Robotic Joint Replacement Surgery

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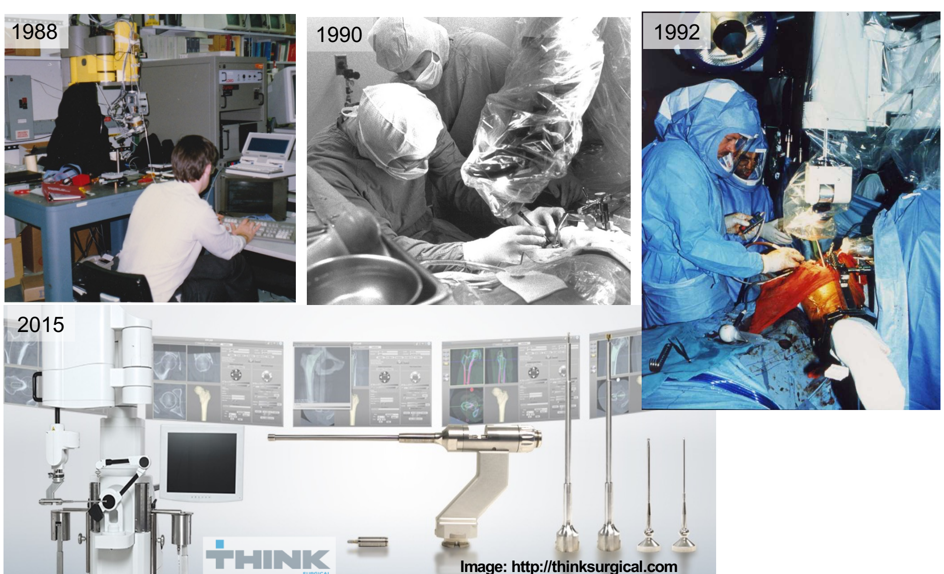
My introduction to medical robotics: Robotic Hip and Knee Replacement



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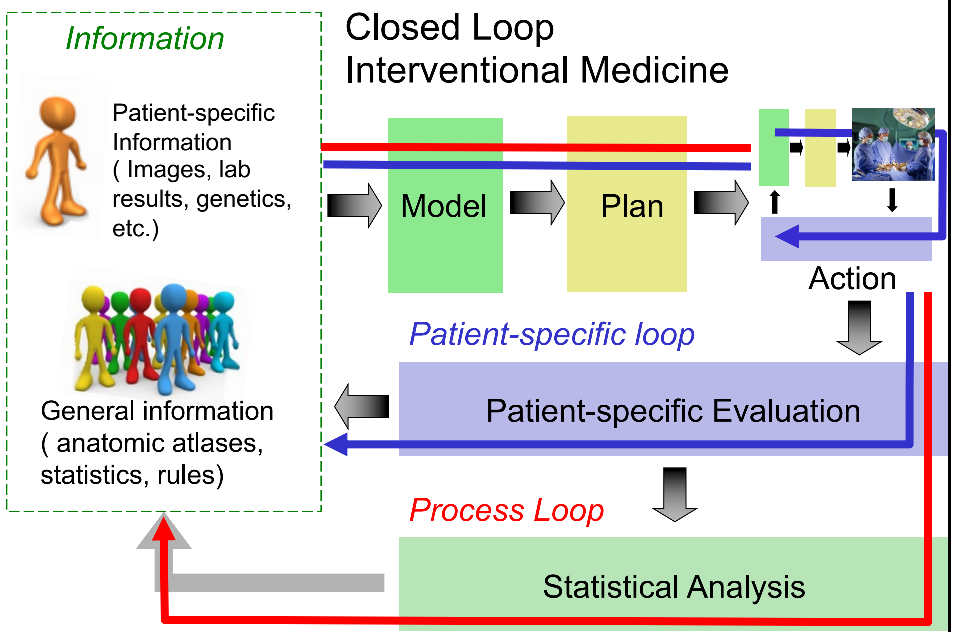

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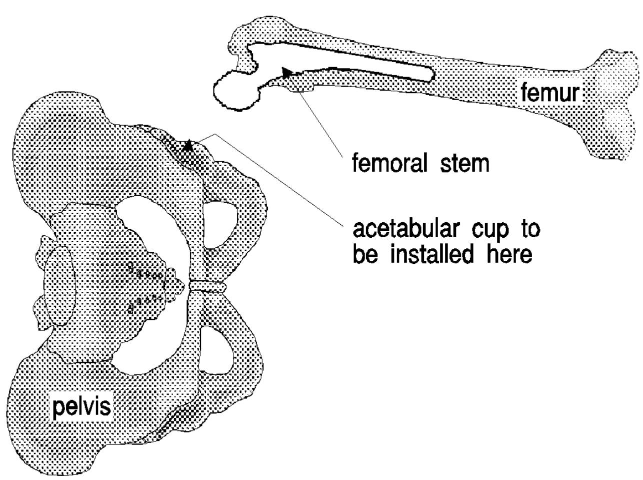
Total Hip Replacement Surgery



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Hip and Knee Implants

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)
- **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
  - New name: Think Robotics

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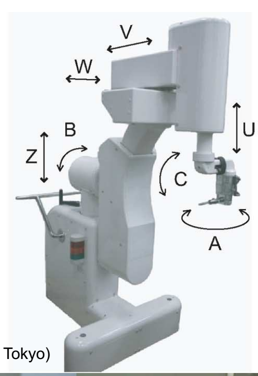
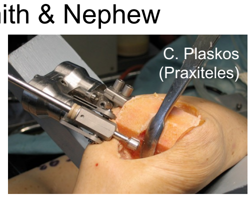
Other Robotic THR & TKR Systems (Partial List)

- “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)
  - Stryker (Mako Rio)
- Freehand Navigation-Assisted
  - Smith & Nephew



Mitsuishi *et al.* (U. Tokyo)



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- Freehand Navigation-Assisted
  - Smith and Nephew

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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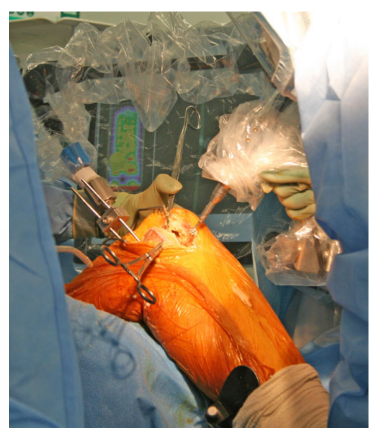

ACROBOT surgical robot

Mako Robotics Rio (Stryker)
http://www.makosurgical.com/

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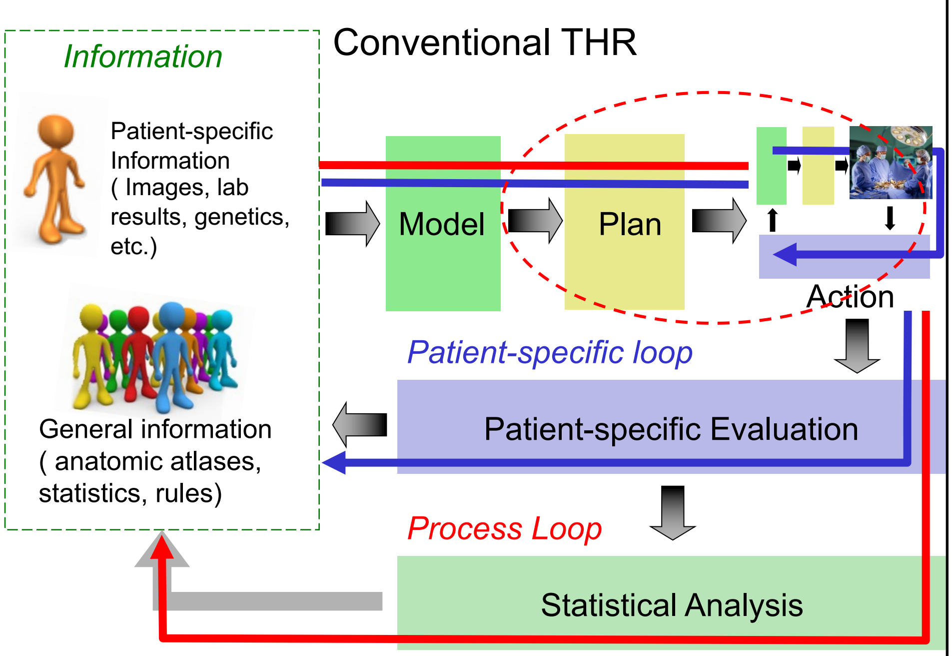
Blue Belt Technologies: http://www.bluebelttech.com/
(Now owned by Smith and Nephew)



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

Integrated Surgical Systems marketing video

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Conventional Total hip replacement

Integrated Surgical Systems marketing video

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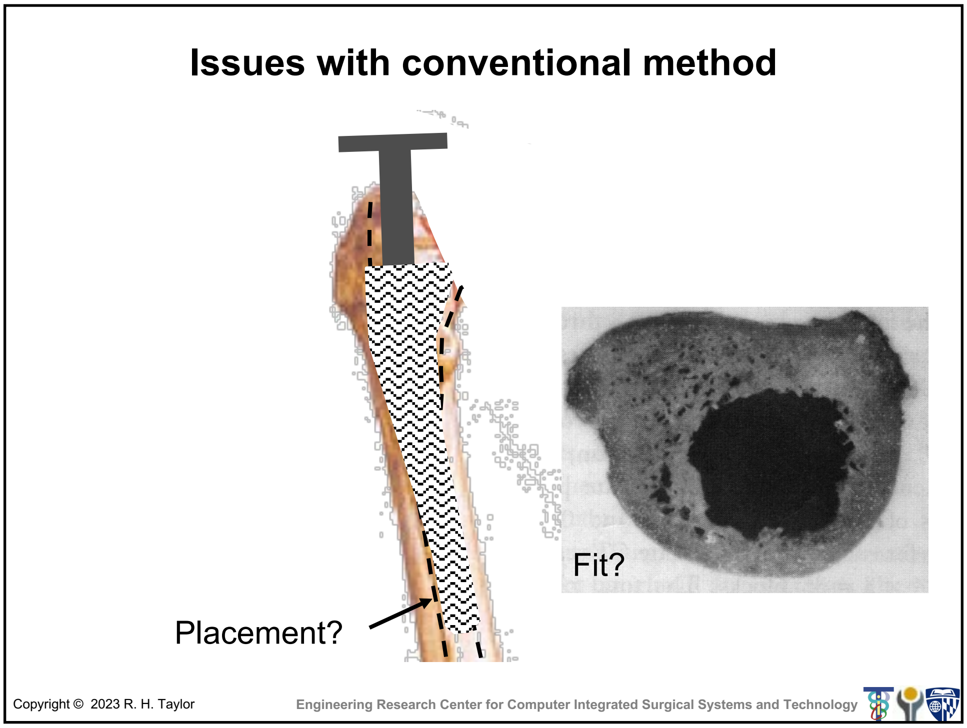
Issues with conventional method
Fit?
Placement?
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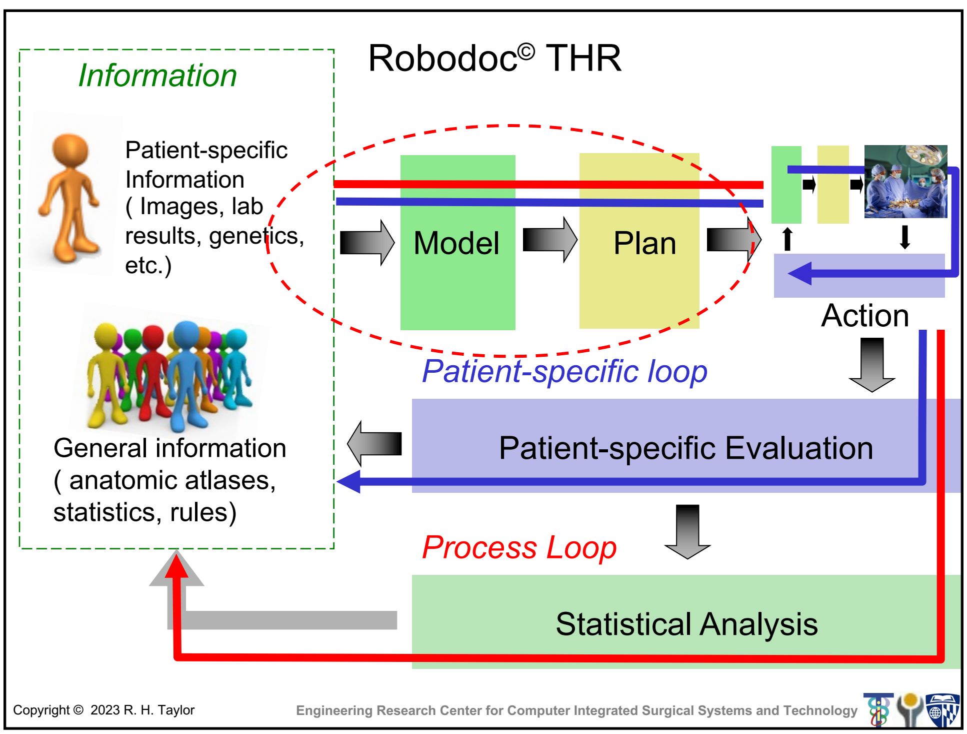
Robodoc© THR
Information
Patient-specific Information (Images, lab results, genetics, etc.)
General information (anatomic atlases, statistics, rules)
Model
Plan
Action
Patient-specific loop
Patient-specific Evaluation
Process Loop
Statistical Analysis
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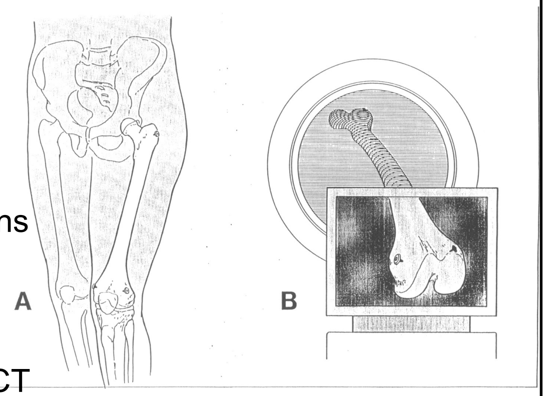
Robodoc THR Planning

- 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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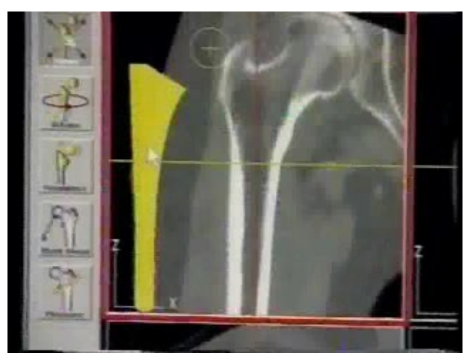

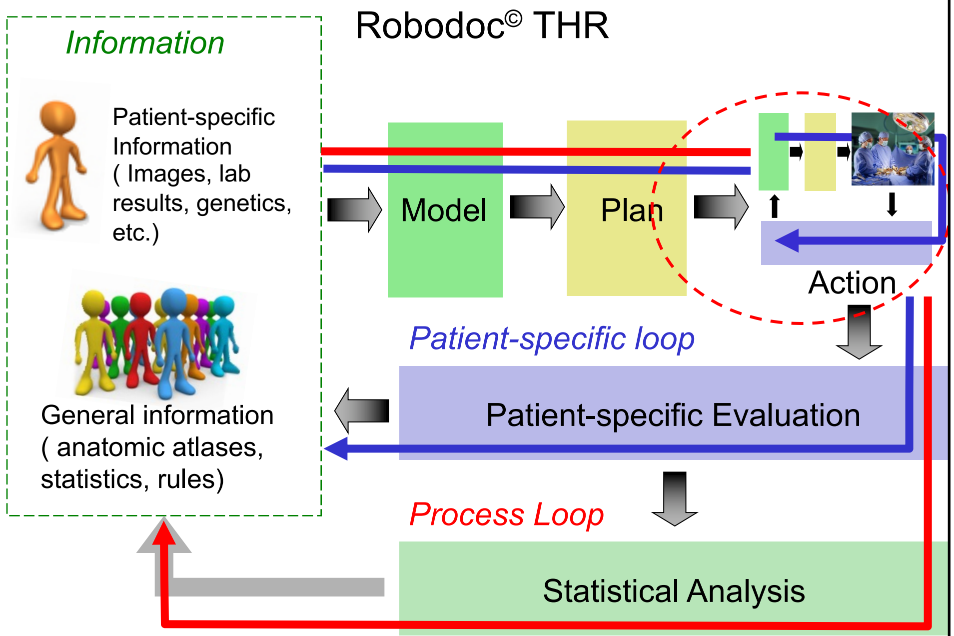

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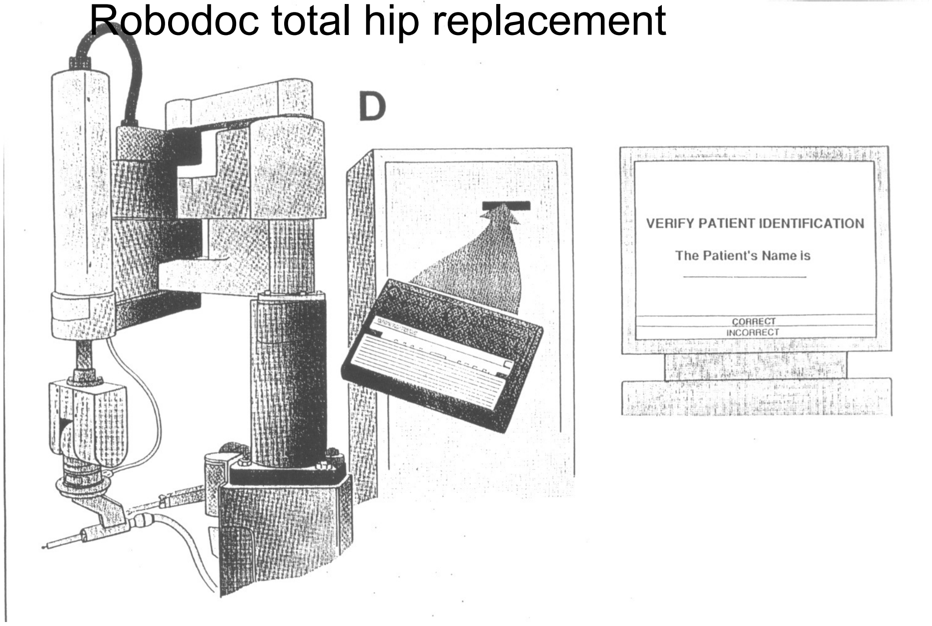
Robodoc total hip replacement



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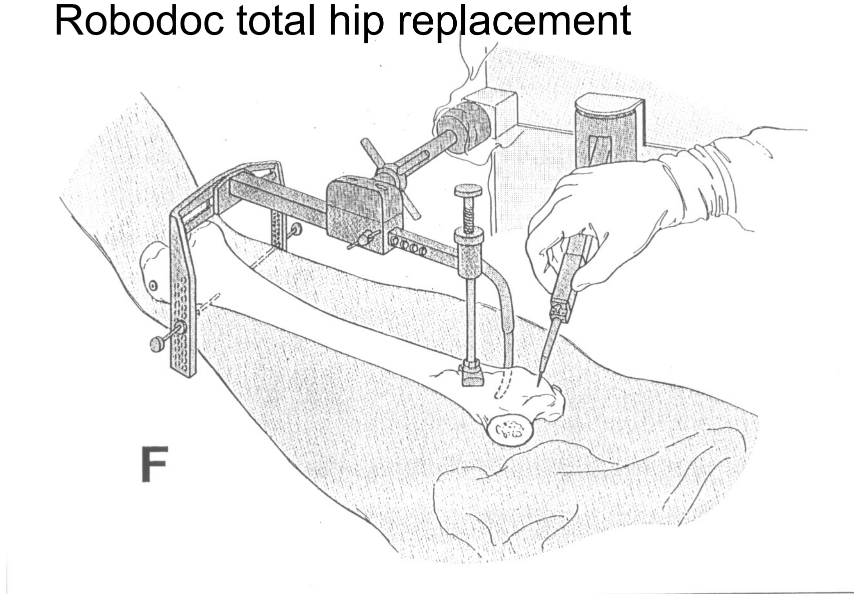
Robodoc total hip replacement



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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.

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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)

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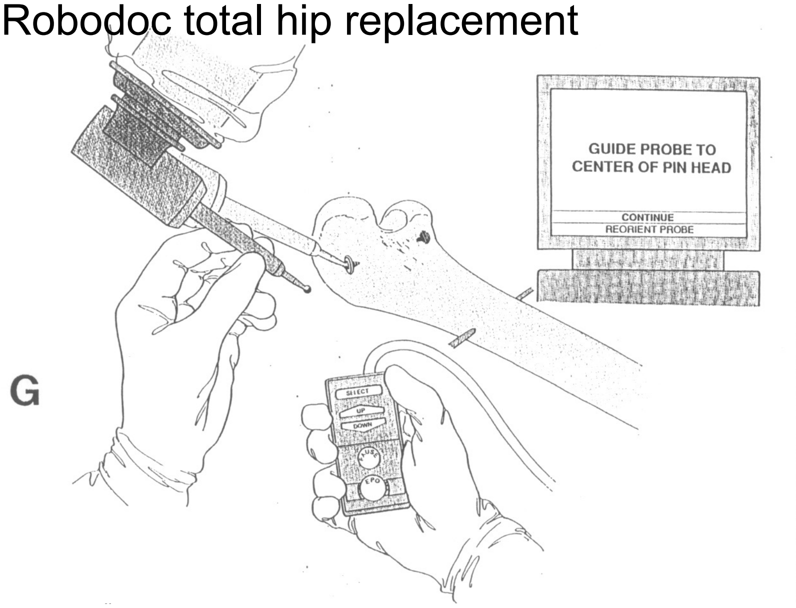
Robodoc total hip replacement



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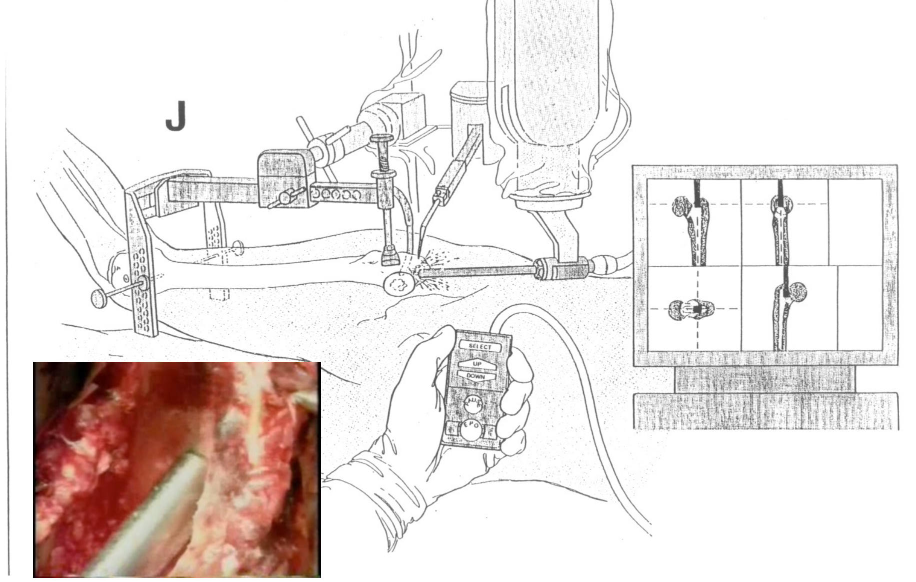
Robodoc total hip replacement



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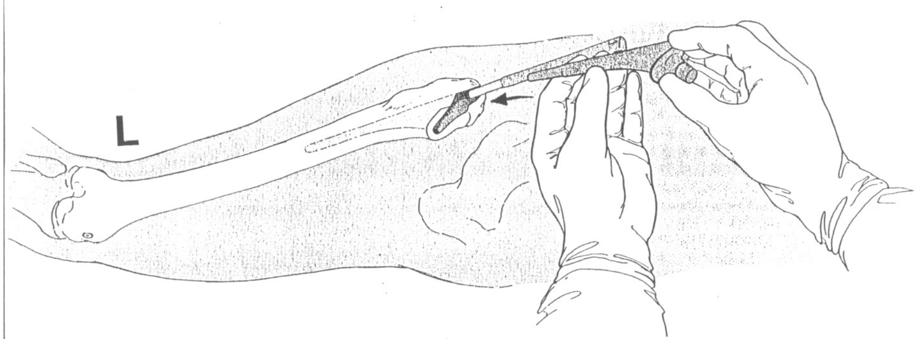
Robodoc total hip replacement



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Movies

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Pin-Based Registration

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

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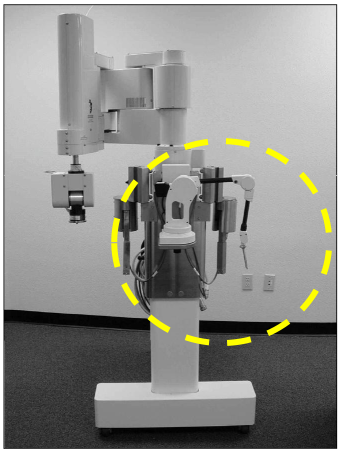
Pinless Registration

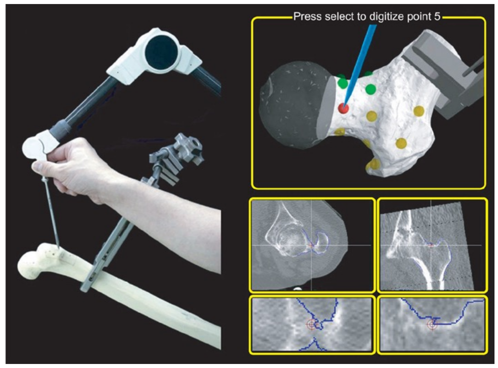
- More complex (point-to-surface matching)
- Surgeon creates surface model of bone from preoperative CT (semi-automatic software).
- Surgeon uses digitizing device to collect bone surface points intraoperatively.
- Software ensures good distribution of points
- Surgeon verifies result



Movies

Pinless Registration Step

ROBODOC: *Feature*-Based Registration

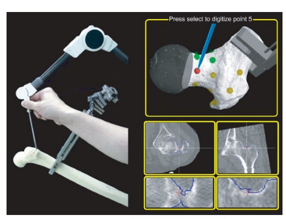


- ✔ Accurate
- ✔ No Pre-Op Surgery
- ✔ No Post-Op Knee Pain from Fiducial
- ✘ Extra Incisions Near Knee

Slide credit: Seth Billings

Figures: http://synapse.koreamed.org/DOIx.php?id=10.4055/cios.2013.5.1.1& vmode=PUBREADER#!po=26.0000 slide from Peter Kazanzides

New Approach: *Feature*-Based Registration with *Tracked Ultrasound*



Sample Proximal Bone with Tracked Pointer

Sample Distal Bone with Tracked Ultrasound

- ✔ Accurate
- ✔ No Pre-Op Surgery
- ✔ No Post-Op Knee Pain from Fiducial
- ✔ No Extra Incisions Near Knee

Slide credit: Seth Billings

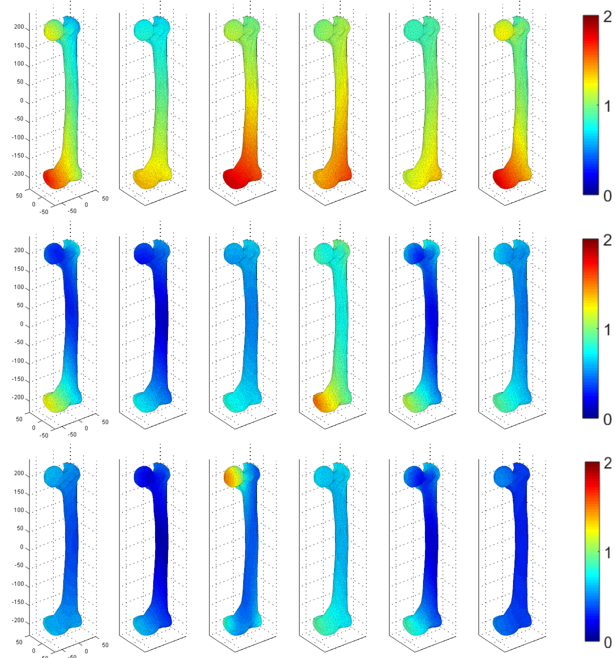
Figures: http://synapse.koreamed.org/DOIx.php?id=10.4055/cios.2013.5.1.1& vmode=PUBREADER#!po=26.0000
http://img.medicalexpo.com/images_me
/photo-g/array-ultrasound-transducer-linear-70298-4700463.jpg

Results

Distal Incision with ICP

Ultrasound with ICP

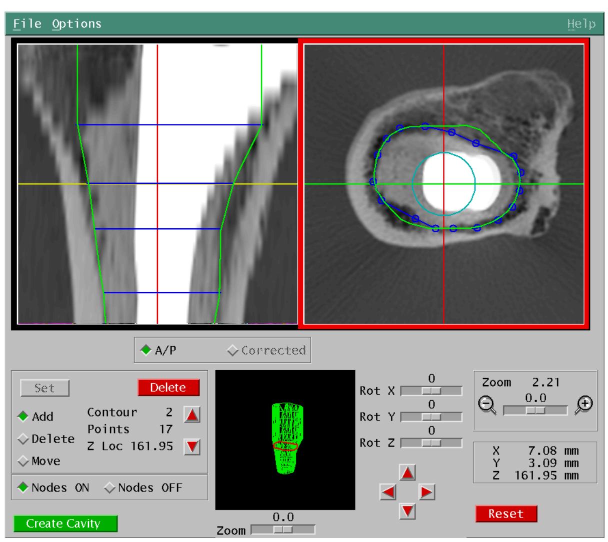
Ultrasound with P-IMLOP



Slide credit: Seth Billings

Modified from Source: Billings SD, Kang HJ, Cheng A, Boctor EM, Kazanzides P, et al. (2015) Minimally invasive registration for computer-assisted orthopedic surgery: combining tracked ultrasound and bone surface points via the P-IMLOP algorithm. Int J Comput Assist Radiol Surg: 1–11. doi:10.1007/s11548-015-1188-z.

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

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Leverage from Surgical CAD/CAM in Robotic THR

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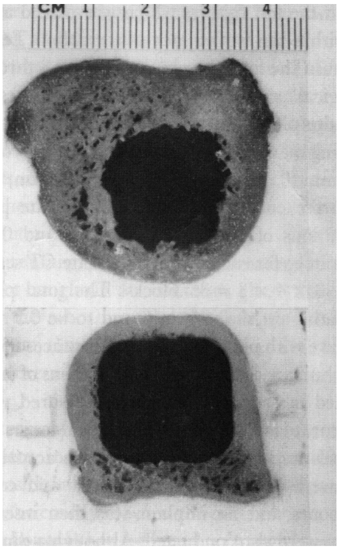

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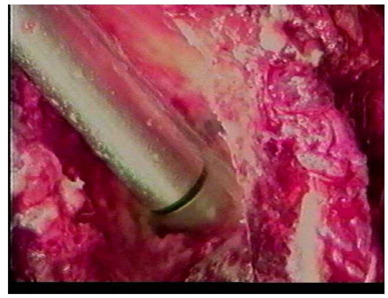

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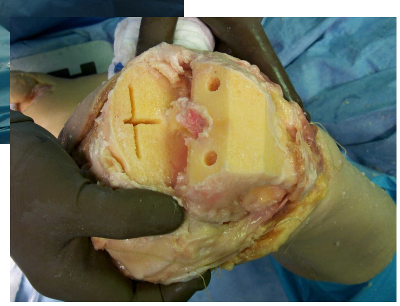
Robodoc® Total Knee Replacement



Photos: Think Robotics and Integrated Surgical systems

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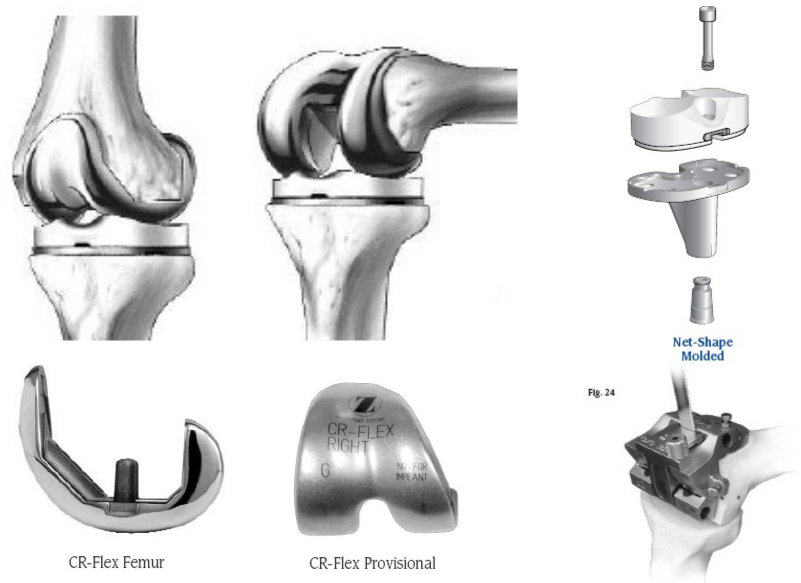

Illustrations: Zimmer, Inc.

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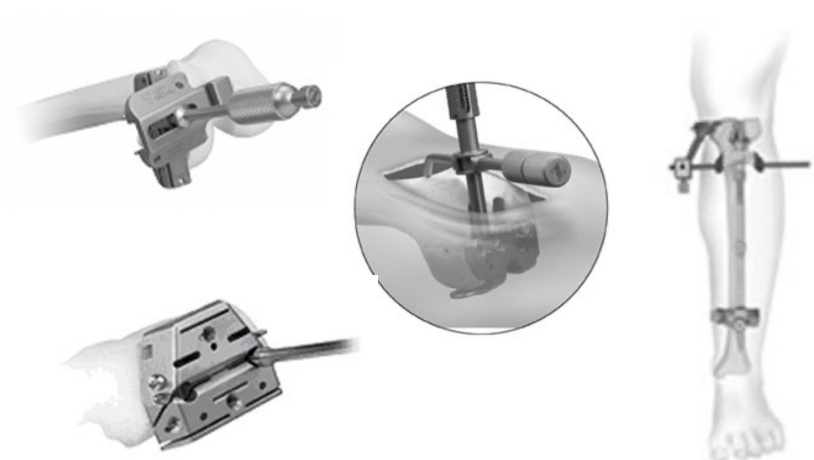
Manual Practice



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

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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

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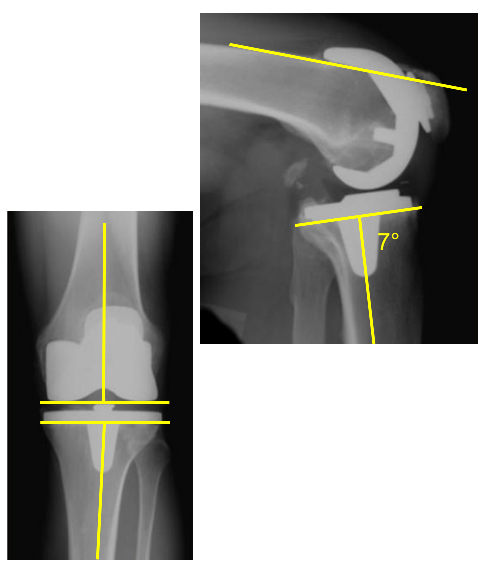
Fundamental Challenges

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



Thanks to Eric Stindel, MD, Ph.D.

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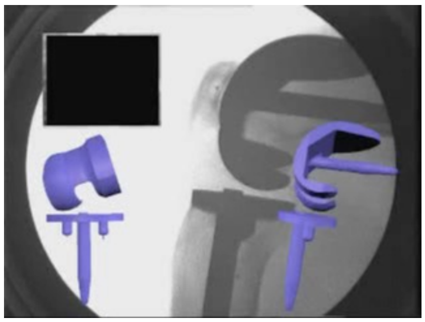
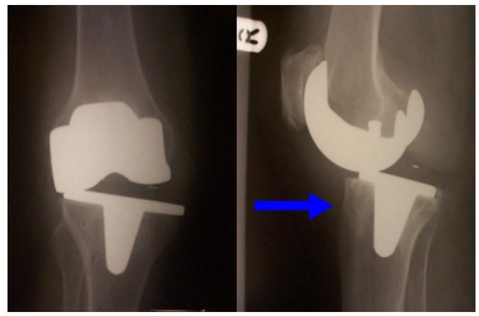
Ligament Balancing

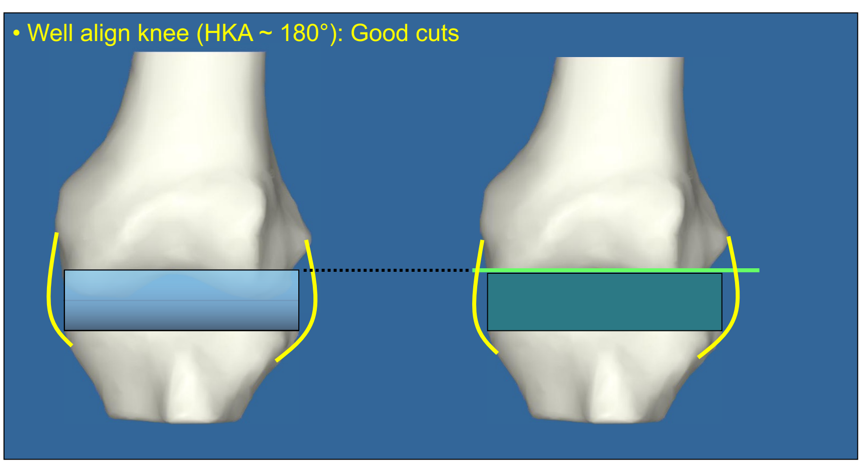




- Lift-off = wear
- Instability

Thanks to Eric Stindel, MD, Ph.D.

Ligament Balancing



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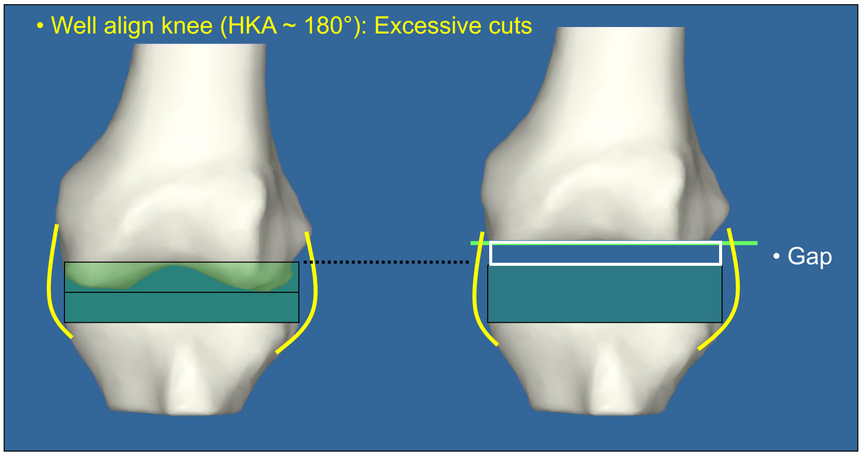

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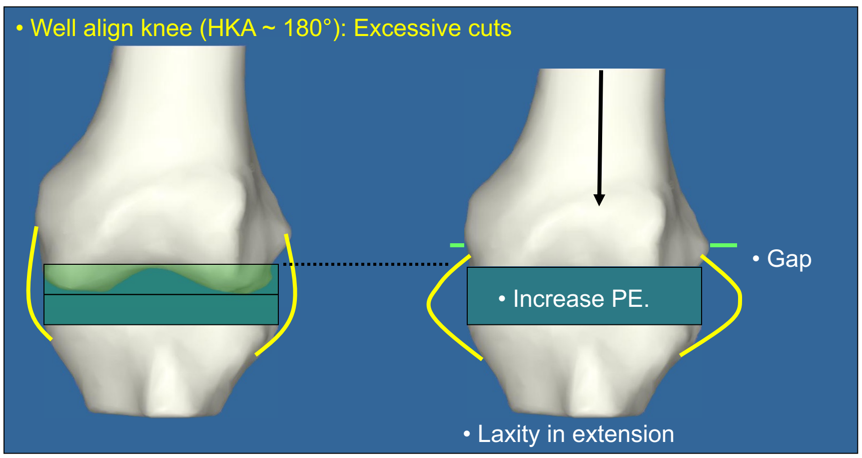
Ligament Balancing



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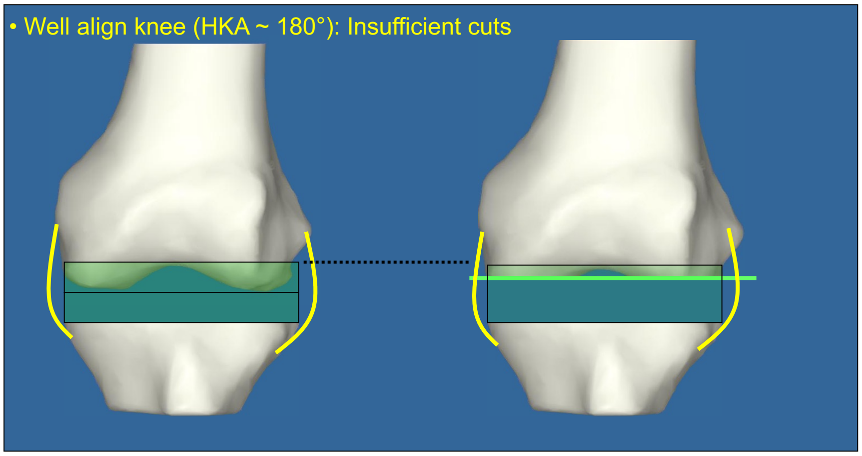
Ligament Balancing



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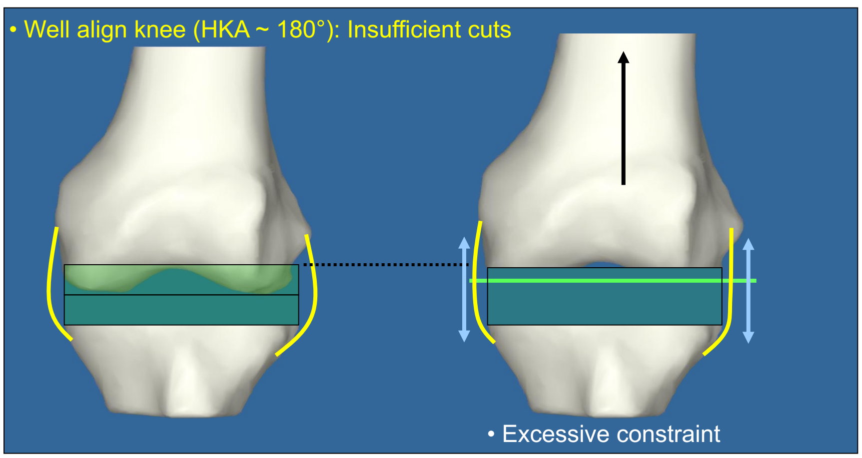

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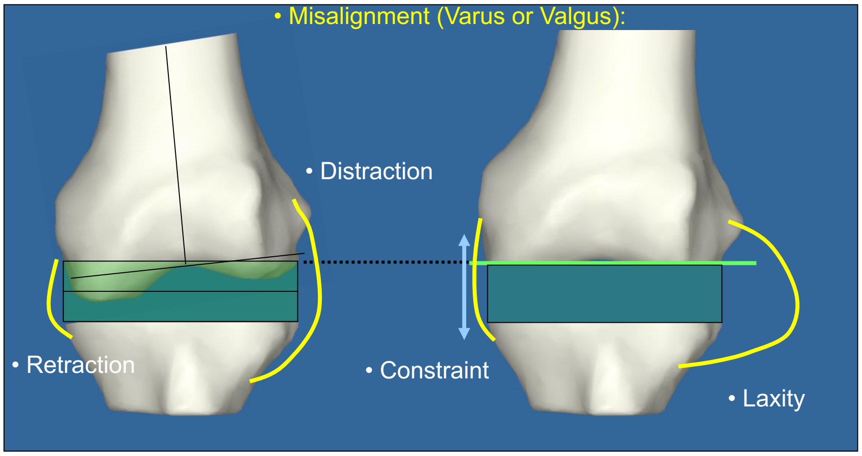

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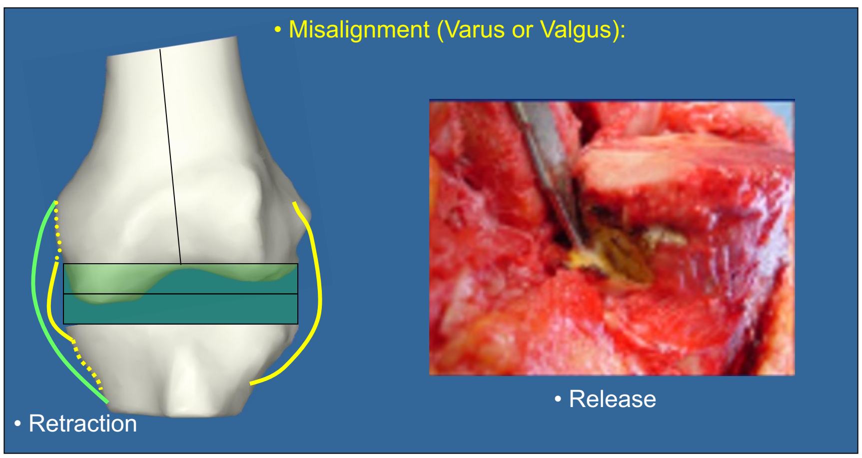

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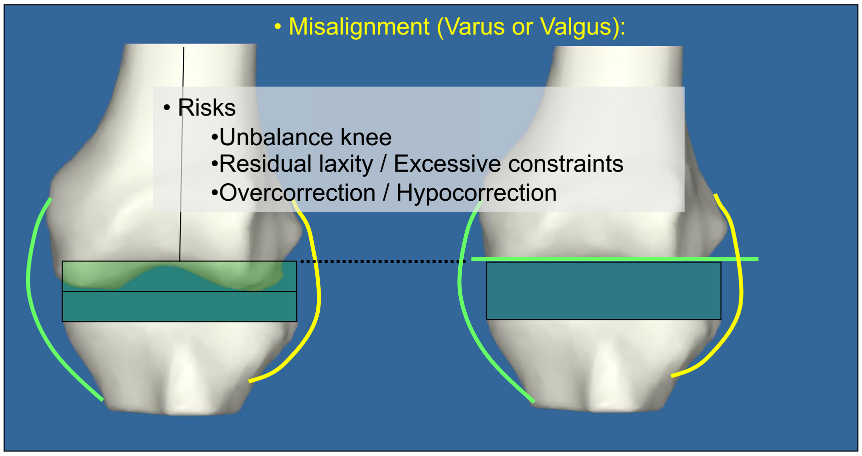

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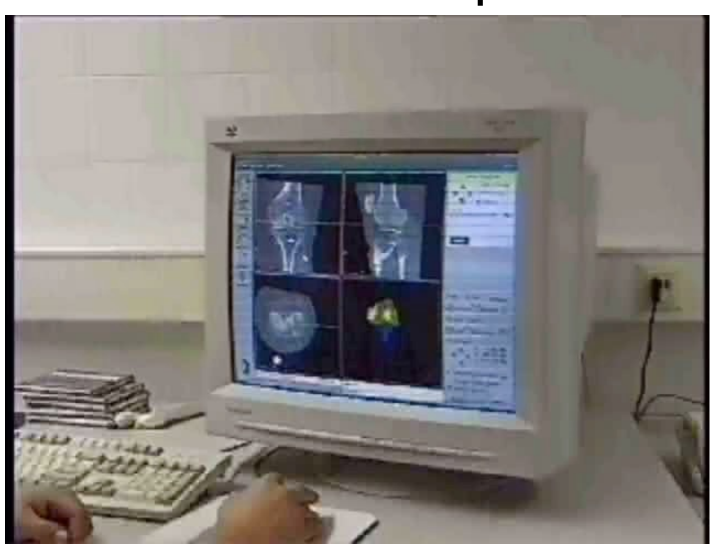
Robodoc® Total Knee Replacement



Robot follows preplanned cutting path after registration

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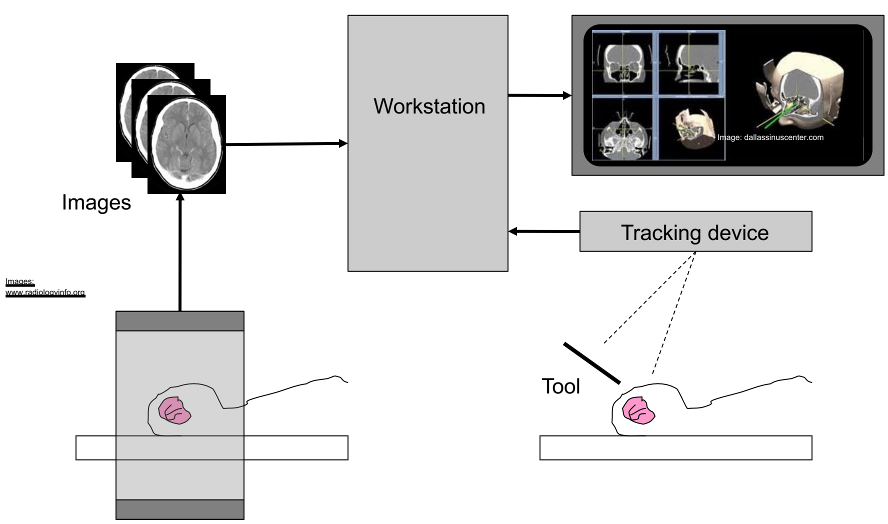
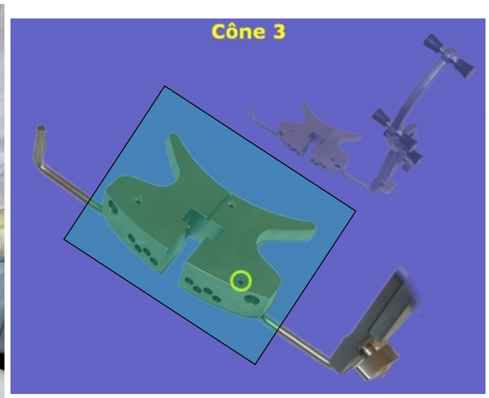
Manual Instrumentation (with navigation markers)

Thanks to Eric Stindel, MD, Ph.D.

Surgical Navigation Systems



Navigated Cutting Guides



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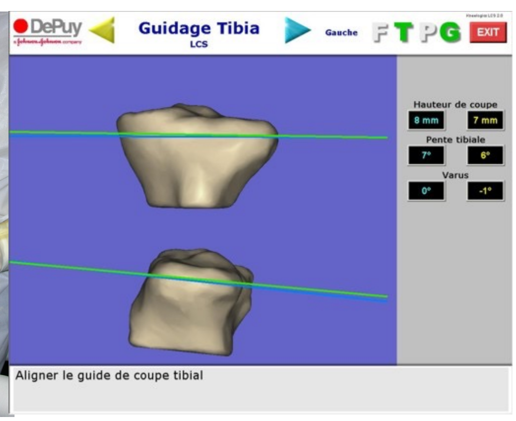
Navigated Cutting Guides



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Mako Rio System (Stryker)

Hand-over-hand cooperative control with constraints

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

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Blue Belt freehand system (Smith & Nephew)

Hand-held navigated cutter with detachable shield that enables cutting based on location with respect to the bone

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

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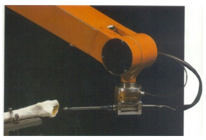
Case Study: Robodoc Early History

- 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

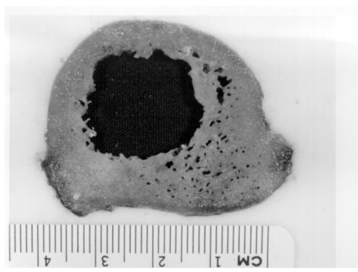
1995-2002

Robodoc Early History (as seen by Peter Kazanzides)

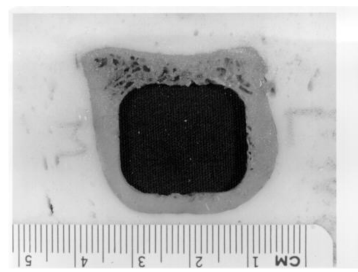
- Ph.D. EE, Brown University (Robotics)
- Post-doc at IBM T.J. Watson Research Ctr.
- Visiting Engineer at UC Davis
- Founder and Director of Robotics and Software at Integrated Surgical Systems
- Chief Systems and Robotics Engineer at JHU ERC for CISST

ROBODOC Benefits

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



Broach



Robot

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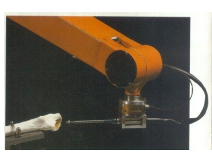
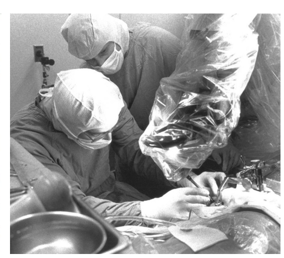
ROBODOC History

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



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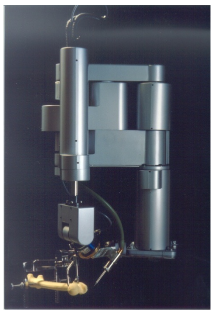
ROBODOC History

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



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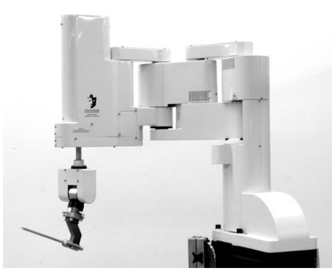
ROBODOC History

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



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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)
	Company now operates in the US as Think Surgical

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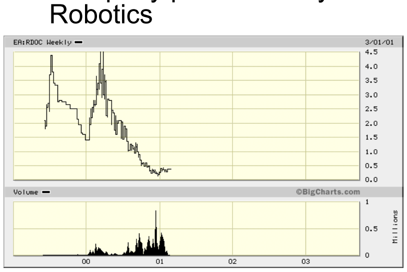
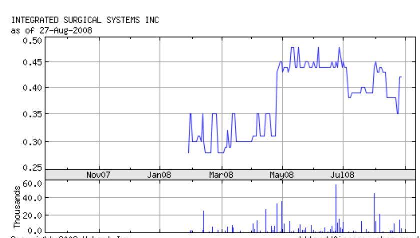
ROBODOC Status

- 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
- Company purchased by Korean company; now operates as Think Robotics





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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

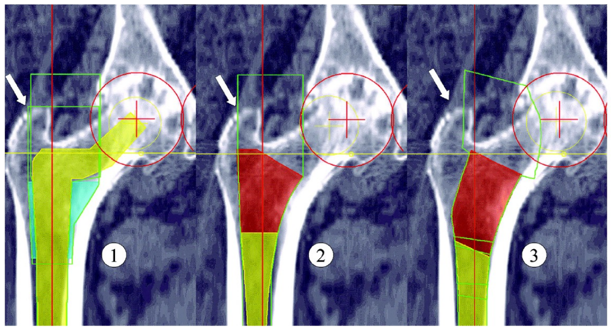

Fig. 5
Comparison of the robotic planning sketches for different prostheses in the same patient. 1 = S-ROM (DePuy, Leeds, United Kingdom), 2 = Osteolock (Howmedica, Rutherford, New Jersey), and 3 = ABG (Howmedica). The arrow indicates the muscle insertion area. The areas framed by the thin green line indicate the structures that will be removed during the reaming process. It can be seen that reaming for the so-called anatomic ABG prosthesis will not encroach as much on the insertion of the abductor muscles on the greater trochanter.

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.

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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

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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.