Development of the ROBODOC® System for Image-Directed Surgery

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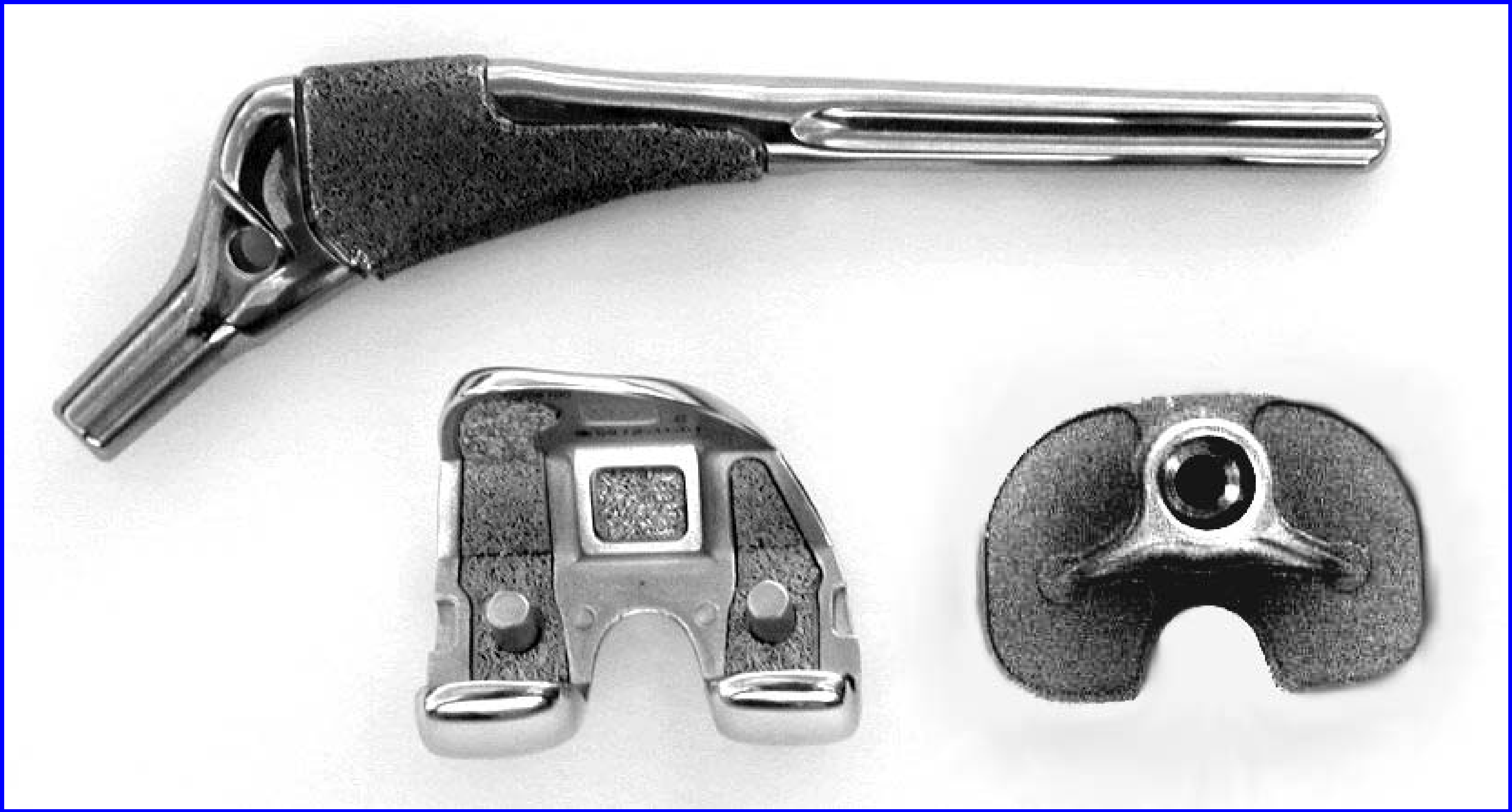
Outline

- Application Overview
- Registration Methods
- ROBODOC History (Design Iterations)
  - Design goals
  - System description
  - Safety systems
  - Lessons learned
- Summary

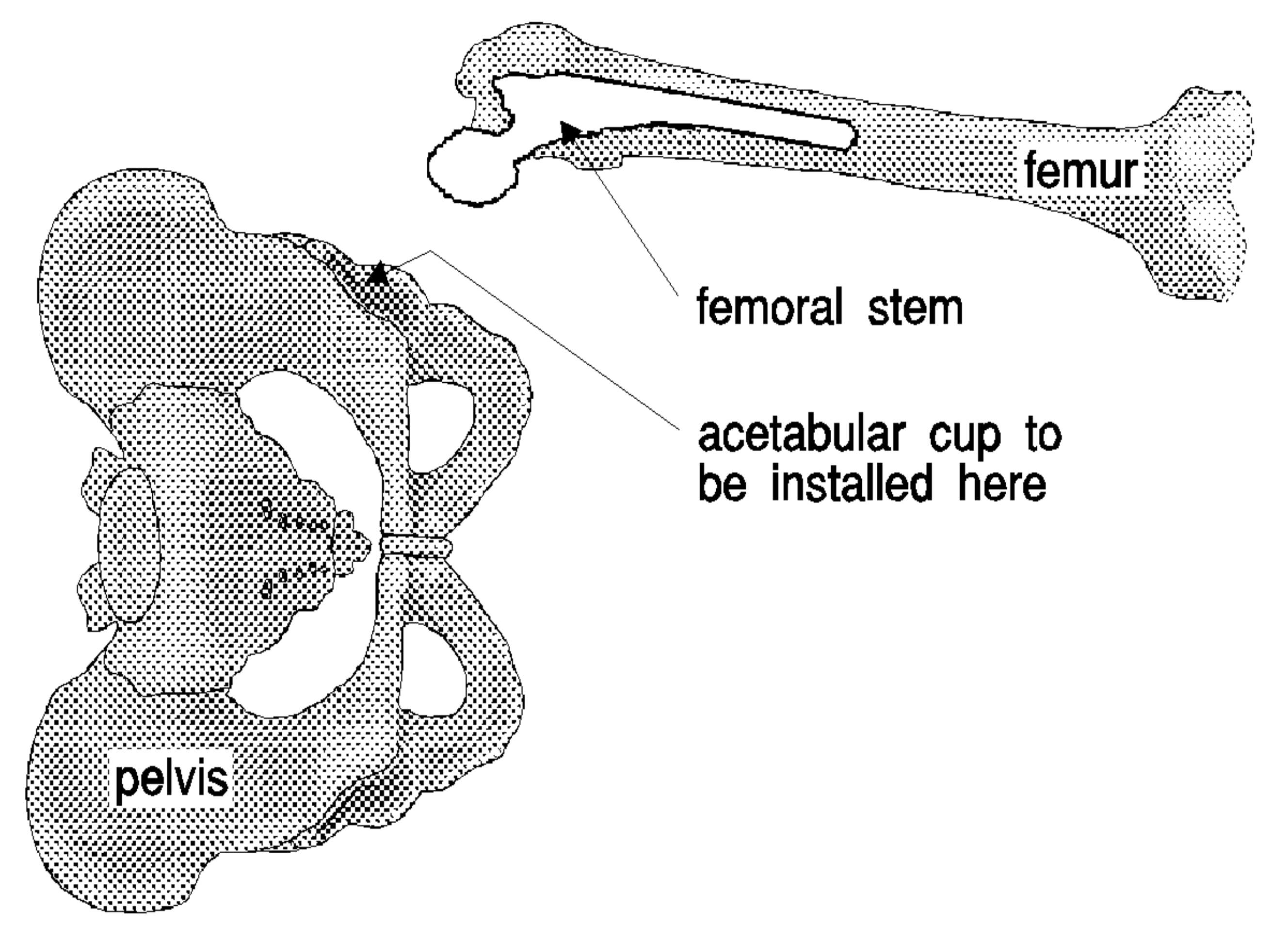
Application Overview

- Total Hip and Knee Replacement Surgery
  - replace damaged articulating surfaces with implants
    - cemented - use cement to attach to bone
    - cementless - rely on bone ingrowth
  - position/orientation is important
  - proper fit can be important (cementless)

Hip and Knee Implants



Total Hip Replacement Surgery



ROBODOC Video (1991)

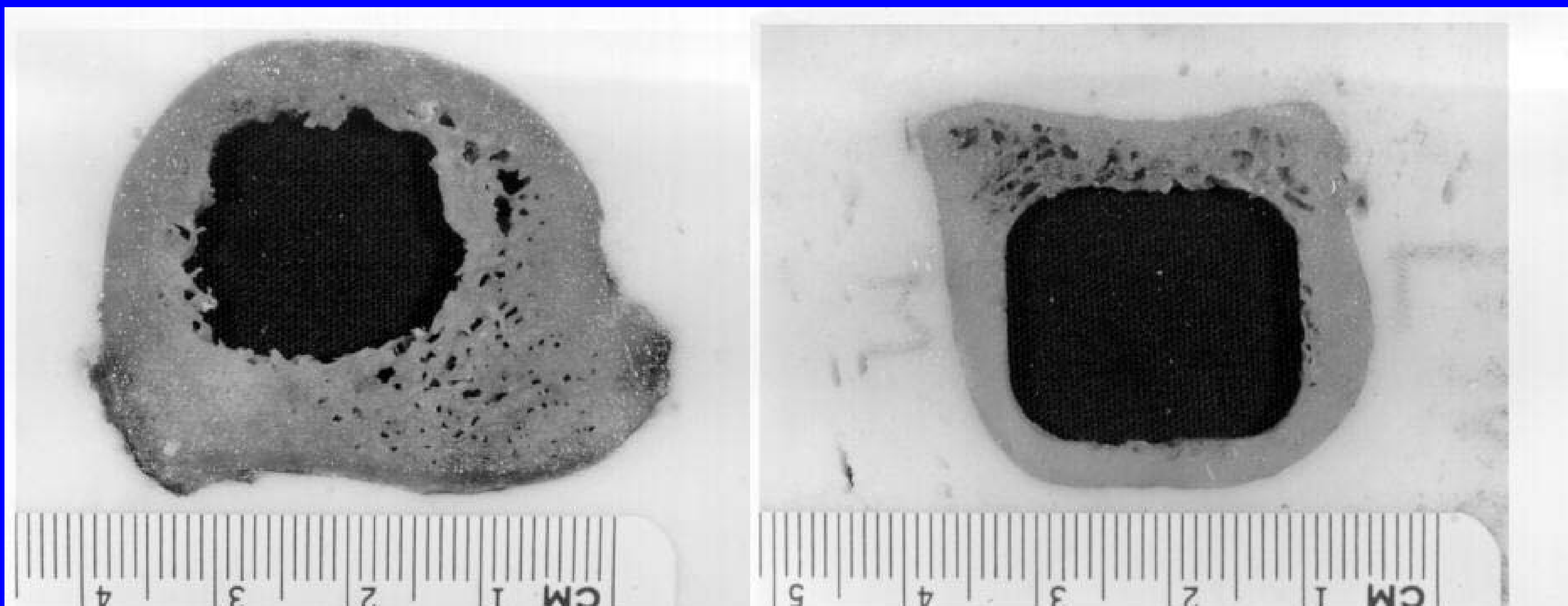
Current Technique for THR

- Pre-operative planning using X-rays and acetate overlays
- Surgical preparation using mallet and broach or reamer
- Relies on surgeon's "feel"
- Outcome depends on surgeon experience

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
  - Increased dimensional accuracy
  - Increased placement accuracy
- Outcome more consistent

Manual Broach vs. Robot



ROBODOC Procedure Overview

- Perform orthopedic procedures (hip and knee replacement):
  - Preoperative CT scan
  - Preoperative planning
  - Intraoperative registration
  - Robotic machining of bone

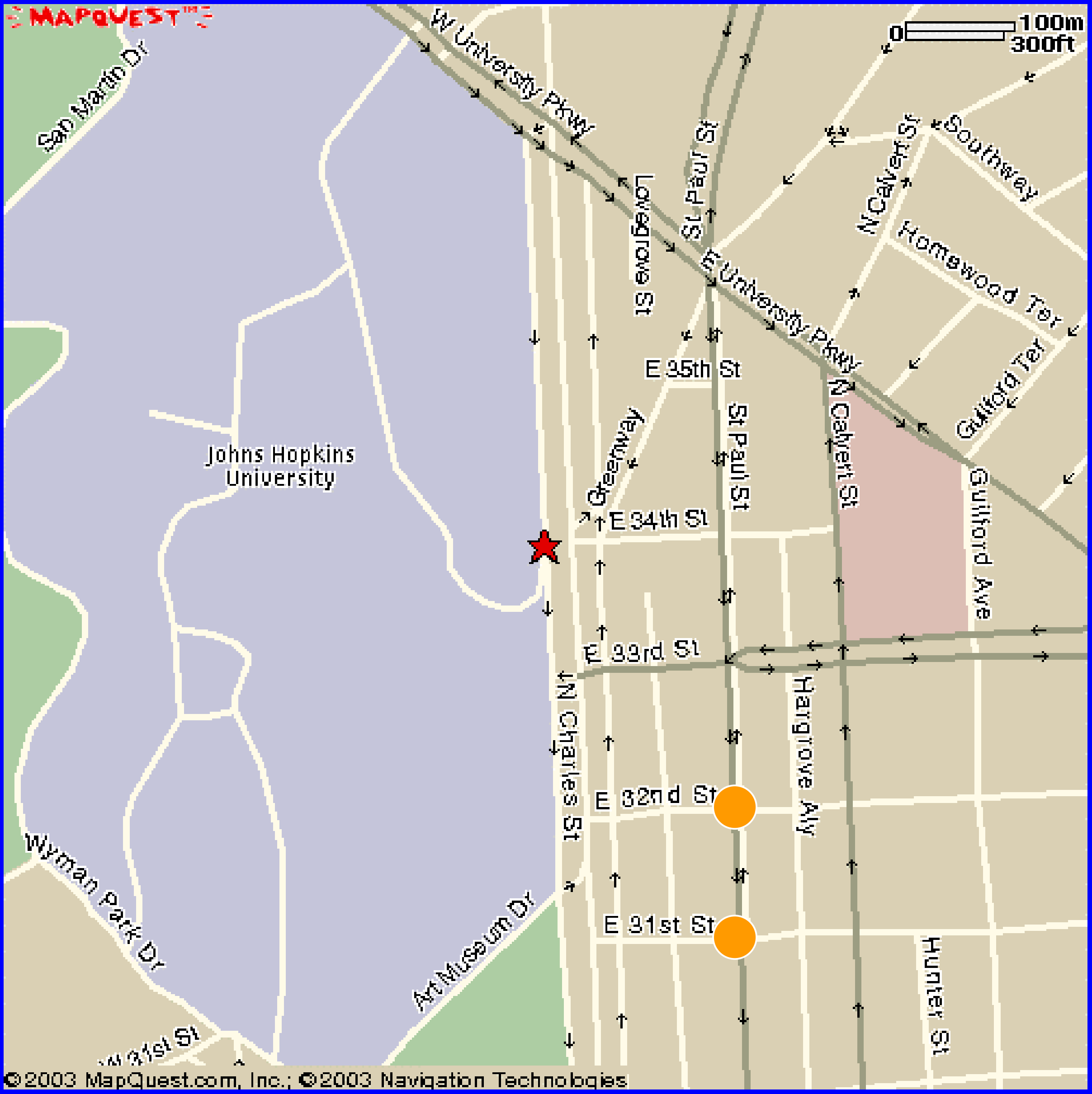
What is Registration?

- Establishing a transformation (conversion) from one coordinate system to another
  - CT coordinates (preoperative plan)
  - Robot coordinates (surgery)

➔ Allows the robot to cut the implant in the position planned by the surgeon.

Simple Registration Method

- Use reference points (fiducials) that can be seen in each coordinate system
- Simple example: using a map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How Many Points Do You Need?

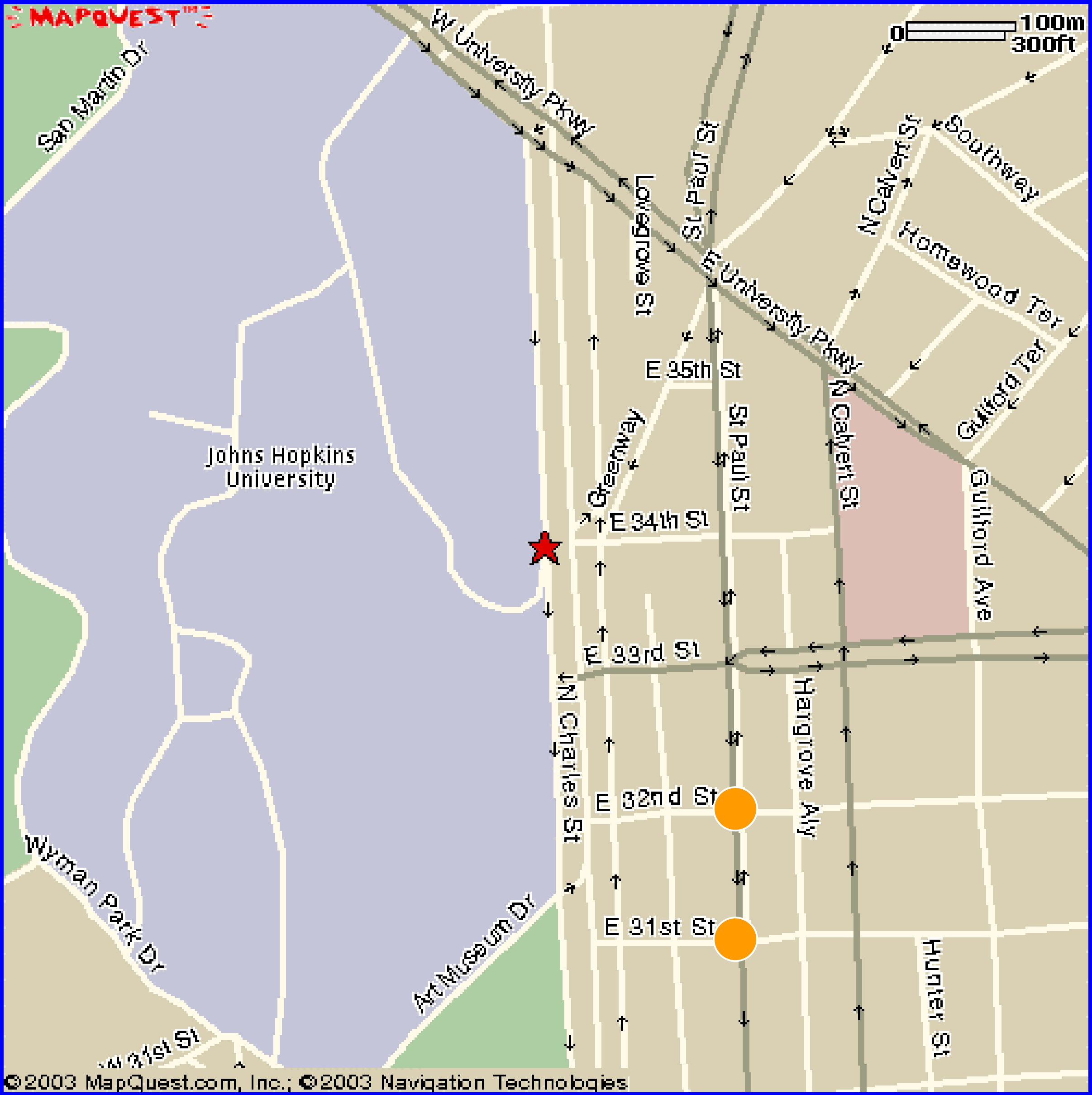
- 2D world has 3 degrees of freedom
  - X, Y, θ
- 3D world has 6 degrees of freedom
  - X, Y, Z, Rx, Ry, Rz

For 2-D:

➔ 1 point (x_1,y_1) is not enough

➔ 2 points (x_1,y_1), (x_2,y_2) is more than enough

Redundant information: distance between points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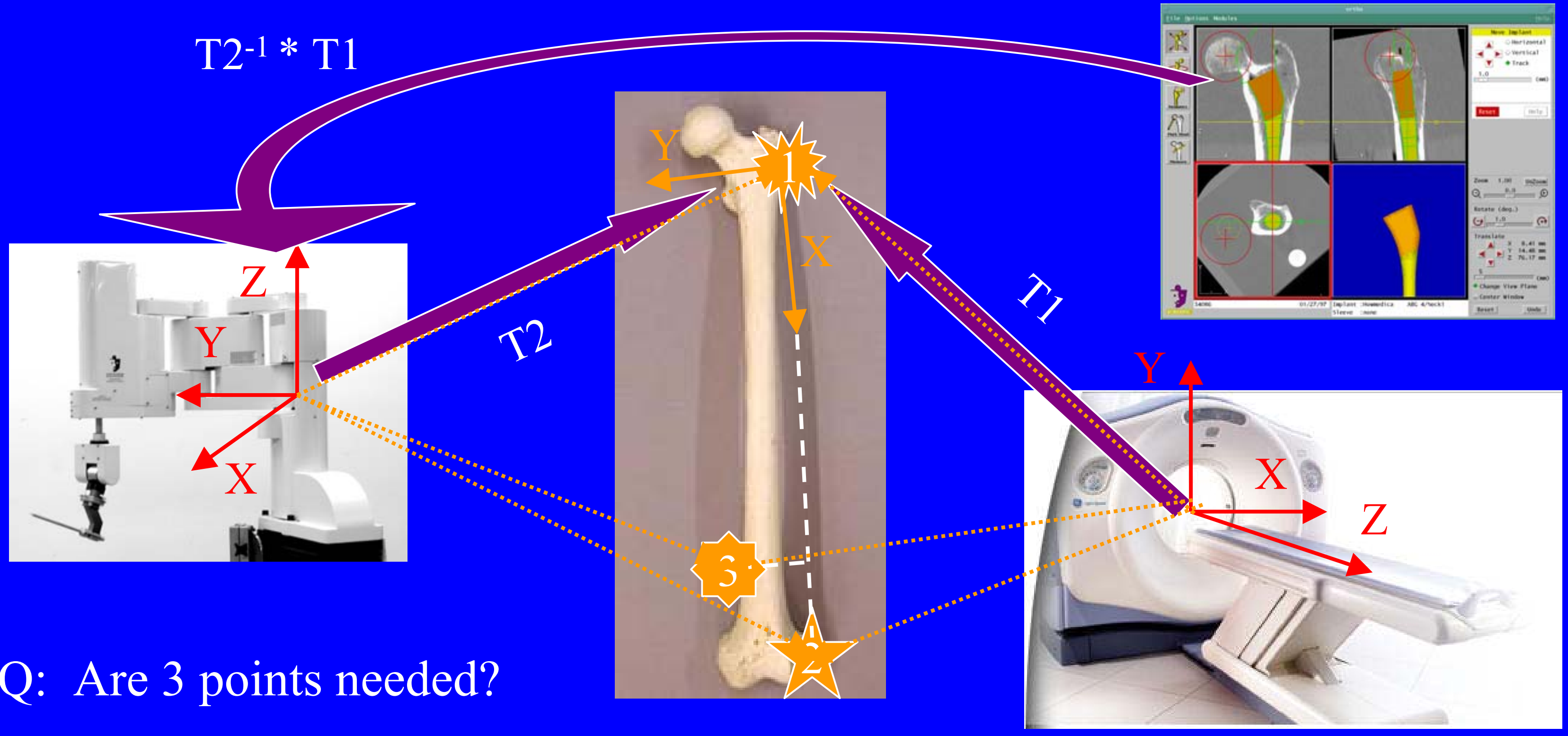
ROBODOC Example

- Using 3 reference points (fiducials)



Q: Are 3 points needed?

Mathematical Basis

- Define a fiducial coordinate system by some convention, e.g.,
  – X is unit vector from Point 1 to Point 2
  – Y is unit vector that is perpendicular to X and points towards Point 3.
- Each observer (CT/Orthodoc and Robot) finds fiducials in its own coordinate system and computes transformation (T1 and T2).

Mathematical Basis (Cont.)

- Use T1 to convert implant position from CT coordinate system to fiducial coordinate system.
- Use $T2^{-1}$ to convert implant position from fiducial coordinate system to Robot coordinate system.
- By combining transformations ($T2^{-1} * T1$), we can determine the transformation between the CT and Robot coordinate systems.
  - Key result for surgical navigation and robotics!

Alternate Computation

Define: $A = T2^{-1} * T1$

$P_R = A * P_{CT}$

Given 3 points P1, P2, P3 that are located in Robot and CT coordinates, solve simultaneous equations for A

(e.g., least-squares estimation)

ROBODOC Pin-Based Registration

- Surgery to implant pins (bone screws) prior to CT
- Planning software detects pins in CT coordinates
- Robot finds pins in Robot coordinates
- Software checks pin distances (safety check) and then computes transformation between CT coordinates and robot coordinates
- Software uses transformation to convert planned implant position (CT coordinates) to surgical position of bone (Robot coordinates)

Pin-Based Registration

- Q: How many pins are needed?

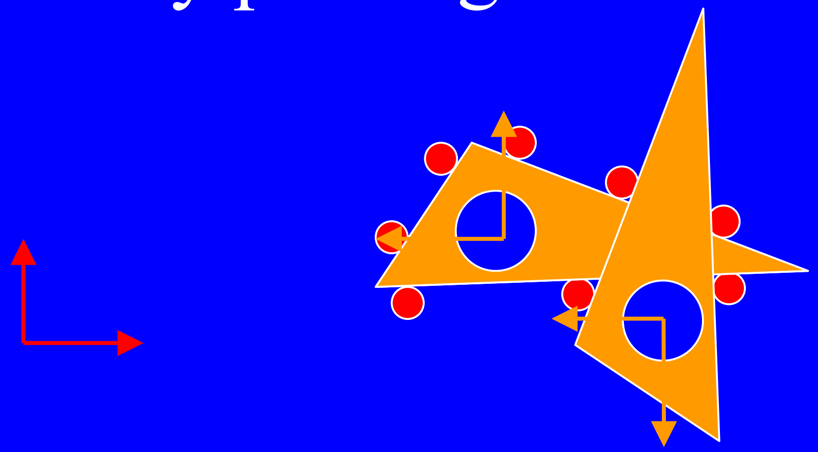
- A: Need at least 3 “features”
  - 3 Pin Registration: uses center of each pin
  - 2 Pin Registration: uses center of each pin and axis of one pin

Pin-Based Registration

+ Easy to implement
+ Easy to use
+ Very accurate (if pins far enough away)
+ Very reliable
- Requires extra surgery
- Causes knee pain in many patients

Harder Registration Method

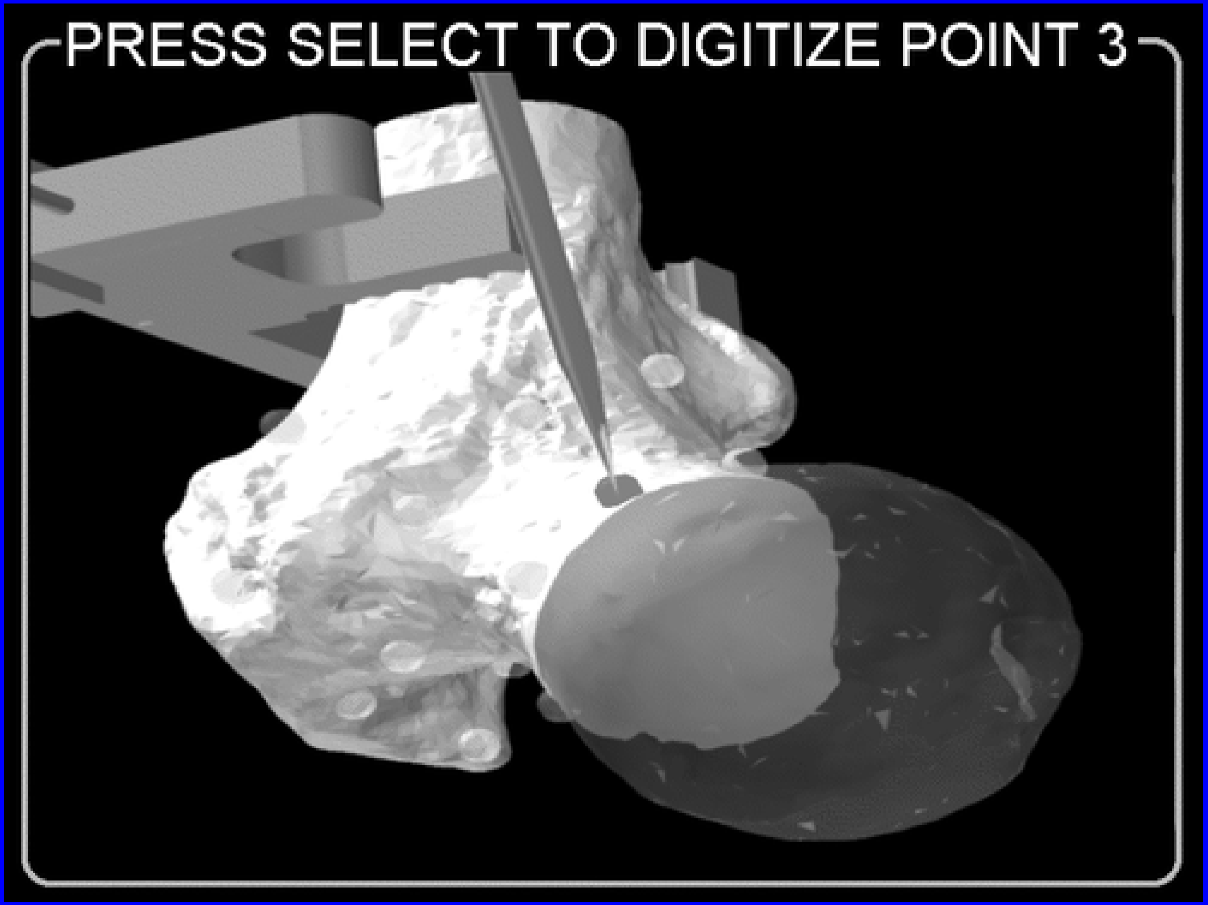
- If there are no easily identifiable features, must find another way to establish correspondences
- Example: finding a known object in the dark by probing



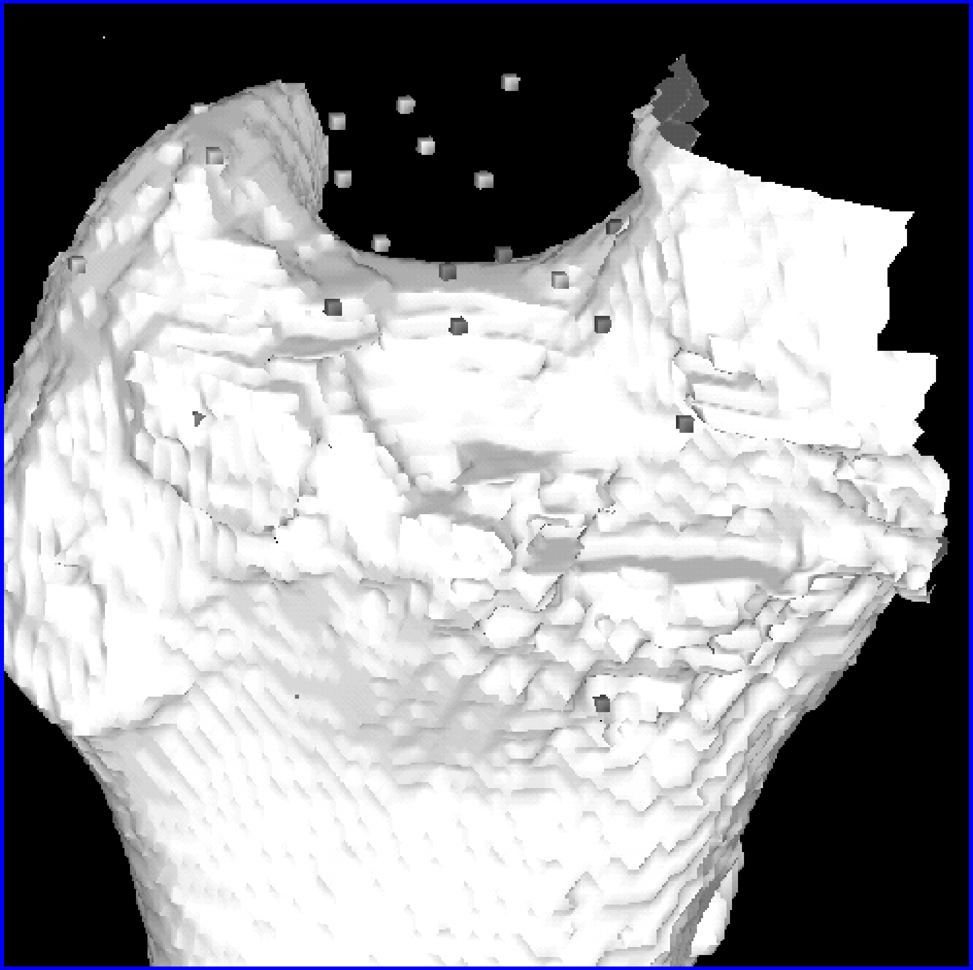
ROBODOC Pinless Registration

- More complex (point-to-surface matching)
- Surgeon creates surface model of bone from preoperative CT (semi-automatic software).
- Surgeon uses digitizing device to collect bone surface points intraoperatively.
- Software ensures good distribution of points
- Surgeon verifies result

Intraoperative Point Collection



Pinless Registration



Handling Re-Registration

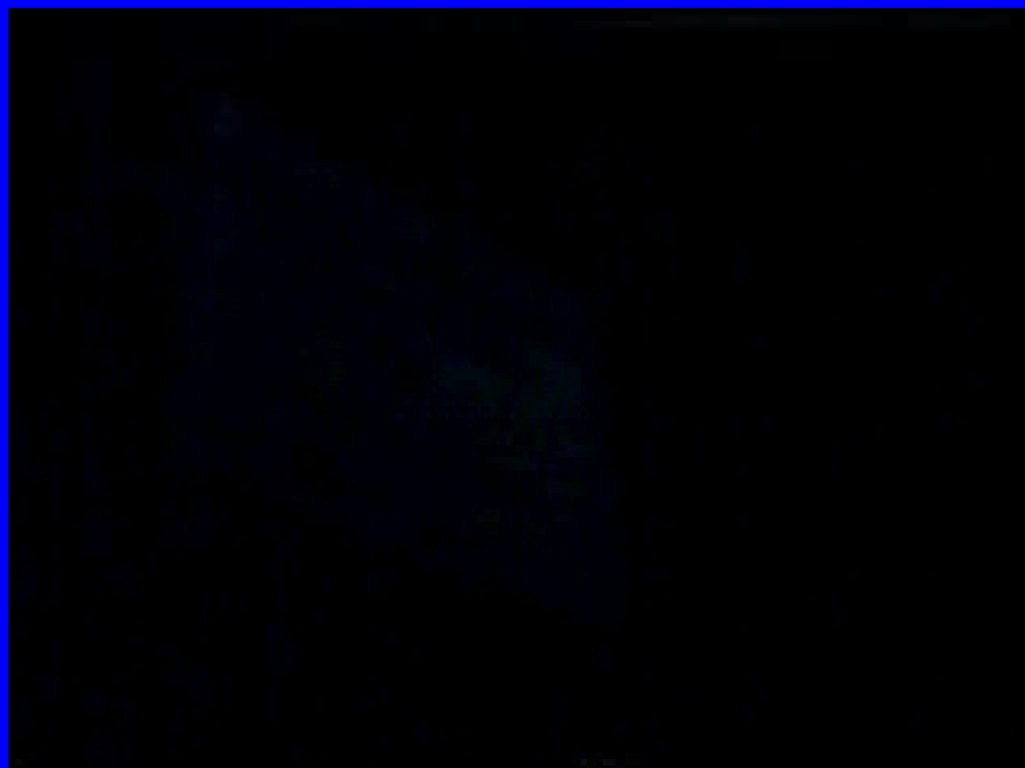
- Problem: How to re-register if bone moves during procedure?
  - Required bone surfaces may have been machined away
  - Pinless registration can be time-consuming

Handling Re-Registration

Solution: Implant markers (pins) during surgery.

1. Expose femur and implant markers
2. Perform pinless registration
3. Locate markers
4. Use pinless registration result to transform marker positions to CT coordinates
5. Start cutting implant cavity
6. If motion occurs, use pin-based registration

Pinless Video (1998)



ROBODOC History

1986-1988 Feasibility study and proof of concept at U.C. Davis and IBM

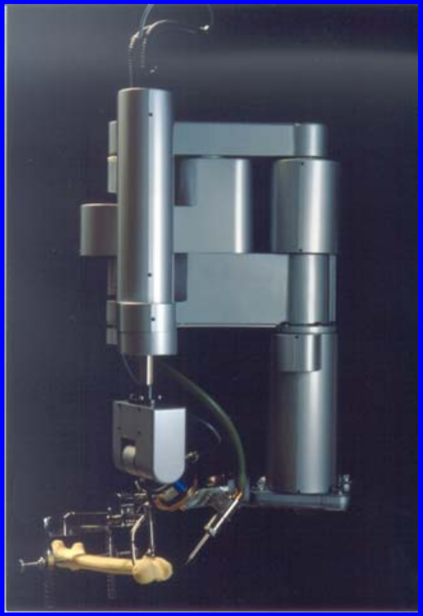
1988-1990 Development of canine system

May 2, 1990 First canine surgery

ROBODOC History

1990-1995 Human clinical prototype

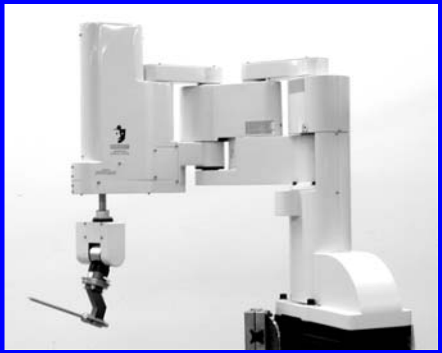
Nov 1, 1990	Formation of ISS
Nov 7, 1992	First human surgery, Sutter General Hospital
Aug 1994	First European surgery, BGU Frankfurt

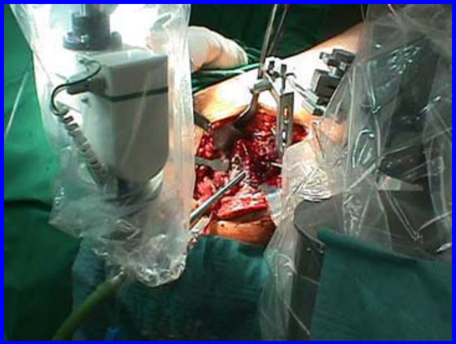


ROBODOC History (cont.)

1995-2002 ROBODOC as a Medical Product

March 1996	CE Mark (C System)
April 1996	First 2 installations (Germany)
Nov 1996	ISS initial public offering (NASDAQ)
Sept 1997	IMMI acquisition (Neuromate)
March 1998	First pinless hip surgery
April 1999	New electronics design (D System)
Feb 2000	First knee replacement surgery





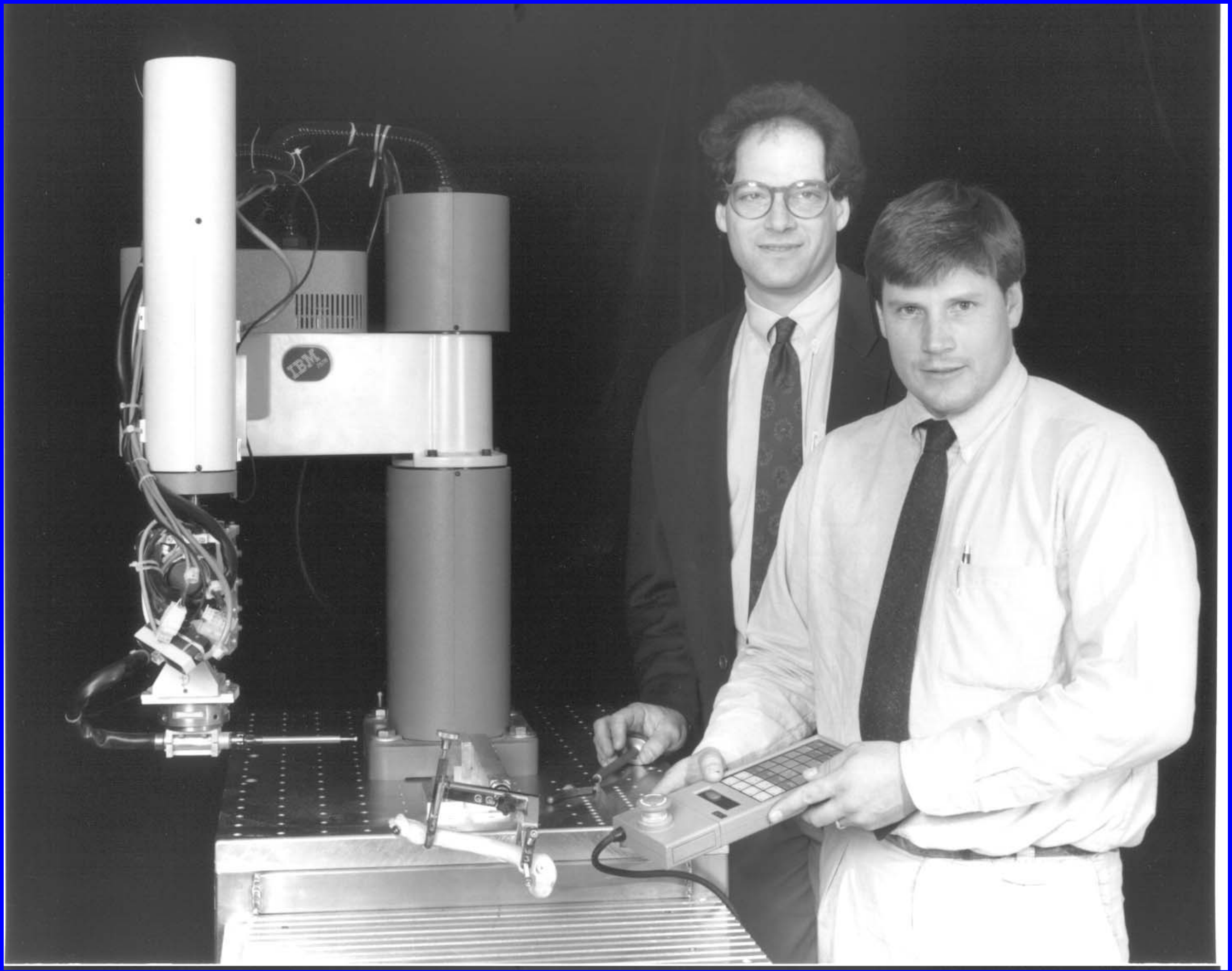
ROBODOC Generations

- Alpha: Canine System (1990)
- Beta: Human clinical prototype
  - Version 1: 10 patient study (1992)
  - Version 2: Multi-center trial (1993)
- Commercial Product
  - C System: First version (1996)
  - D System: Custom electronics (1999)

Canine System Goals

- Proof of concept
  - procedural flow
  - high accuracy (small bones)
  - operating room compatibility (sterility)
- Focus on application, not system design
  - Use primarily off-the-shelf hardware
- Rely on engineering supervision in OR
- Research mode: no formal design process

Canine System Design



Canine System Design

Canine System Design

- Prototype appearance (external cables, etc.)
- Primitive (text-based) user interface
  - Engineer operated robot for all 26 surgeries
  - Graphical display during cutting (RTM)
- Software written in AML
- Primitive computer hardware (286/386)
- Did not use some safety systems in surgery

Canine System Safety

- Force sensor to detect collisions
- Optical tracking system (Optotrack) to independently track robot end-effector
  - not used clinically
- Bone motion monitor
  - design not completed
- Visualization of cutting procedure (RTM)
  - display cut paths on CT cross-sections

First Surgery - May 2, 1990

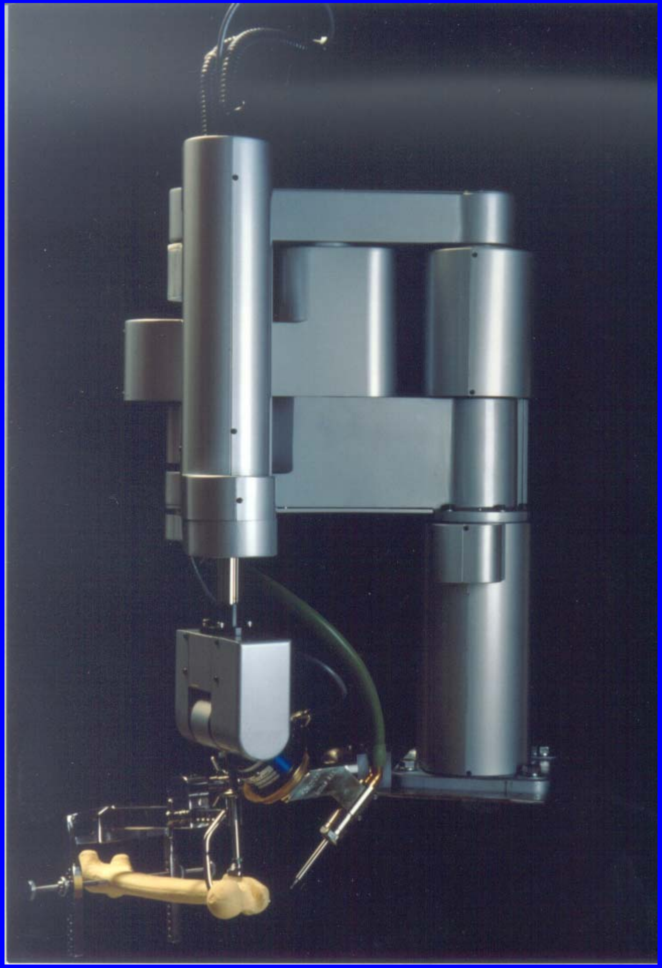
Canine System Lessons

- The procedure works!
- The user interface needs improvement
- Error recovery can be complex
- Bone motion detection is critical
- Avoid special power requirements

Beta System Goals

- Re-design system for production
  - Create specifications, risk analysis, etc.
  - Improve system appearance
  - Rewrite software in industry-standard language
- Create user interface for surgeon use
  - graphical user interface and simple pendant
- Support longer tools (higher stiffness)
- Reduce cost

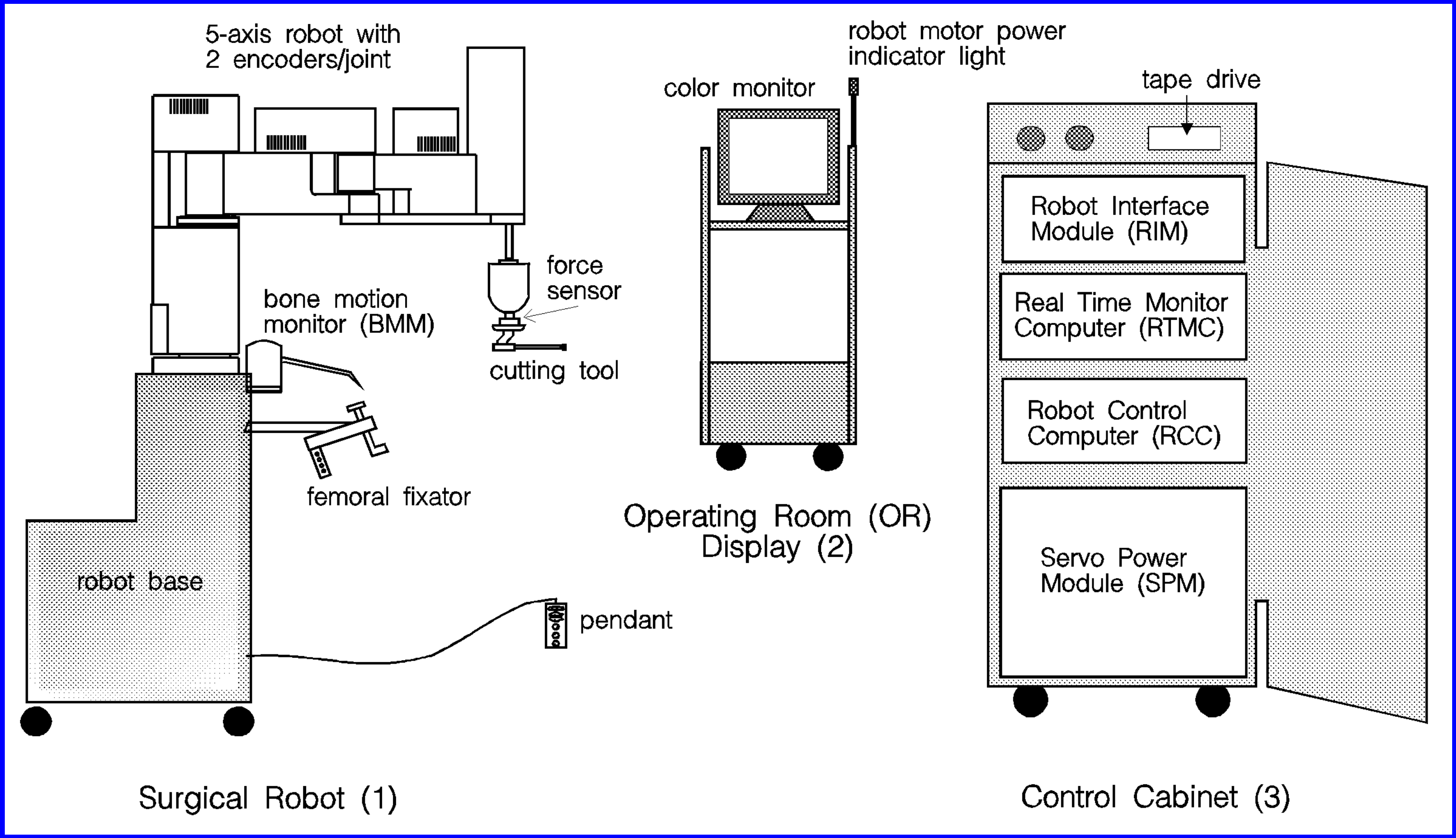
Beta System Design



Beta System Design

- Customized industrial robot (Sankyo Seiki)
  - Integrated pitch axis
  - Integrated redundant encoders
  - Improved stiffness (roll axis)
  - Reduced force and speed for safety
  - High accuracy specifications
- Adjustable base to increase workspace

Beta System Design



Beta System Design

- Significantly improved appearance
  - Still a few external cables
- Graphical user interface and pendant
- Software written in C and C++
- Additional safety features
- Improved error handling software

Safety Design Overview

- Driven by risk analysis (FMECA)
  - Eliminate single points of failure
- Fail Safe design
  - System fails to a safe state (robot powered off, finish procedure manually)
- Limited Fault Tolerance
  - System can continue without RTM graphics
- Completely different from industrial robots

Beta System Safety Design

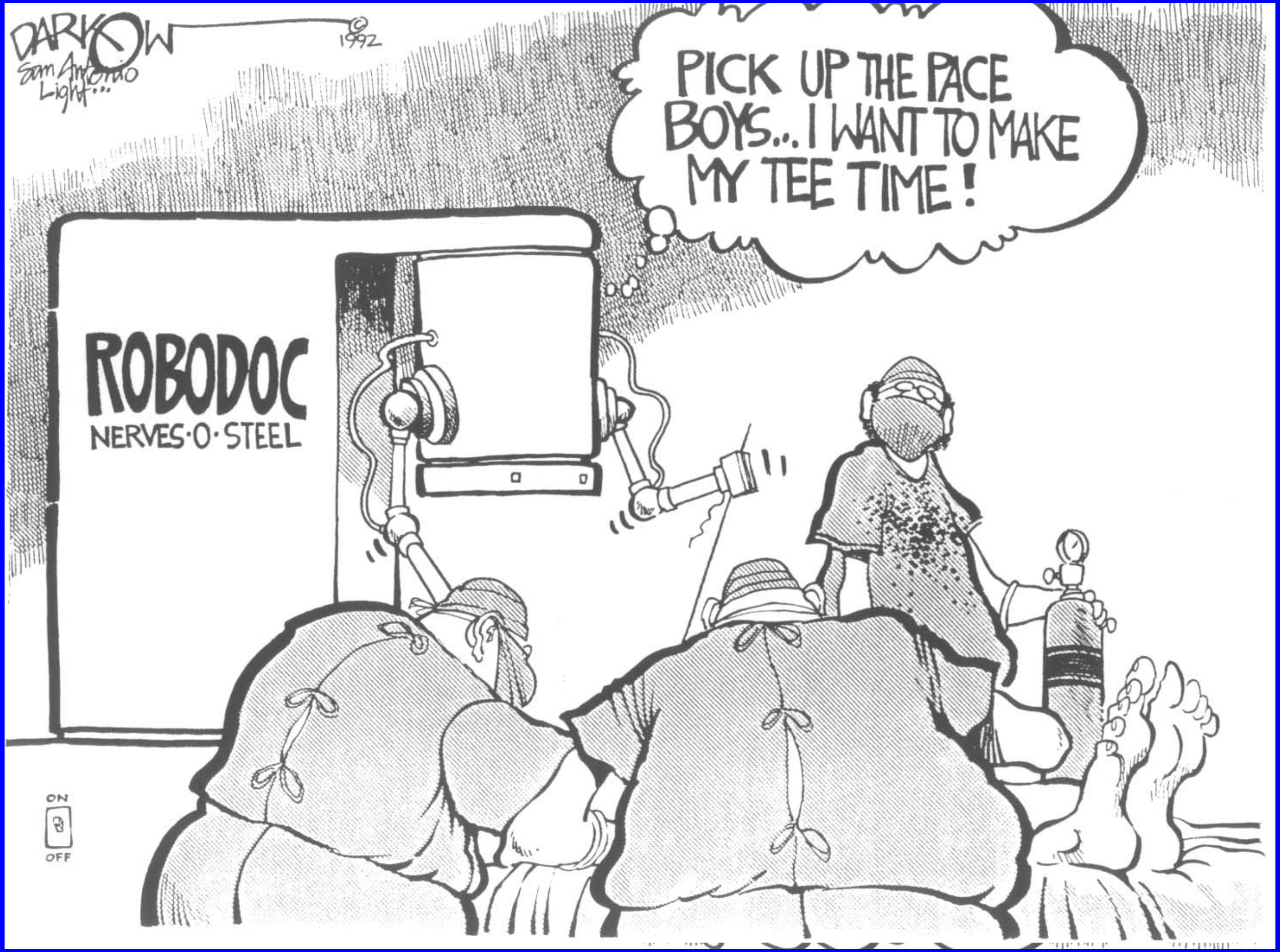
- Force sensor to detect collisions
- Visualization of cutting procedure (RTM)
- Redundant joint encoders
  - primary encoders on motor shaft
  - redundant encoders at joint
- Bone motion monitor (intraoperative)
- Bone motion detection during CT scan

Beta System Safety Design

- Safety Volume
  - Independent check that tool is in implant cavity
- Startup Diagnostics
  - Verify force sensor, robot, BMM
- Mechanical changes to robot
  - higher gear ratios to reduce speed
  - smaller motors to reduce torque
- Low-level software speed limit

First Surgery - Nov 7, 1992

The Press Reacts...



Beta System Lessons

- Did not meet EMC requirements
  - Emissions marginal
  - Susceptible to interference (cautery mode)
- Required larger vertical workspace
  - Version 2 system had base encoder
- Difficult to move robot
- System too large for OR

Commercial System Goals

- Meet regulatory requirements
  - CE Mark
  - UL/CSA
- Improve maneuverability
- Reduce size
- Improve system appearance
- Support local languages

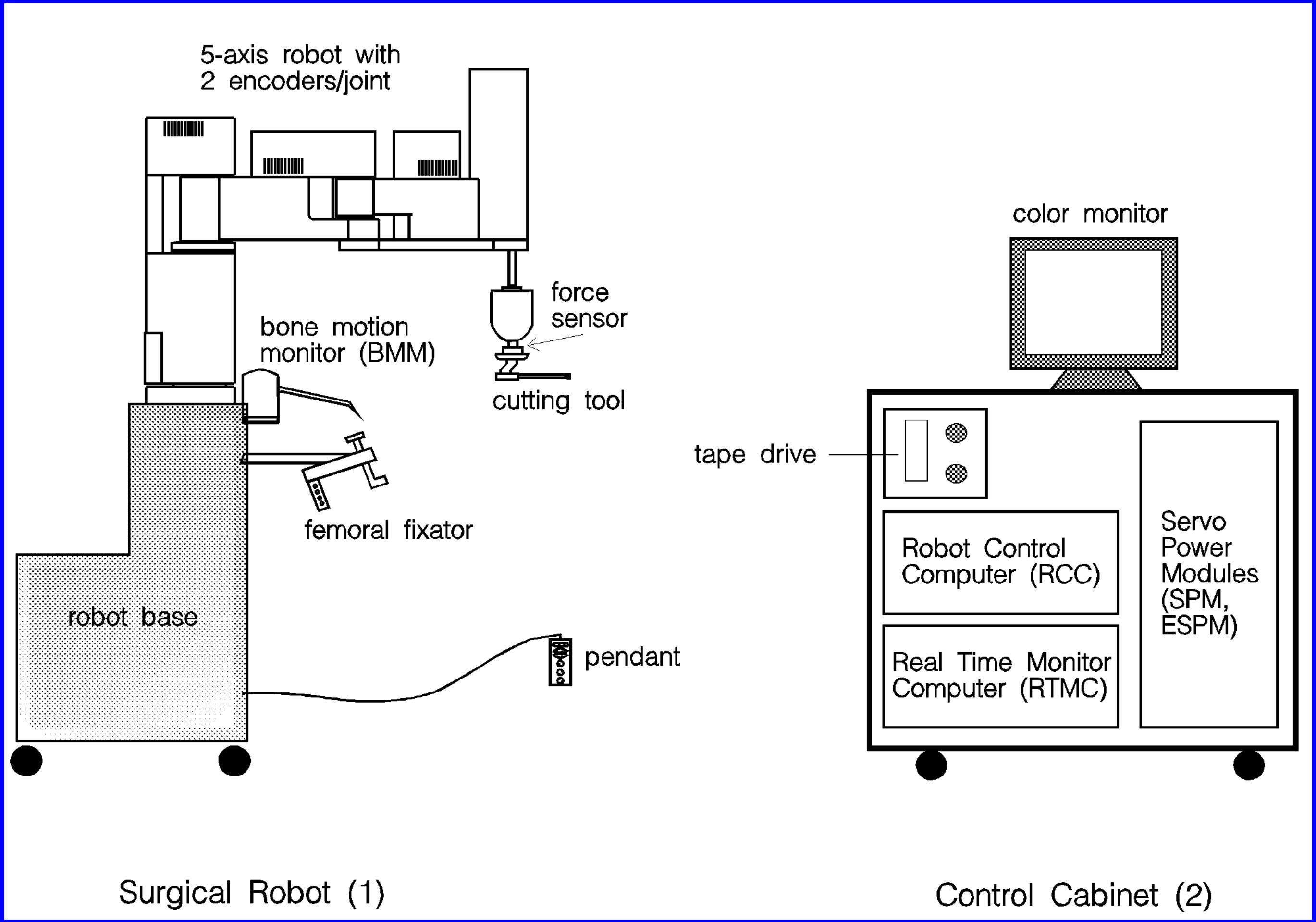
Quality Systems

- "Design controls" are now required
  - By FDA (GDP)
  - For ISO9000 certification
- Regulatory agencies do not prescribe QS
  - Company defines Quality System
  - Regulatory agency certifies Quality System and monitors compliance (Quality Records)

Quality System Documents

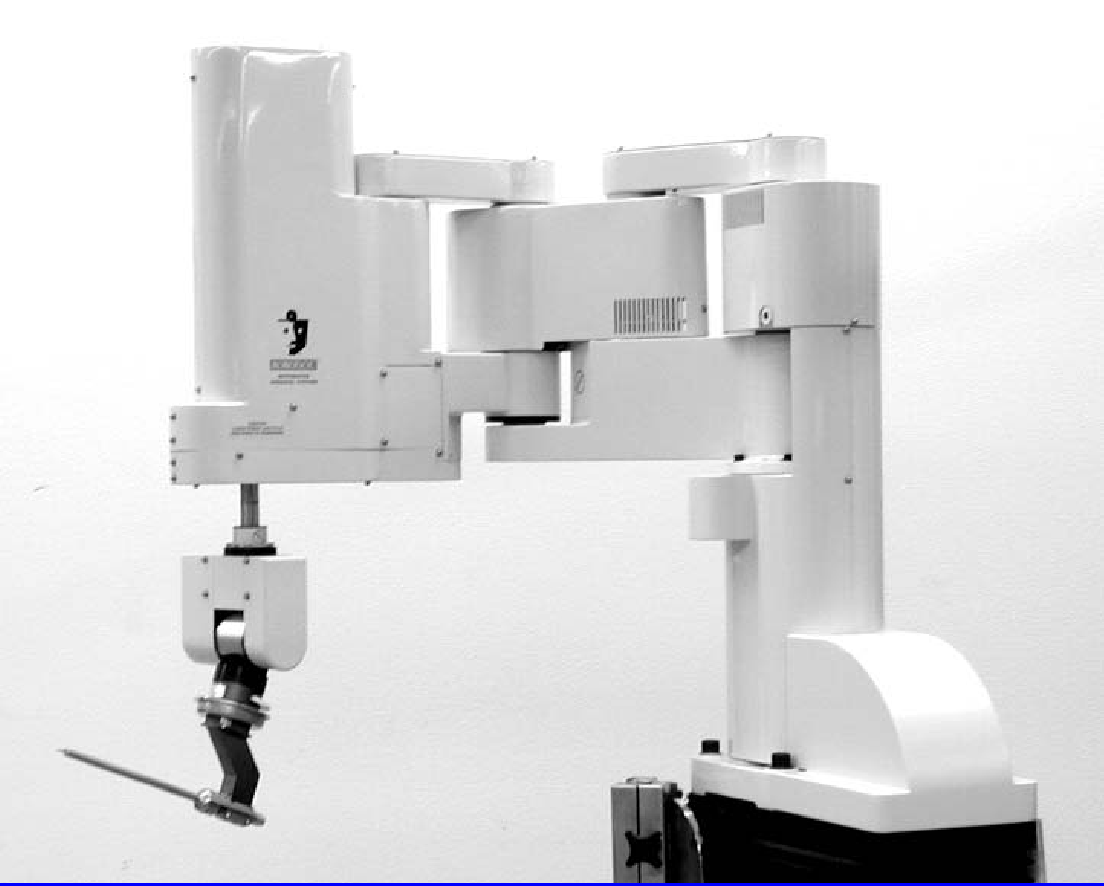
- Project Plan
- Software Development Procedure
- Software Quality Assurance Plan
- Risk or Hazard Analysis
- Requirements Specifications
- Verification and Validation Plan
- Change Control Procedures

Commercial System Design



Commercial System Design

Commercial System Design



Commercial System Design

- Distributed architecture
  - EMC compliance
- Two units (Robot and Control Cabinet)
- More attractive robot and base
  - Force sensor cable inside robot arm
- Base easier to maneuver
  - Steering system

Commercial System Safety Design

Safety design reviewed by notified body (TUV) for CE mark

- Electrical safety requirements
- Electromagnetic emissions/susceptibility
- Risk Analysis

Commercial System Surgery

Commercial System Lessons

- Robot should either save time (money) or provide substantial clinical benefit (enable new procedures).
- Robot must interface with other devices in the operating room of the future.
- Registration should not require an additional surgery.
- Further size reduction is necessary.

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

Total Knee Surgery (2000)

Summary

- The ROBODOC System has evolved over the past 15+ years:
  - Laboratory prototype
  - Canine system
  - Clinical prototype
  - Commercial product

Summary

- Experience has led to changes in:
  - System architecture (distributed)
  - Safety design (risk analysis)
  - User interface (ease of use)
  - Ergonomics (OR compatibility)

ROBODOC Video (1995)