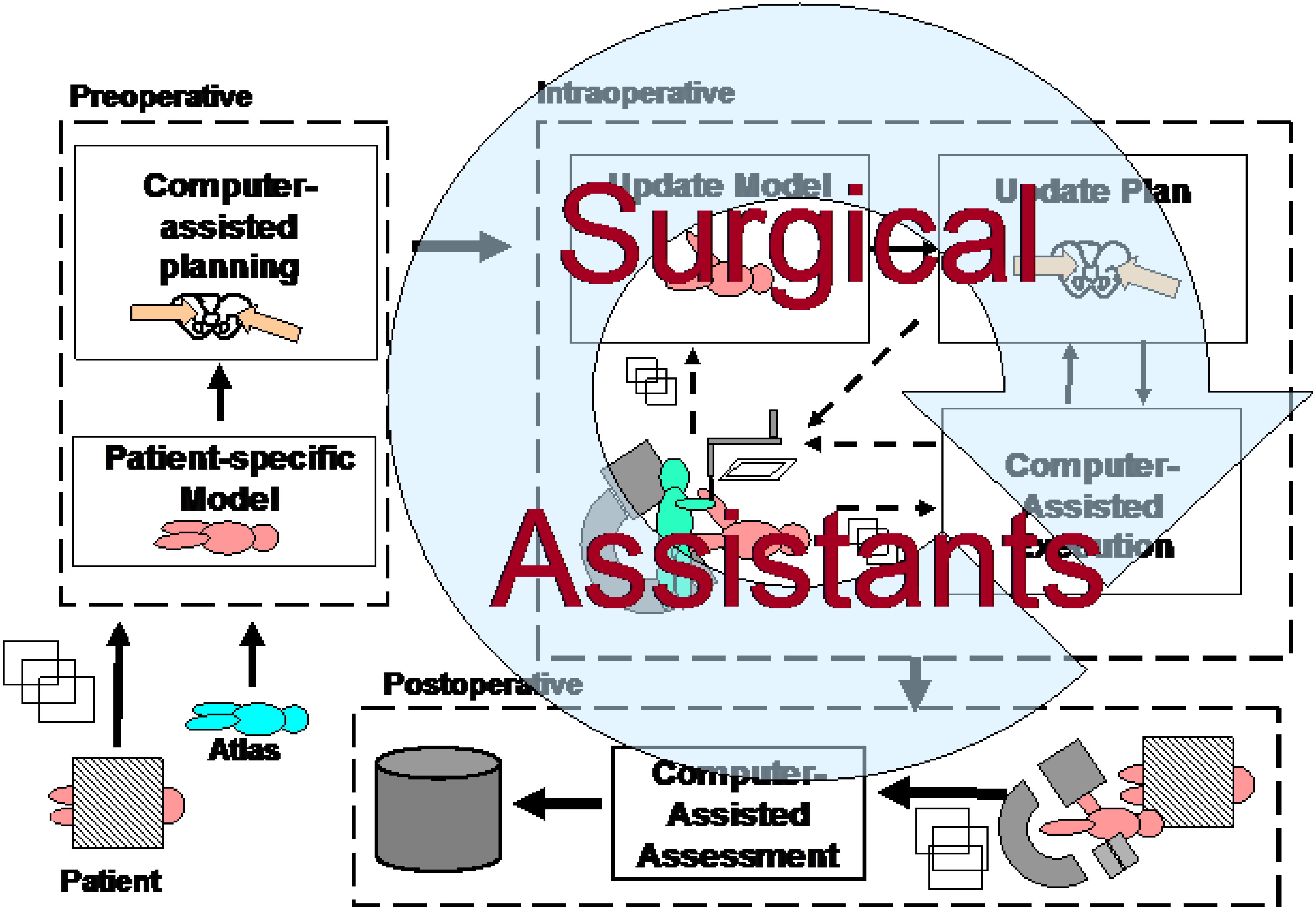
- ➢ Surgical robot classifications
  - – Surgical CAD/CAM, Surgical Assistants
  - – Active, semi-active, and passive
- Review of surgical robots
  - – Focus on orthopaedics
- Safety and Performance Issues
- Metrology and Standards



Preoperative
Computer-assisted planning
Patient-specific Model
Patient
Atlas
Intraoperative
Update Model
Update Plan
Computer-Assisted Execution
Postoperative
Computer-Assisted Assessment


Preoperative
Computer-assisted planning
Surgical "CAD"
Patient-specific Model
Intraoperative
Update Model
Update Plan
Surgical "CAM"
Computer-Assisted Execution
Postoperative
Computer-assisted assessment
Surgical "TQM"
Patient

Surgical Assistants



Active or Passive Robots?

- Some ambiguity in terminology
  - Is a robot active by definition because it contains motors?
  - What if motors cannot cause motion?
    - Cobot, PADyC
  - What about an active robot used passively?
    - Instrument guide, etc.

One Classification

- **Active**: robot autonomously performs part of the procedure
  - ROBODOC, Caspar
- **Semi-active**: robot performs the procedure under direct control of surgeon
  - Acrobot, JHU Steady Hand Robot
- **Passive**: robot does not actively perform any part of the procedure (e.g., positions instrument guide)
  - Neuromate, Galileo, GP System

A comment about active robots

- The goal **is not** to replace the surgeon!
  – Bad for the business
  – Bad for technical reasons as well

- The goal **is** to give the surgeon better instruments
  – coupling information to action
  – “power tools for surgeons”

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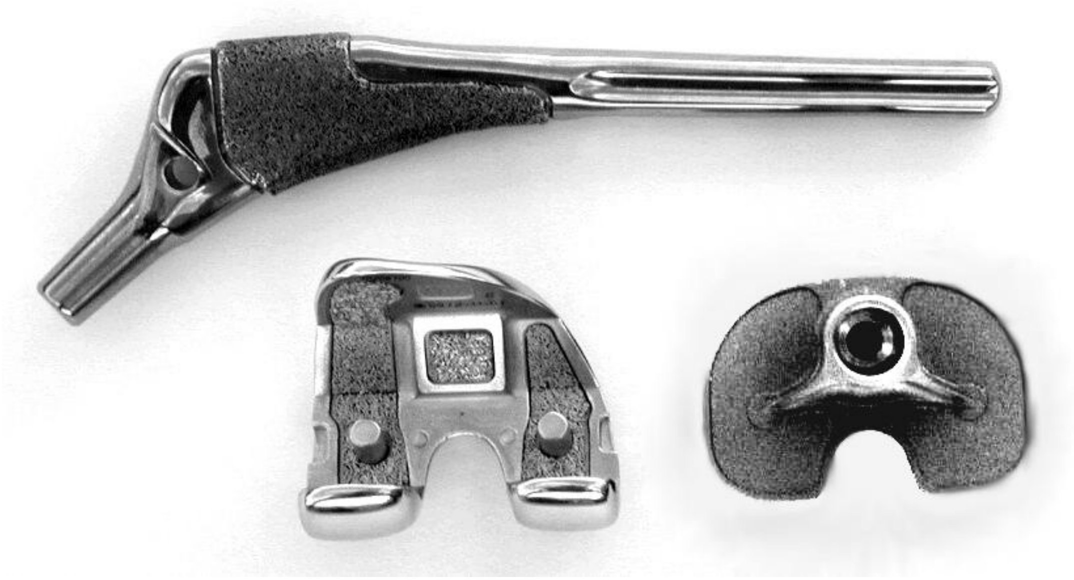
Why Orthopaedics?

- Bones are rigid
  - Minimal deformation or motion during procedure (if fixtured)
- Good image contrast
  - Preoperative CT, X-ray
  - Intraoperative X-ray, Ultrasound
- Some high volume applications
  - Total hip and knee replacement
  - Sports medicine (ACL)

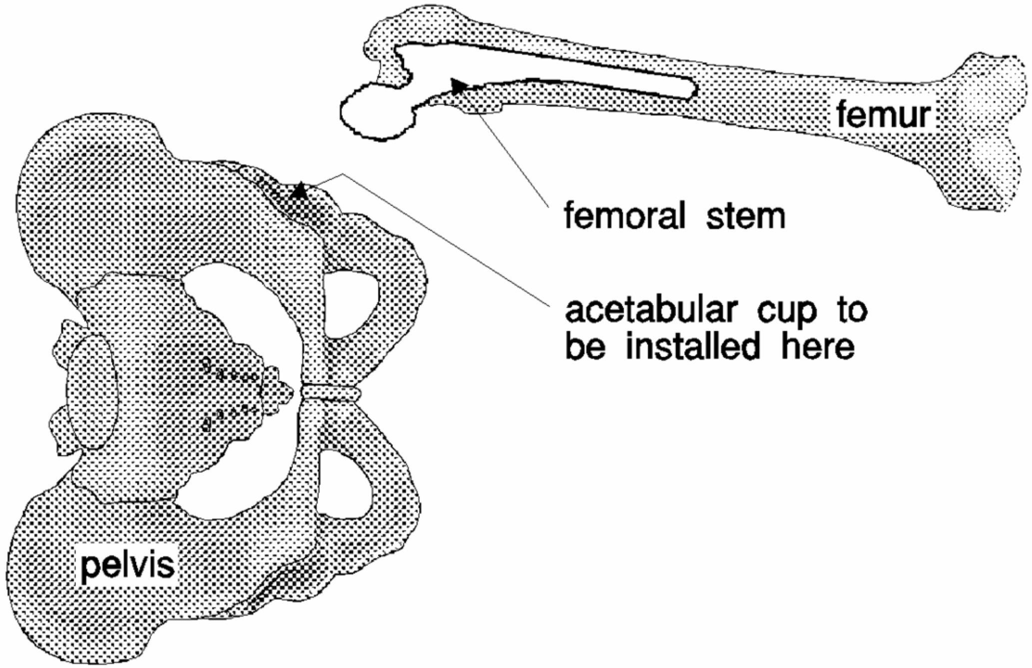
Total Joint Replacement

- Goal is to replace failing joint with metal or plastic prosthesis (implant)
  - Position/orientation important for restoring joint biomechanics
  - Prosthesis fit may be important
    - Cementless: rely on bone ingrowth



ROBODOC® System

- First clinical system for orthopaedics
- Initially developed to assist with Total Hip Replacement (THR) surgery
  - machine femur for cementless prosthesis (femoral stem)

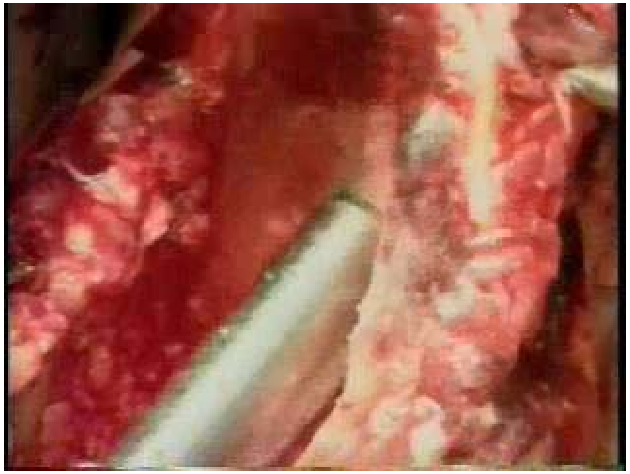


Conventional THR Procedure

- Pre-operative planning using X-rays and acetate overlays
- Surgical preparation using mallet and broach or reamer (relies on surgeon's "feel")

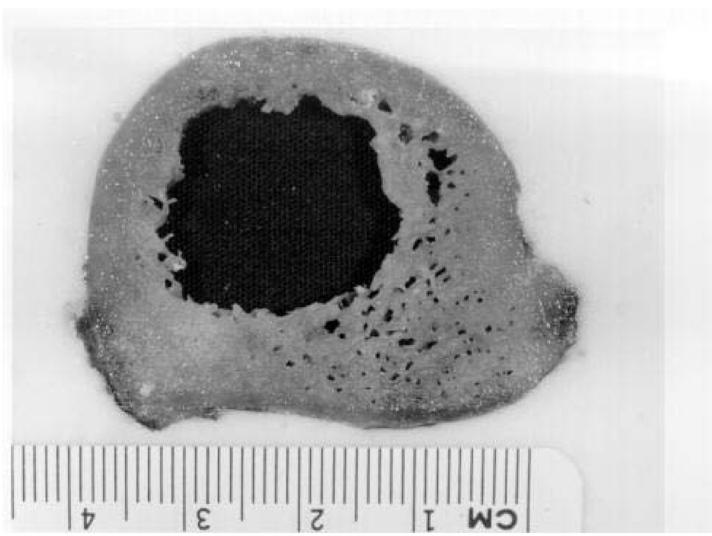
ROBODOC THR Procedure

- Pre-operative planning using 3-D CT scan data and implant models (ORTHODOC®)
- Surgical preparation of bone by robot using milling tool

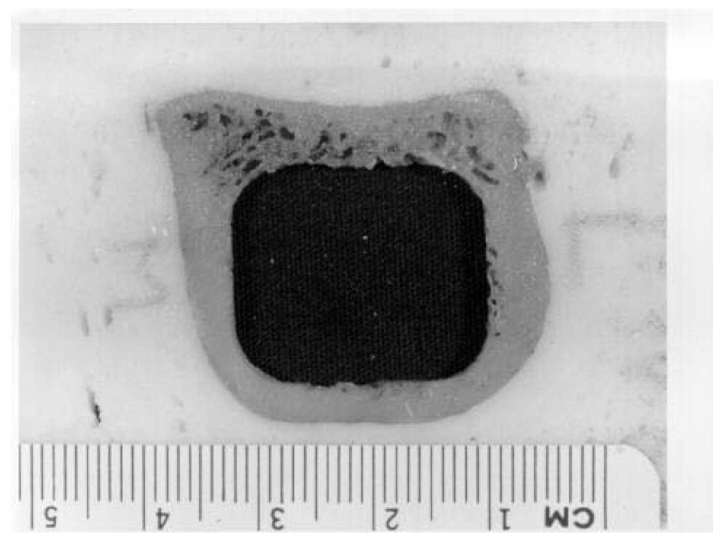


ROBODOC Benefits

- Intended benefits:
  - Increased dimensional accuracy
  - Increased placement accuracy
  - More consistent outcome



Broach



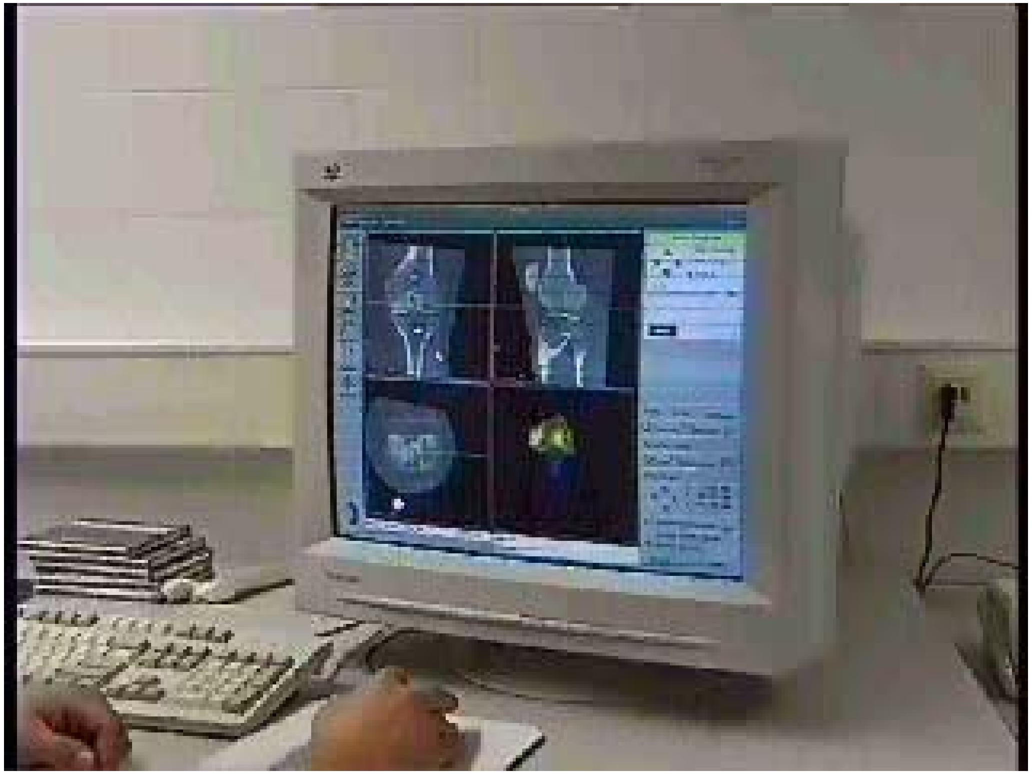
Robot

ROBODOC Hip Surgery (1995)

(Pin-based registration)

Credit: M. Börner, A. Bauer, A. Lahmer, BGU Frankfurt

ROBODOC Knee Surgery (2000)



Credit: M. Börner, A. Bauer, A. Lahmer, BGU Frankfurt

ROBODOC Status

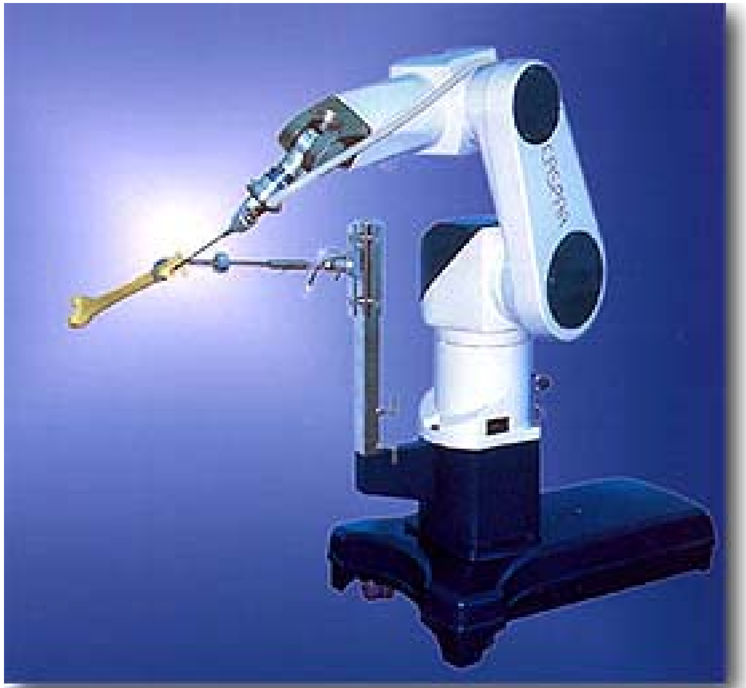
- Approximately 50 systems installed worldwide
  - Europe (Germany, Austria, Switz., France, Spain)
  - Asia (Japan, Korea, India)
  - U.S. (Clinical trial for FDA approval)
- Over 10,000 hip replacement surgeries
- Several hundred knee replacement surgeries
- ISS “ceased operations” on June 2, 2005
- ISS resumed operations in Sept. 2006 (investment by Novatrix Biomedical)

Other Robots for Hip/Knee Surgery

- Large, floor-mounted robots
  - ROBODOC, CASPAR, Acrobot
  - Research systems at Univ. Washington, Northwestern Univ., Rizzoli Clinic (Italy)
- Compact, bone-mounted robots
  - MBARS, Arthrobot, Galileo, Praxiteles, GP System
- Hand-held robots
  - PFS, ITD

CASPAR^{TM} System

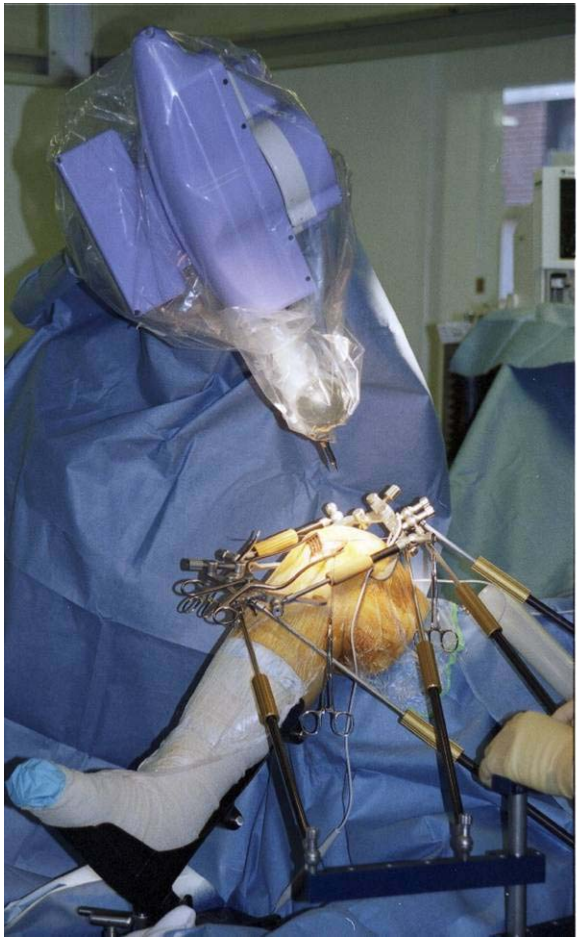
- Direct competitor to ROBODOC
  - Introduced 1997 by Orto Maquet
  - About 50-100 installations
  - Total hip and knee replacement
  - ACL repair
  - No longer in business

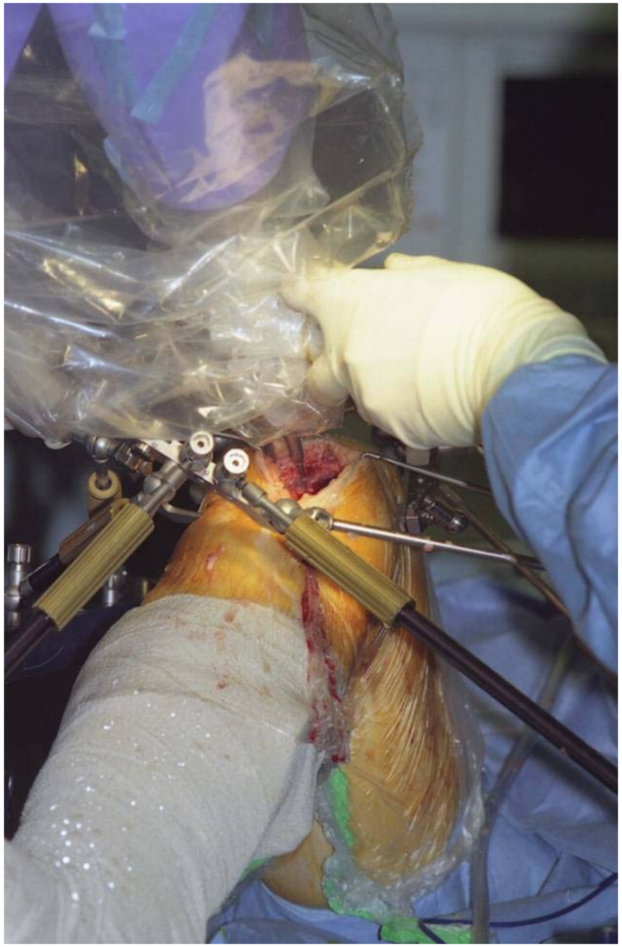


Acrobot System

- Developed at Imperial College, London
- Currently being commercialized for knee surgery
- Active constraint control: surgeon moves cutting tool (force control), robot restricts motion based on preoperative plan
  - Semi-active robot

Acrobot System

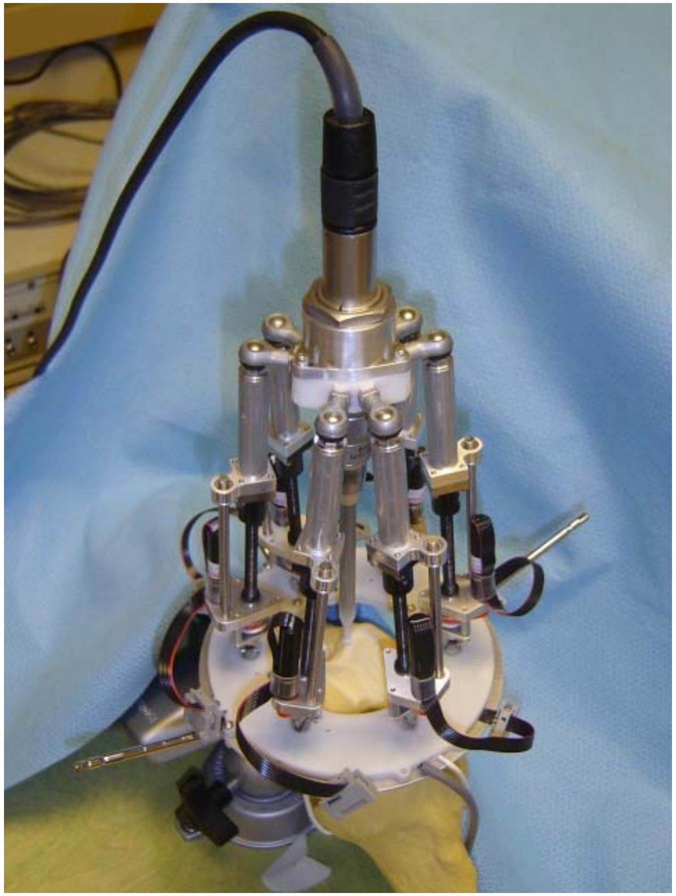




Courtesy of Acrobot Co. Limited, UK

MBARS

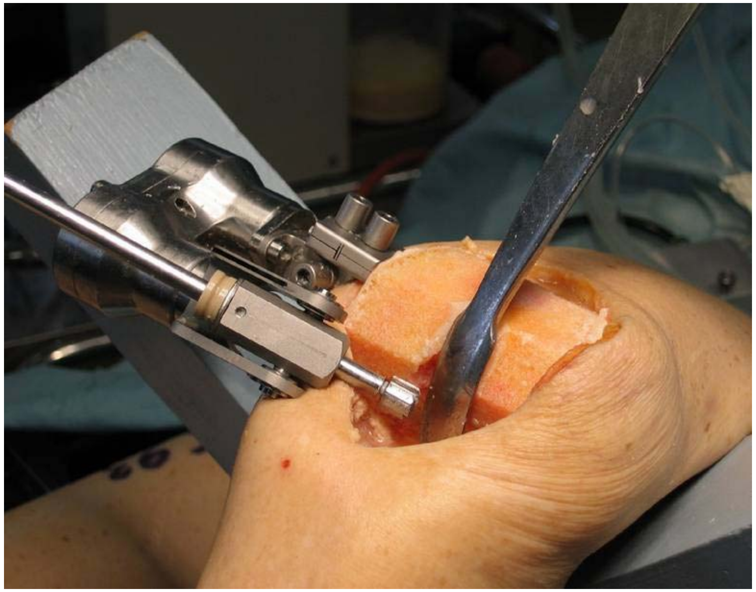
- Mini Bone-Attached Robotic System
- Developed at CMU
  - developer now at Technion
- Small parallel robot for knee surgery (patello-femoral arthroplasty)



Courtesy of Alon Wolf, Ph.D.

Praxiteles

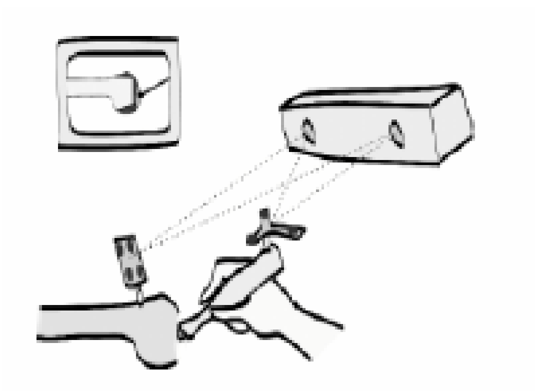
- Developed by Praxim-Medivision (France)
- Integrates with Surgetics navigation system
- Two active joints to position saw/drill guide
- Developed for knee surgery

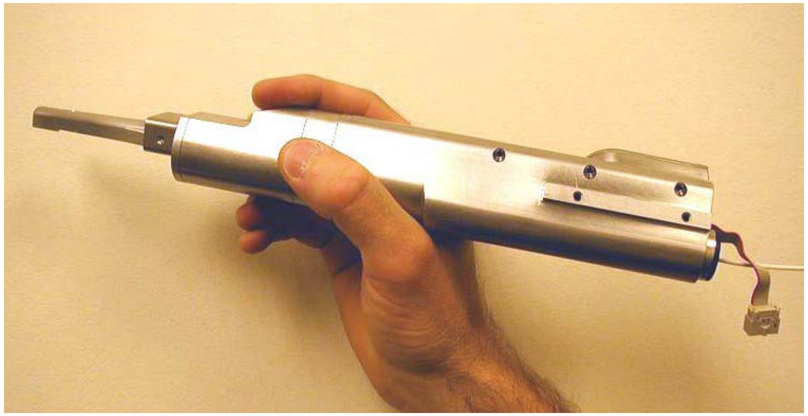


Courtesy of Christopher Plaskos, Praxim-Medivision

PFS

- Precision Freehand Sculptor, developed at CMU
- Position of hand-held tool tracked by optical navigation system
- Computer-controlled retractable blade
  - Retracted when bone should not be cut





Courtesy of Gabriel Brisson, CMU

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- ➢ Safety and Performance Issues
- Metrology and Standards

Safety and Performance Issues

Q: What are people most worried about?

1. Robot going out of control (“going crazy”)
2. Robot with large errors (“off by a mile”)
3. Robot with small errors (“off by a few mm”)
4. Robot being misused (“user error”)

A: Depends on who you ask*

– General public? Surgeons? Patients? FDA?
– My vote (developer): #3, followed by #4

*And on the application

The Problem of Small Errors

- Can be caused by many factors
  - Calibration error (of robot or robot tool)
  - Registration error (e.g., robot to preoperative plan)
- Difficult for humans to detect
- **This issue is not unique to autonomous robots.**
  - If a “trusted” passive robot or navigation system positions an instrument guide in the wrong place, the surgeon will perform the procedure in the wrong place!
- Metrology and standards can address this

Still Have to Worry About…

- Don't let robot get out of control
  - Good engineering techniques exist
    - Risk management
    - Fail-safe or fault-tolerant design
  - Standards (beyond IEC 60601) may be needed
- Enable surgeon to detect/prevent errors
  - The surgeon must always be informed and in control!
- Ensure that robot is used correctly
  - Human factors design (UI standards?)
  - Training

Safety Design

- Fail-Safe: system fails to a safe state (e.g., turn off robot motor power)
  - Many medical devices (if surgeon can remove device and finish manually).
- Fault-Tolerant: system continues to operate in presence of failures
  - Aircraft, critical life support equipment

Safety Design

- Q: How large of an error is tolerable before the system fails to a safe state?

Example: Software comparison of primary and redundant robot position sensors:

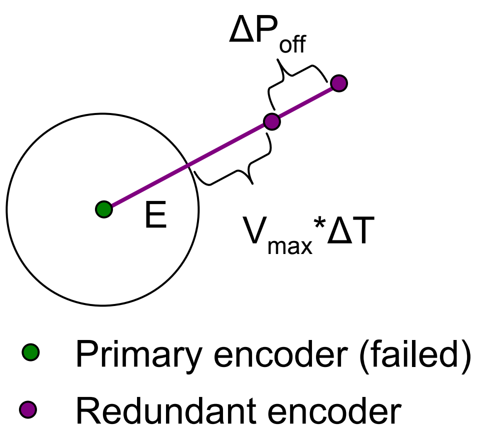
- Performed periodically (sample period ΔT)
- Error tolerance, E, to account for differences in sensor performance, synchronization of readings, etc.

$$MaxError = E + V_{max} * \Delta T + \Delta P_{off}$$

V_{max} = maximum velocity

ΔP_{off} = robot stopping distance

MaxError can be several millimeters!

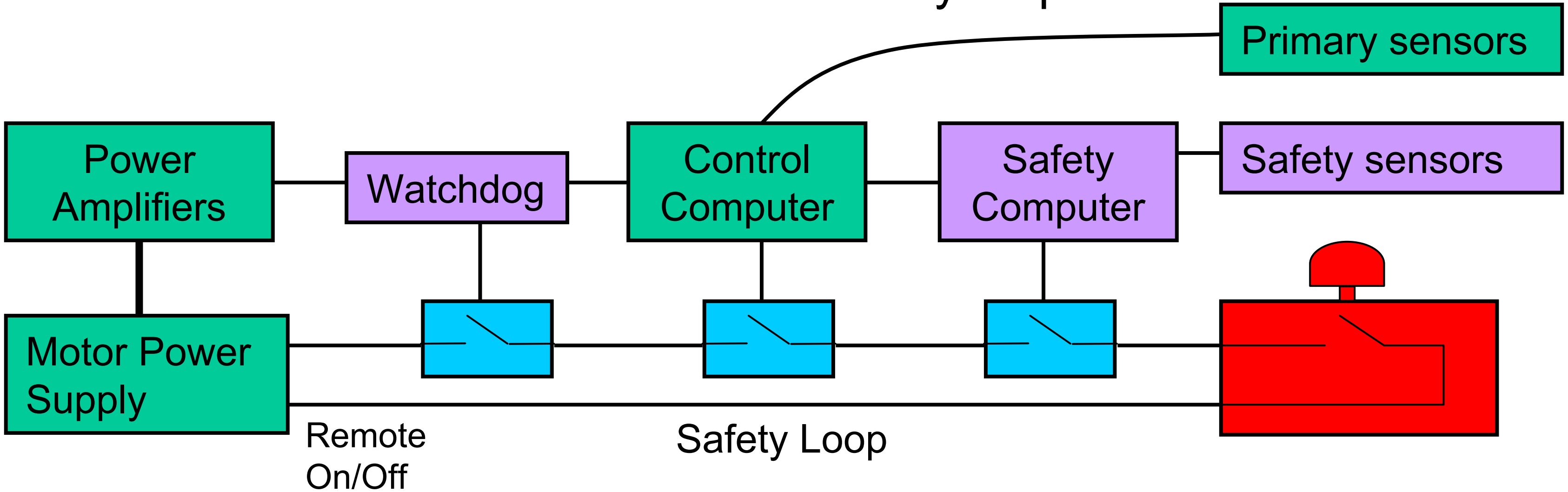


Safety Design

- Q: How large of an error is tolerable before the system fails to a safe state?
- A: Depends on the application (consult application expert/surgeon)
- ROBODOC Case: Although position accuracy of cavity must be within 1 mm, a “glitch” of several millimeters would be acceptable
- For systems operating near critical structures, this would not be acceptable; possible solutions:
  - Reduce V_{max}, ΔP_{off}, ΔT
  - Decoupled kinematics, such as RCM robot
  - Passive systems

Safety Design Approaches

- Eliminate (undetected) single points of failure:
  - Redundant sensors
  - Sensors to detect failures in other components
  - Redundant software
  - Periodic diagnostic testing
  - Watchdogs
- Ensure that safety system(s) can act independently
  - Often achieved via hardware "safety loop"



Safety Design Approaches

- Design system with minimum (speed, torque, workspace, …) needed for task
  - Reduce severity of failure (S)
- Involve user in safety loop:
  - Enhanced information display
  - Controls: stop button, deadman switch, …

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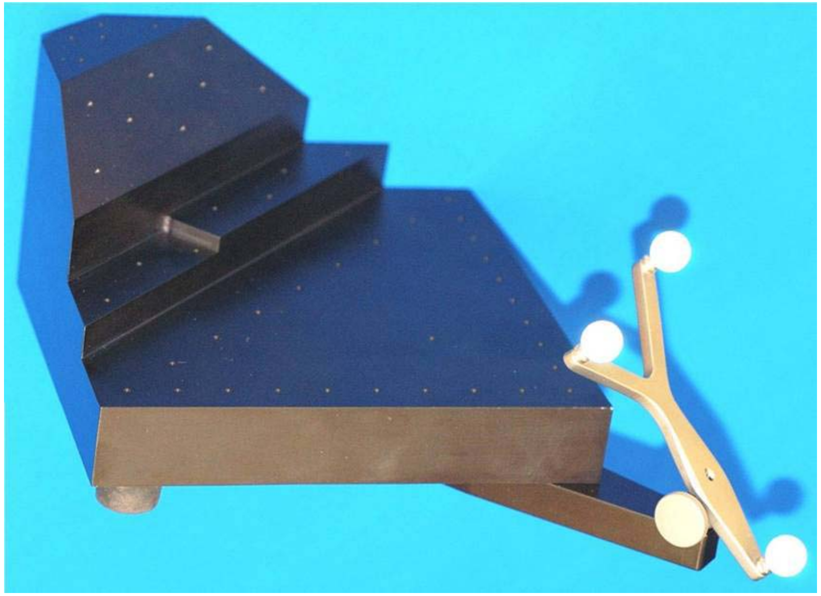
Metrology and Standards

- Accuracy of surgical robots and navigation systems is critical
  - Many applications require sub-millimeter accuracy
  - Can systems satisfy this requirement?
- Clinically achieved accuracy is “bottom line”
  - Difficult to measure routinely
    - Some studies have used postoperative CT
  - Alternative is to test with phantoms (artifacts)
    - Try to replicate clinical conditions as much as possible
    - Ultimate goal is “task specific measurement uncertainty”

ASTM F04.05 Committee

- “Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems”
  - Draft standard in development
  - Initial focus is on accuracy of underlying measurement device (e.g., optical, mechanical, electromagnetic) using generic phantom



ISO 10360

- Set of standards for Coordinate Measuring Machines (CMMs)
  - 10360-1: Vocabulary
  - 10360-2: CMMs for measuring size
- Measure one point at each end of test object
- Size measurement error, MPE_E

$$MPE_E = \pm\min(A+L/K, B)$$

$$MPE_E = \pm(A+L/K)$$

$$MPE_E = \pm B$$

where L is the length and A, B, and K are constants

NIST Phantom

- Designed to mimic hip joint
  - Quantify “task specific measurement uncertainty”
- Uses magnetic ball-and-socket joint

Courtesy of Nicholas Dagalakis, NIST

Summary

- Robots can implement “Surgical CAD/CAM” and/or be “Surgical Assistants” that extend surgeon’s capabilities
- Most surgical robots have similar safety and performance issues:
    1. Must maintain control (no “runaway”)
    2. Must meet accuracy requirements
    3. Must be used correctly
- Metrology and standards to address this

    F04.05 focusing on accuracy (#2)