Robotic Joint Replacement Surgery

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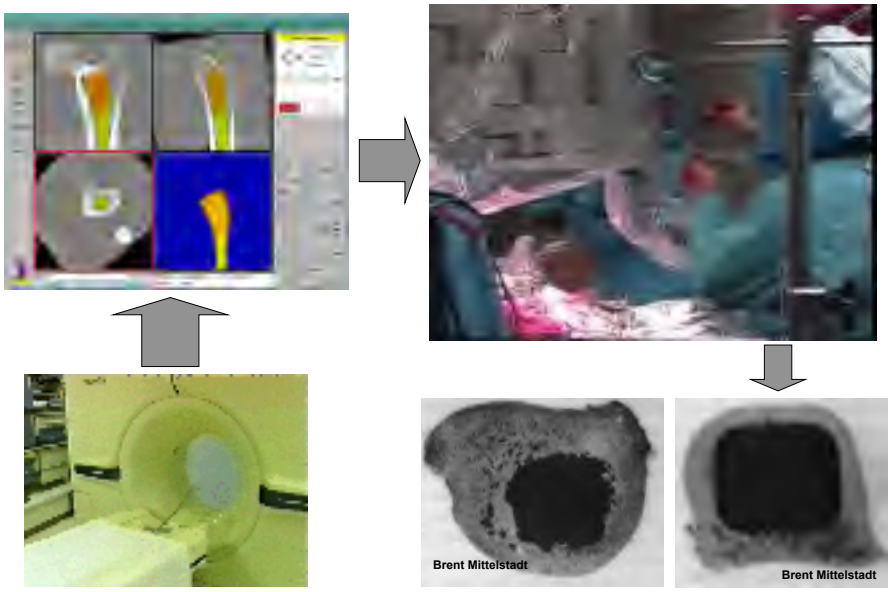
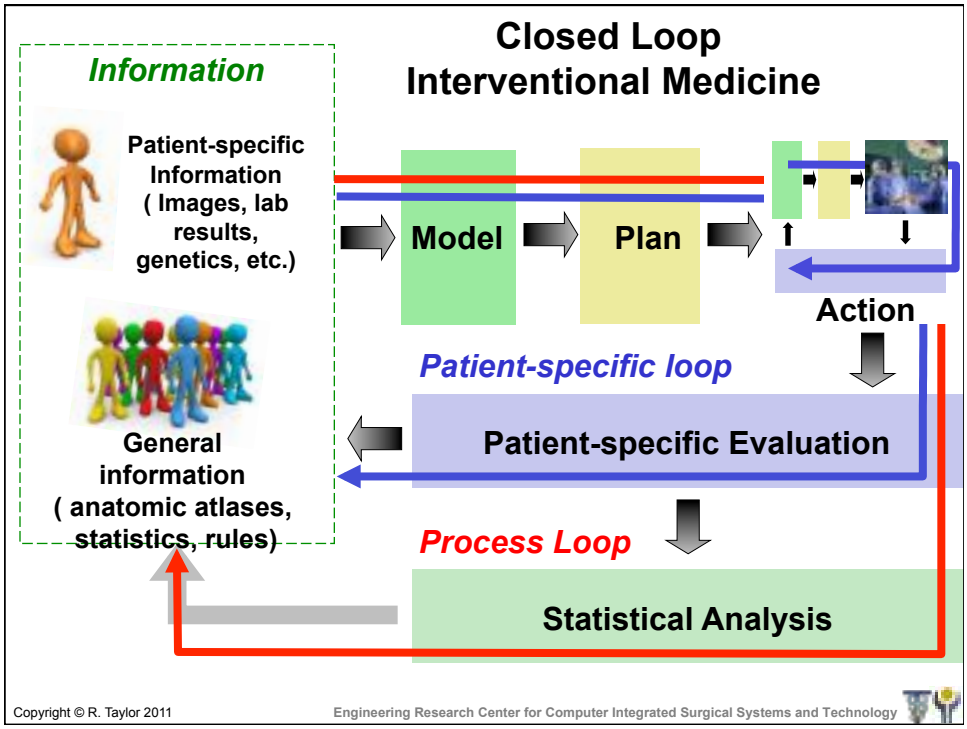
Example: Robotic Joint Replacement Surgery



Taylor, Kazanzides, Paul, Mittelstadt, *et al*.

Manual Surgery **Robotic Surgery**


Closed Loop
Interventional Medicine
Information
Patient-specific
Information
(Images, lab
results,
genetics, etc.)
General
information
(anatomic atlases,
statistics, rules)
Model
Plan
Action
Patient-specific loop
Patient-specific Evaluation
Process Loop
Statistical Analysis
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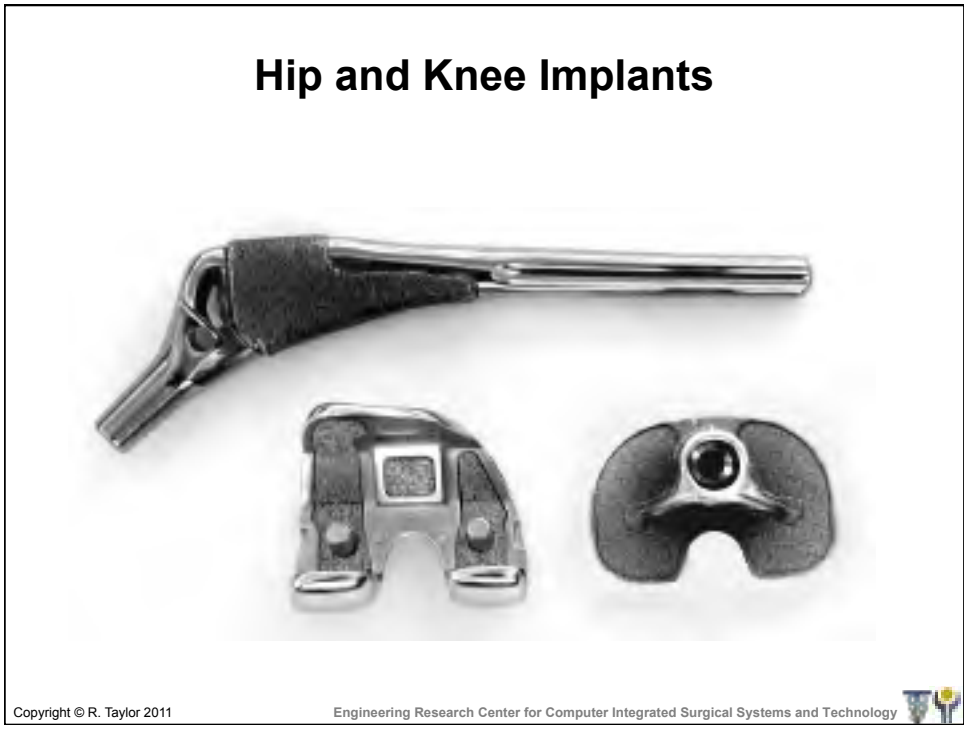
Hip and Knee Implants
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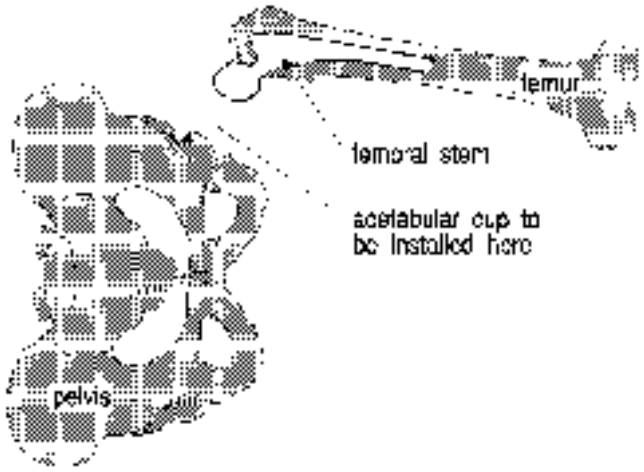
Total Hip Replacement Surgery



ROBODOC® (Integrated Surgical Systems)

- **History**
  - Veterinary use (IBM prototype, ’90)
  - Clinical use (US ’92 Europe, ’94)
  - Marketed in Europe, Asia
  - 30 systems in Europe & Japan (9/’00)
  - FDA approval still pending
- **Total Hip Replacement (THR)**
  - First clinical case 1992
  - ~ 8000 primary, ~300 revisions (9/’00)

  ➡ No fractures or other complications due to robot (9/’00)
- **Total Knee Replacement (TKR)**
  - First clinical case March 2000
  - ~ 30 cases as of September 2000

  ➡ No fractures or other complications

Integrated Surgical Systems
Company History

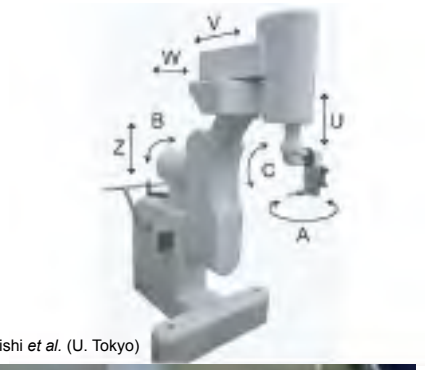
- Founded 1990
- Robodoc system milestones
  - 1st Canine THR - 1990
  - 1st Human THR - 1992
  - 1st European THR - 1994
  - European CEmark - 1996
  - Pinless THR - 1998
  - TKR - 2000
- Other Company milestones
  - IPO - 1997
  - Neuromate Acquisition - 1997
  - Suspended operations - 2005
  - Resumed operations - 2006
  - Assets sold to Novatrix - 7/2007
  - FDA Approval for hip – 2008
  - Robodoc now owned by Curexo

CASPAR™ System (URS)

- **History**
  - Introduced 1997
  - About 50 installed in Europe
- **Experience**
  - ~ 300-500? THR cases
  - TKR demo 4/2000
  - ACL tunnel drilling ?/2000
  - Few complications
- **Company is now defunct**

Other Robotic THR & TKR Systems (Partial List)

- **"Conventional" serial link arms**
  - Northwestern; U. Washington; U. Tokyo; Rizzoli Institute; Grenoble
- **Parallel link approaches**
  - Aachen;Technion; KAIST; Mazor
- **Cooperative Control**
  - Grenoble (PaDyc)
  - Imperial College (ACROBOT)
  - Mako robotics
- **Freehand Navigation-Assisted**
  - Blue Belt Technologies



Mitsuishi *et al.* (U. Tokyo)

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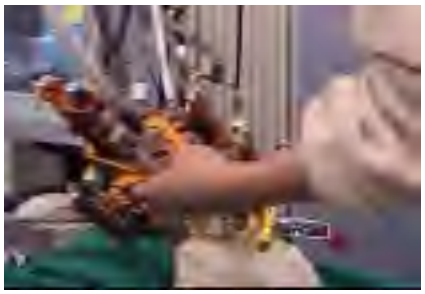

D. S. Kwon, J. J. Lee, Y. S. Yoon, S. Y. Ko, J. Kim, J. H. Chung, C. H. Won, and J. H. Kim, "The Mechanism and the Registration Method of a Surgical Robot for Hip Arthroplasty," presented at IEEE International Conference on Robotics and Automation,1889-2949, 2002.

D. Glozman
& M. Shoham

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ACROBOT surgical robot

Mako Robotics Rio
http://www.makosurgical.com/

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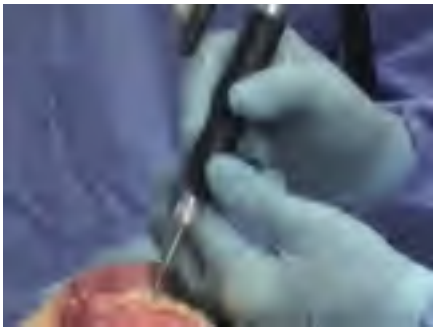


Blue Belt Technologies: http://www.bluebelttech.com/

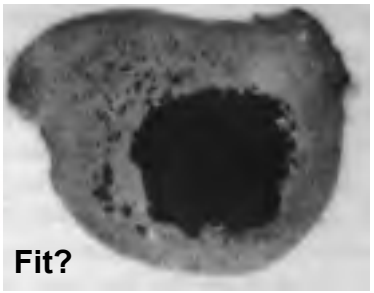
Conventional THR Planning

- Based on patient x-rays
- Surgeon selects implant design based on acetate overlays
- Difficulty in gauging magnification
- Placement determined in the OR

Total hip replacement

Total hip replacement

Placement?



Fit?

Robodoc THR Planning

- Implant pins in hip, knee (original, “pin version” only)
- CT scan patient
- Load images into workstation
- Resample images to produce cross-sections aligned with bone
- Select implant
- Place implant
- Output cutter file (in CT coordinates)

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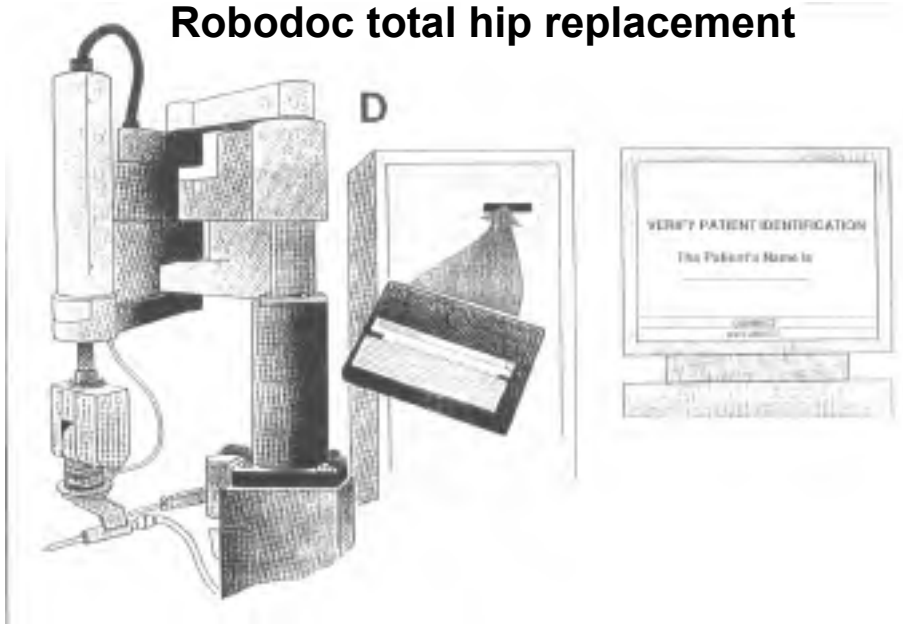
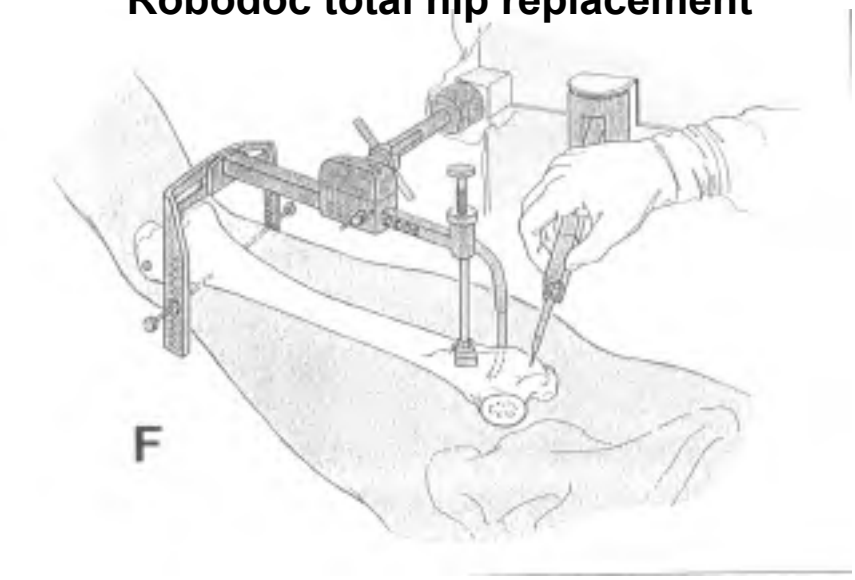
Robodoc total hip replacement



Robodoc total hip replacement



Key Step: Registration

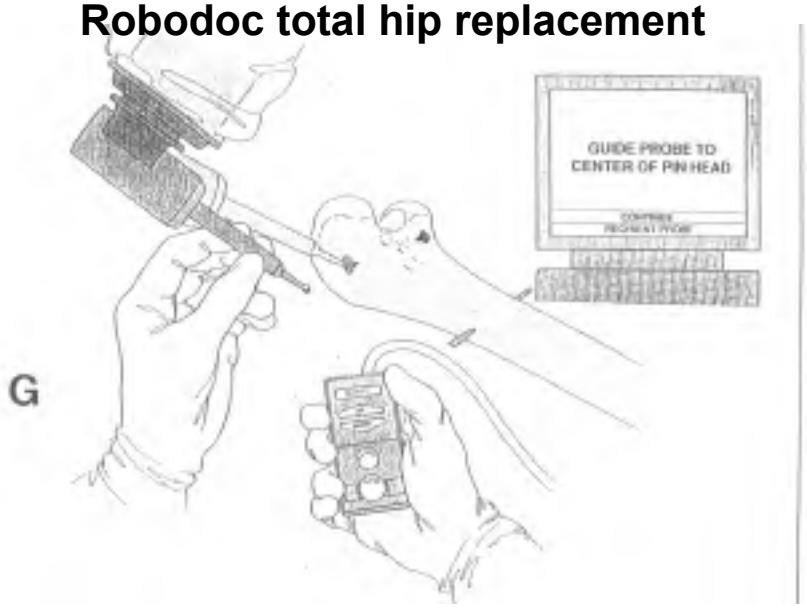
- Establishing a transformation (conversion) from one coordinate system to another
  - CT coordinates (preoperative plan)
  - Robot coordinates (surgery)

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

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 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)

Robodoc total hip replacement



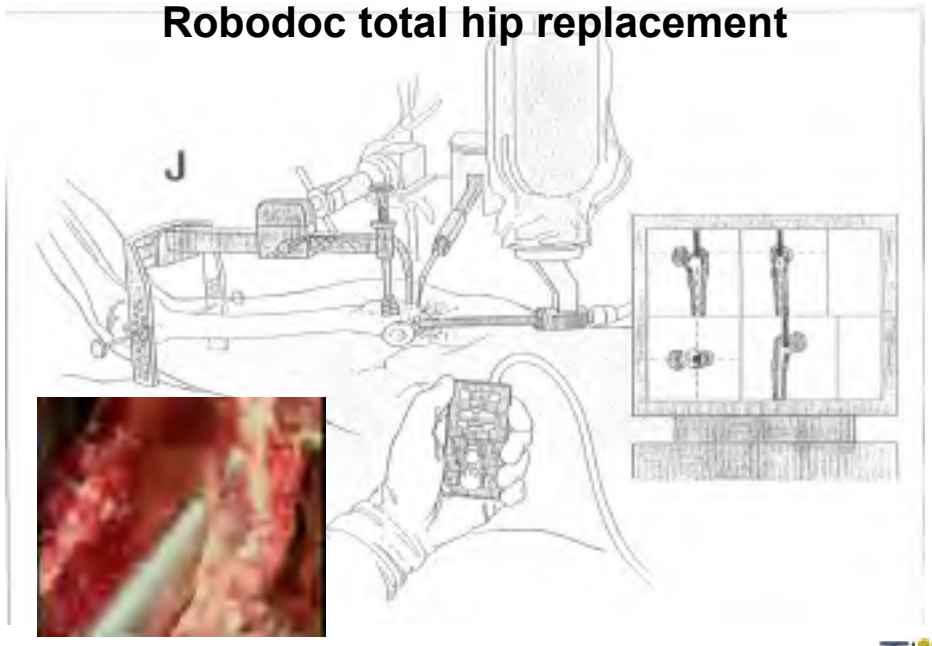
Pin-Based Registration

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

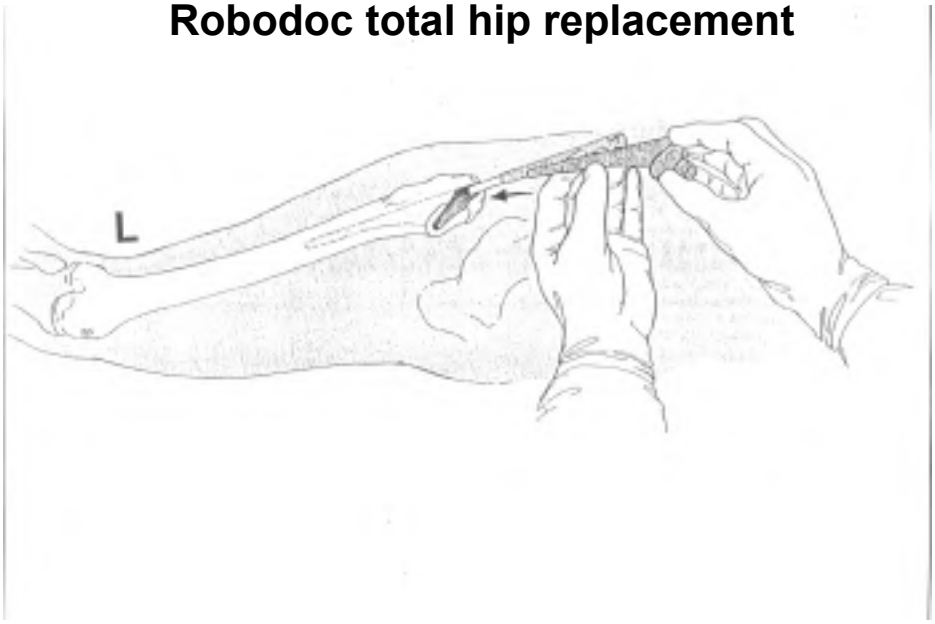
Pinless Registration

- 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

Robodoc total hip replacement



Robodoc total hip replacement



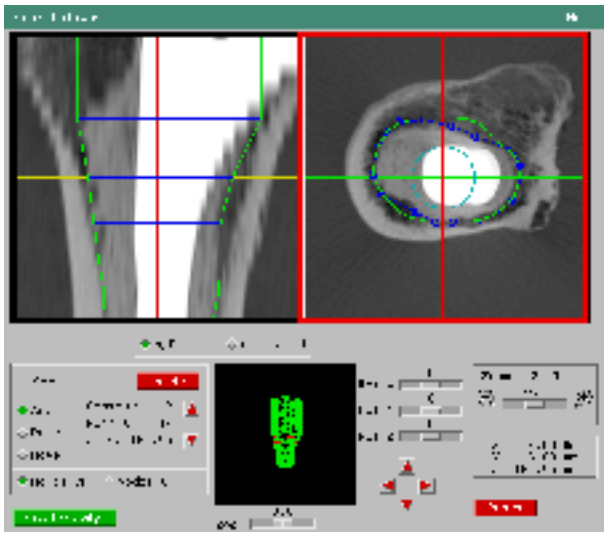
Movies

Börner video – pins

Movies

Pinless

Revision THR (cement removal)



Leverage from Surgical CAD/CAM in Robotic THR

- **Better planning**
- **Ability to carry out the plan**
  - Accurate shape
  - Accurate placement
  - Limited forces
  - Reduced complications
  - Shape flexibility
  - Consistent execution
- **Process learning**

Leverage from Surgical CAD/CAM in Robotic THR

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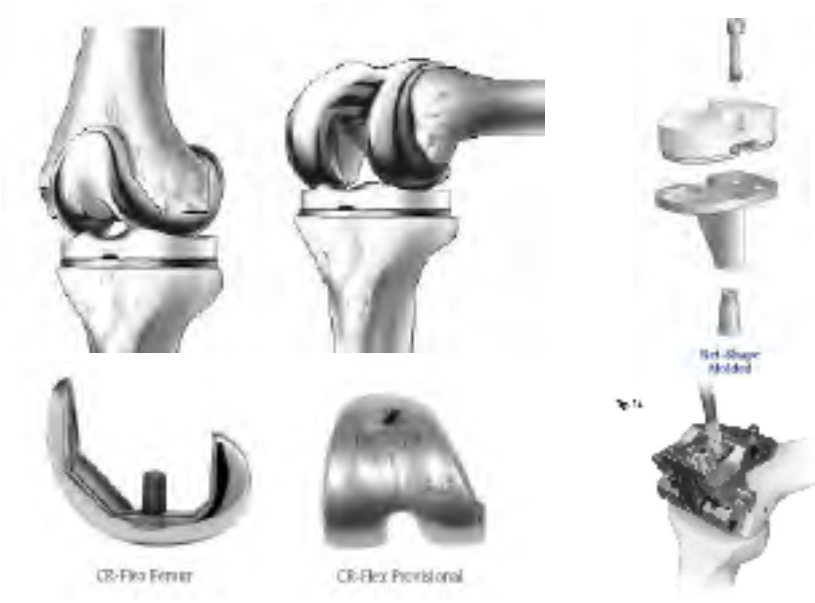
Robodoc® Total Knee Replacement



Illustrations: Zimmer, Inc.

Manual Practice

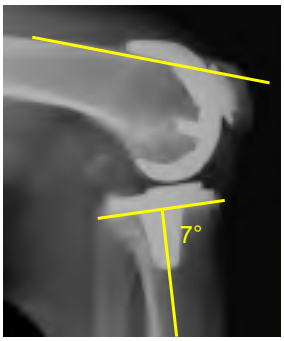
http://www.zimmer.com/z/ctl/op/global/action/1/id/9403/template/MP/prcat/M3/prod/y

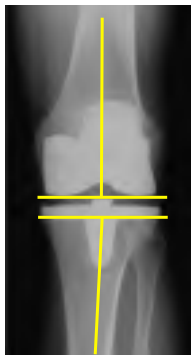
Some useful web links

- Acrobot: http://www.acrobot.co.uk
- Mako: http://www.makosurgical.com
- Robodoc: http://www.robodoc.com
- Blue Belt: http://www.bluebelttech.com
- Zimmer: http://www.zimmer.com

Fundamental Challenges

- **Geometric Challenge**
  - Align mechanical axes
- Functional Challenge
  - Balance ligaments
    - Mobility
    - Stability





Thanks to Eric Stindel, MD, Ph.D.

Fundamental Challenges

- Geometric Challenge
  - Align mechanical axes
- **Functional Challenge**
  - Balance ligaments
    - Mobility
    - Stability

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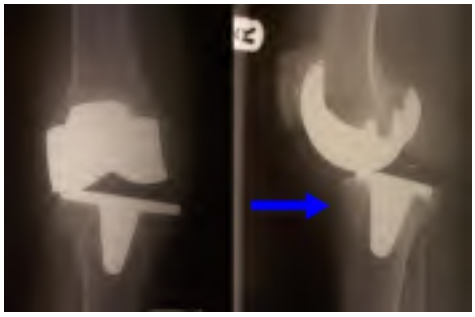
Ligament Balancing

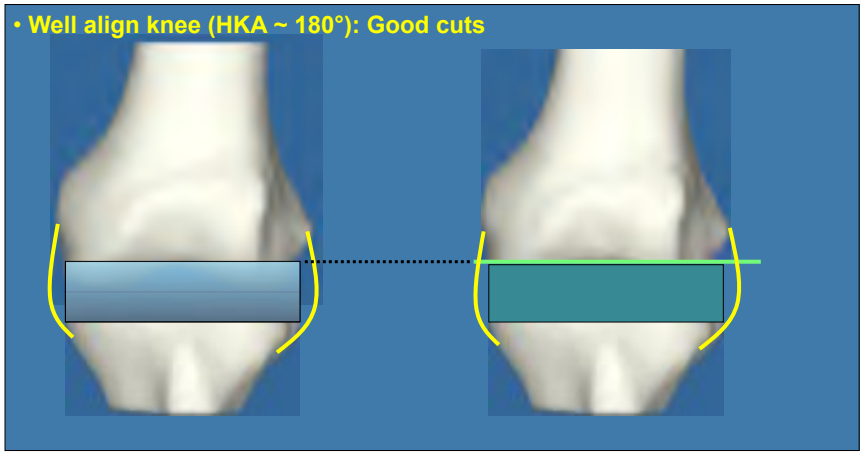


•Lift-off = wear

•Instability

Thanks to Eric Stindel, MD, Ph.D.

Ligament Balancing



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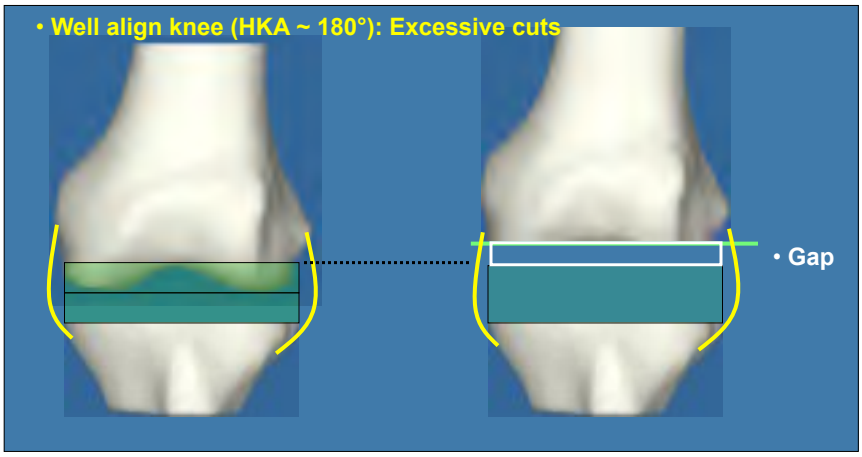

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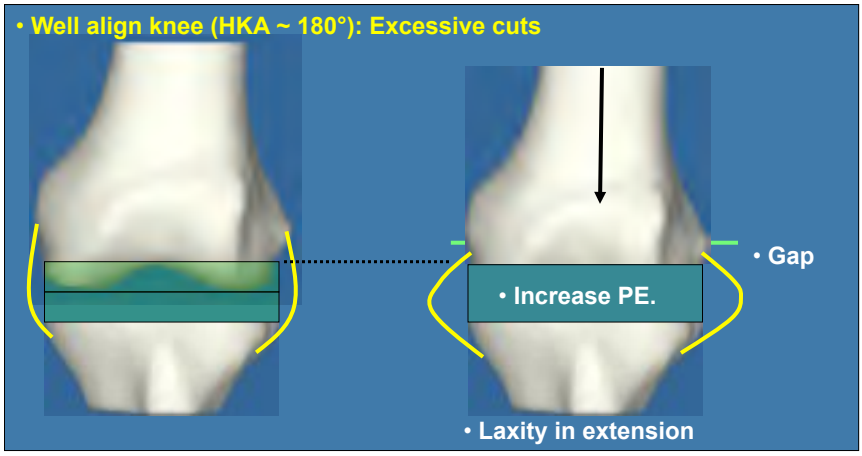

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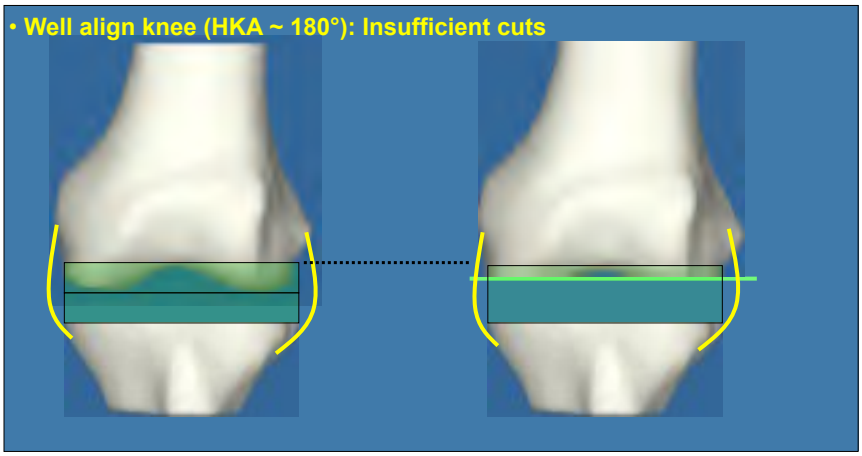

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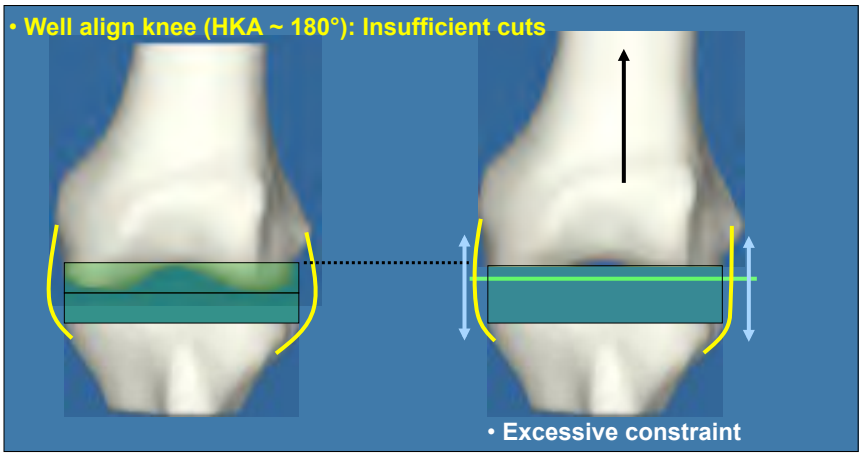

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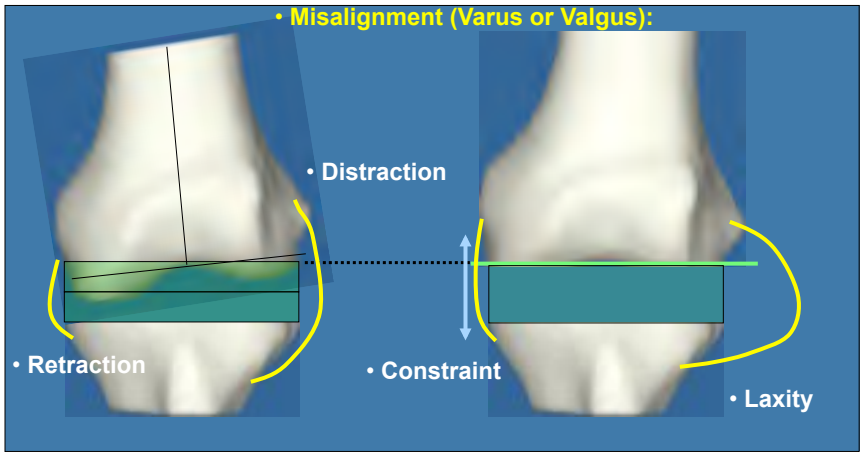

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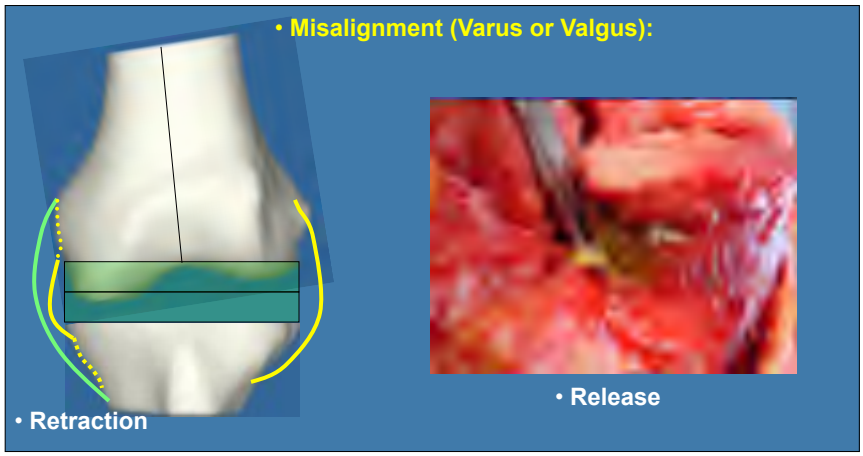

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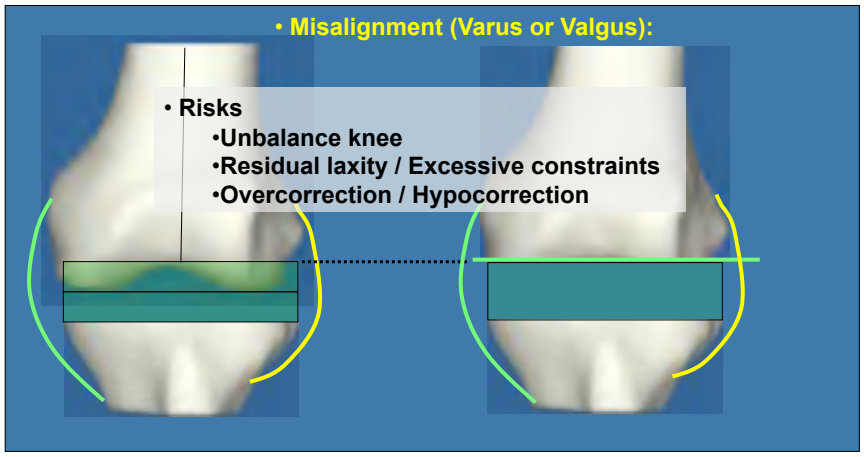

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Manual Instrumentation (with navigation markers)

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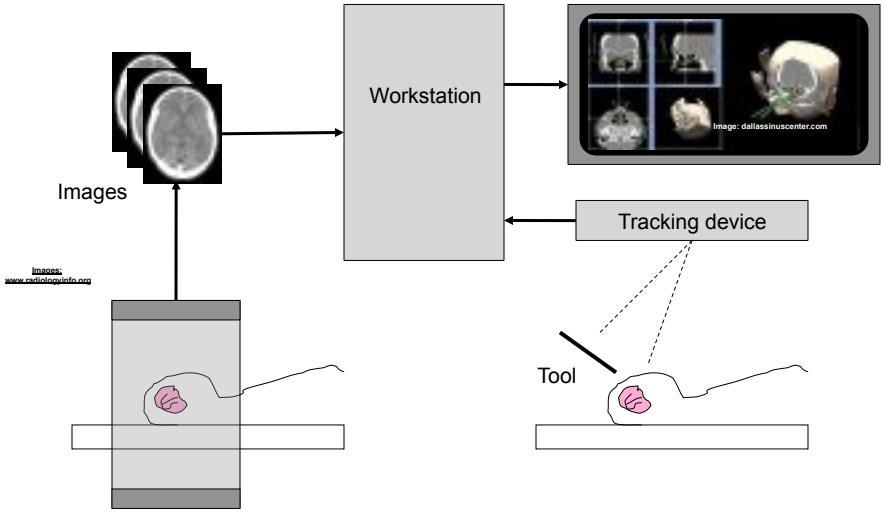
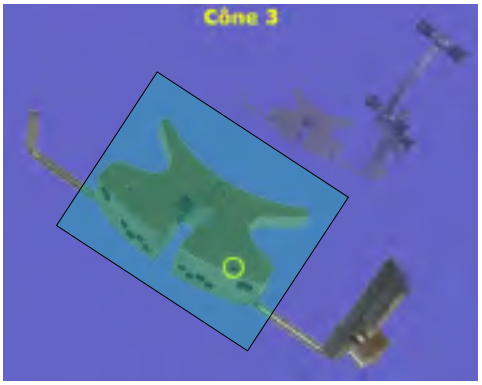
Surgical Navigation Systems



Navigated Cutting Guides



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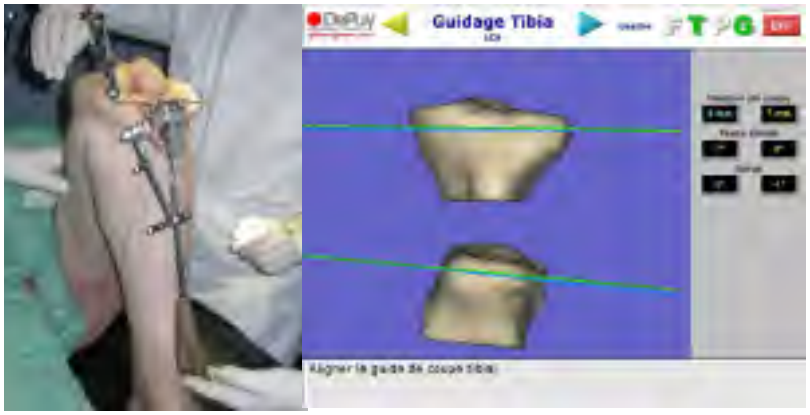

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Robodoc® Total Knee Replacement

Praxiteles Robotized Milling Guide

Thanks to Eric Stindel, MD, Ph.D.

Mako Rio System

http://www.youtube.com/watch?v=Wun4AJcFZSw

Blue Belt PFS system

PFS Knee Resurfacing

http://www.bluebelttech.com/videos.php

Case Study: Robodoc Early History

- Although the experiences here are quite old, this account is still very useful as a case study illustrating the extended path from early bench prototypes through commercial deployment

1988

1990

1992

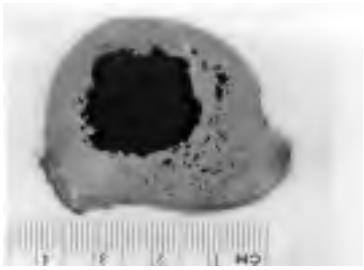
1995-2002

Robodoc Early History
(as seen by Peter Kazanzides)

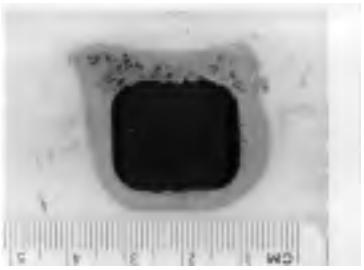
- Ph.D. EE, Brown University (Robotics)
- Post-doc at IBM T.J. Watson Research Ctr.
- Visiting Engineer at UC Davis
- Founder and Director of Robotics and Software at Integrated Surgical Systems
- Chief Systems and Robotics Engineer at JHU ERC for CISST

ROBODOC Benefits

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



Broach



Robot

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

1995-2002 ROBODOC in Europe and Asia

March 1996	C System design completed
April 1996	First 2 installations (Germany)
Nov 1996	ISS initial public offering (NASDAQ)
March 1998	First pinless hip surgery
Feb 2000	First knee replacement surgery

ROBODOC History

2003-2007 ROBODOC RIP

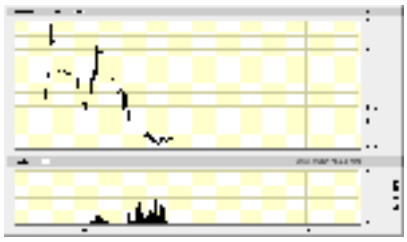
Oct 2003	Class action lawsuit in Germany
June 2005	ISS “ceases operations”
June 2006	German high court ruling against plaintiff
Sept 2006	ISS resumes operations
June 2007	ISS sells assets to Novatrix Biomedical

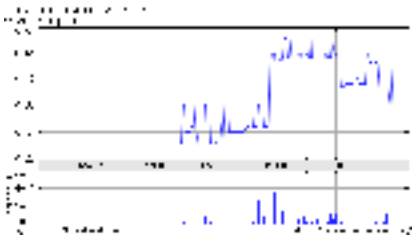
2007-present ROBODOC reborn

Sept 2007	Curexo Technology formed (Novatrix)
Sept 2007	Curexo files 510(K) with FDA
Aug 2008	Robodoc receives FDA approval (for hip replacement surgery)

ROBODOC Status

- Approximately 50 systems were installed worldwide
  - Europe (Germany, Austria, Switz., France, Spain)
  - Asia (Japan, Korea, India)
  - U.S. (Clinical trial for FDA approval)
- Over 20,000 hip and knee replacement surgeries
- ROBODOC no longer used in Europe
- One Korean hospital uses system regularly – claim 2,500 surgeries/year





User Studies of ROBODOC THR

- In-vitro tests (cadavers and synthetic bone)
  - Compare robot and manual techniques
  - Evaluate parameters unique to robot technique
- Controlled clinical trials
  - Small studies comparing robot and manual techniques
- Reports of clinical experience
  - Large number of patients, no control group

In-Vitro Test Results

- Several studies showed that ROBODOC achieves more accurate placement
  - Is this clinically relevant?
- Other studies found that implant stability after robotic surgery is not always better than after manual surgery
  - Implies sub-optimal specification of implant cavity

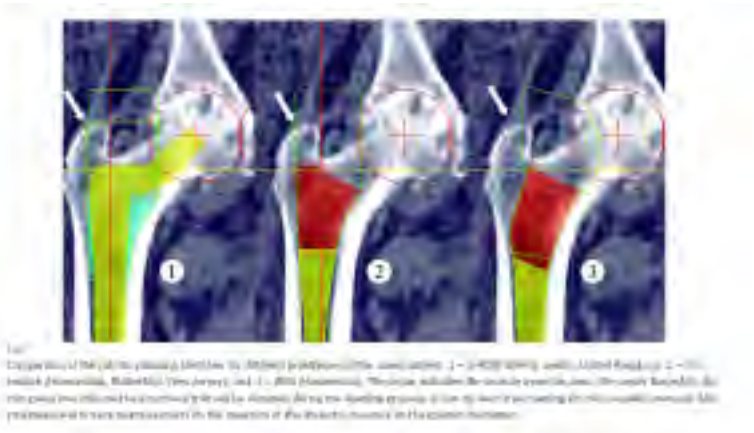
Controlled Clinical Trials

- Two multi-center clinical trials in U.S. (pin-based and pinless)
- One clinical trial in Germany (pin-based)
- One clinical trial in Japan (pin-based)

Clinical Trial Results

- Robot procedure is longer than manual procedure
- In some cases, less postoperative pain in robot group
+ Radiographic analysis showed better position and fit for robot group
+ Fewer intraoperative fractures in robot group
- German study had a higher revision rate (due to dislocations) for robot group
  – Result of bad surgical plans

German Clinical Trial



Honl M, Dierk O, Gauck C, Carrero V, Lampe F, Dries S, et al. Comparison of Robotic-Assisted and Manual Implantation of a Primary Total Hip Replacement, A Prospective Study. J of Bone and Joint Surgery. 2003 Aug;85-A(8):1470–1478.

Routine Surgical Use

- BGU Frankfurt had 3 ROBODOC systems and performed over 5000 robot surgeries
  - Average surgery time was 20 minutes longer
  - No intraoperative fractures
  - Overall good results

Commercial System Lessons

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