



# Robotic Joint Replacement Surgery

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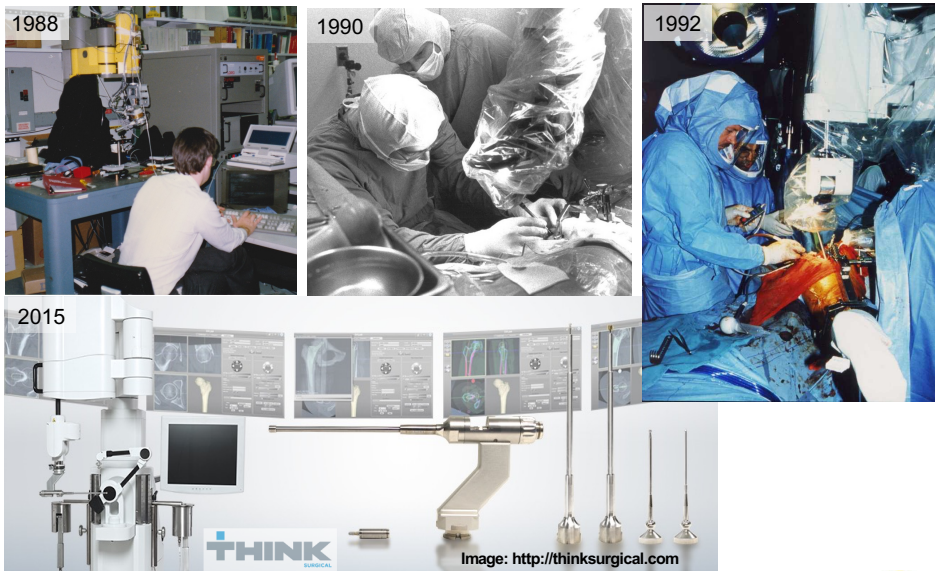
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## My introduction to medical robotics: Robotic Hip and Knee Replacement

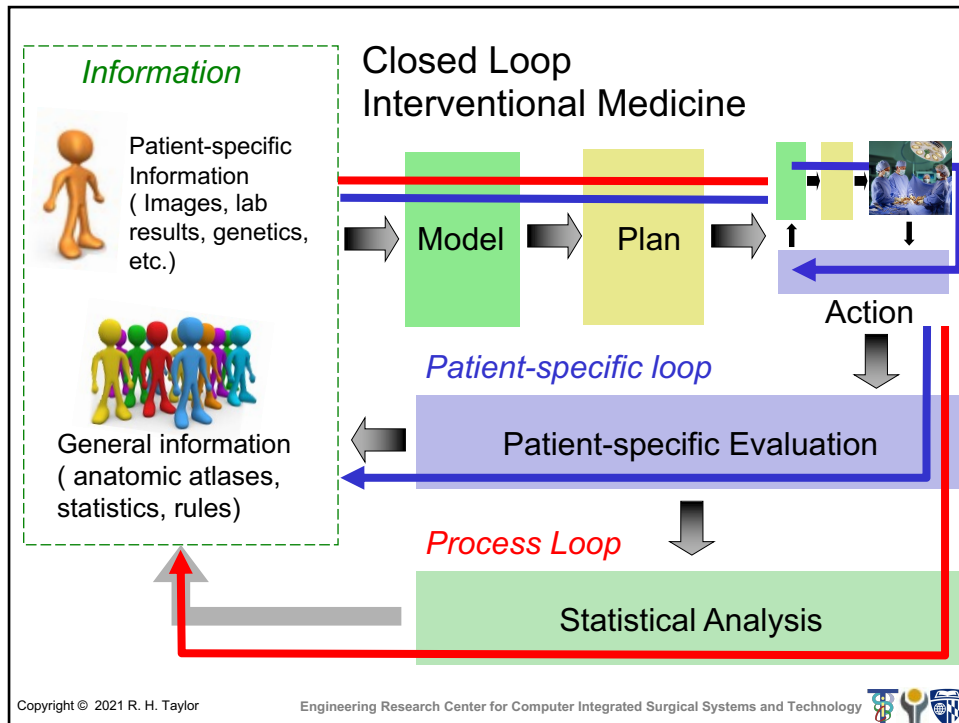


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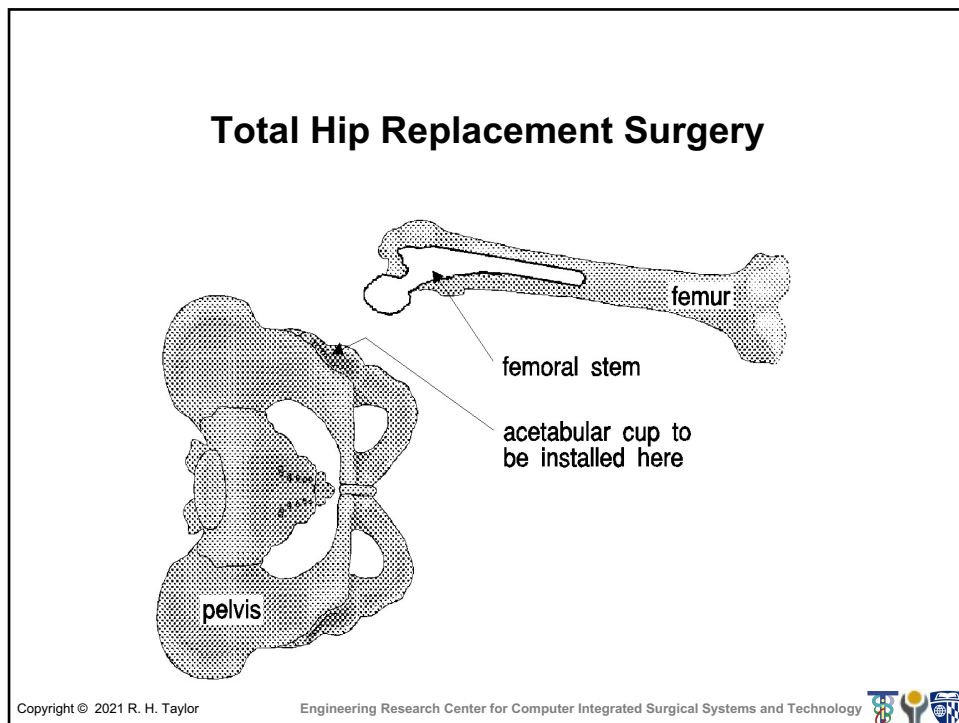
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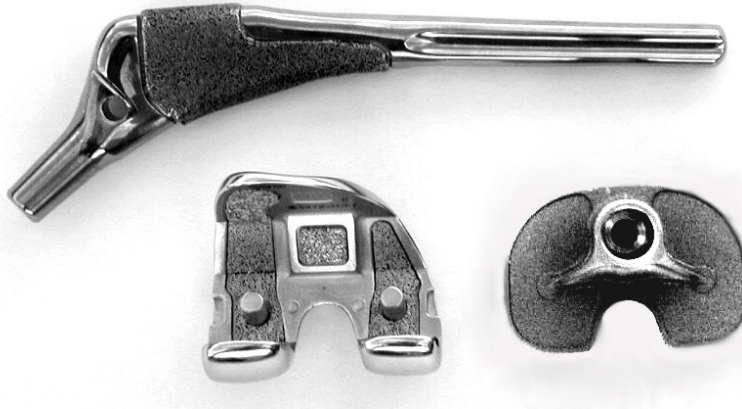


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## Hip and Knee Implants



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## 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



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## Integrated Surgical Systems Company History

- Founded 1990
- Robodoc system milestones
  - 1<sup>st</sup> Canine THR - 1990
  - 1<sup>st</sup> Human THR - 1992
  - 1<sup>st</sup> 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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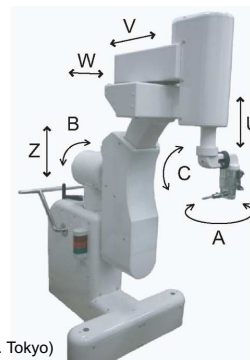
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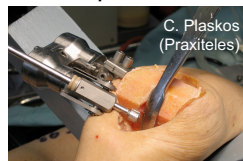
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## Other Robotic THR & TKR Systems (Partial List)

- “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



Mitsuiishi *et al.* (U. Tokyo)



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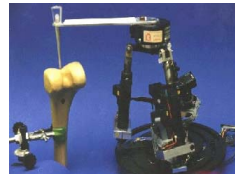
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  - Mako robotics
- Freehand Navigation-Assisted
  - Smith and Nephew



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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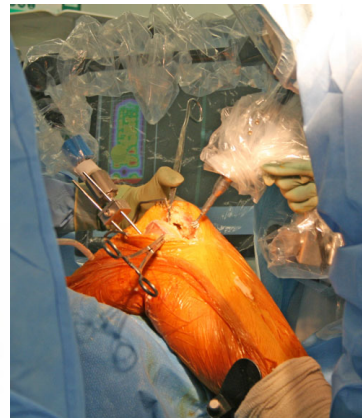
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  - Stryker (Mako Rio)
- Freehand Navigation-Assisted
  - Smith & Nephew (Blue Belt Technologies)



ACROBOT surgical robot

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

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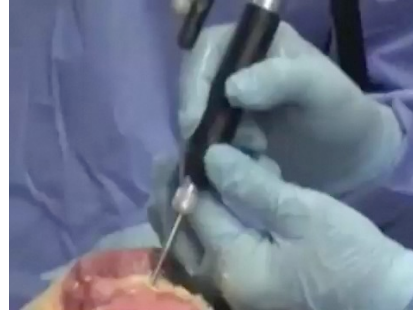
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  - Imperial College (ACROBOT)
  - Stryker (Mako Rio)
- **Freehand Navigation-Assisted**
  - Smith and Nephew (Blue Belt)



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



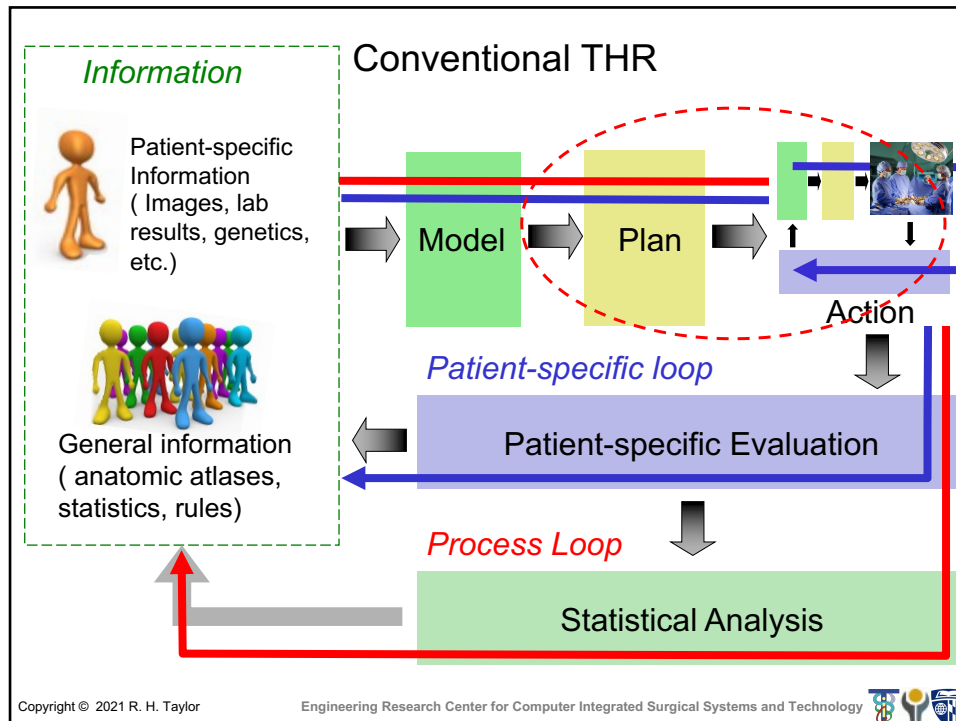
PFS® devices “snap on” to existing drill platforms. The PFS® instrument has been designed for use in neurosurgical and orthopedic applications.

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## 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

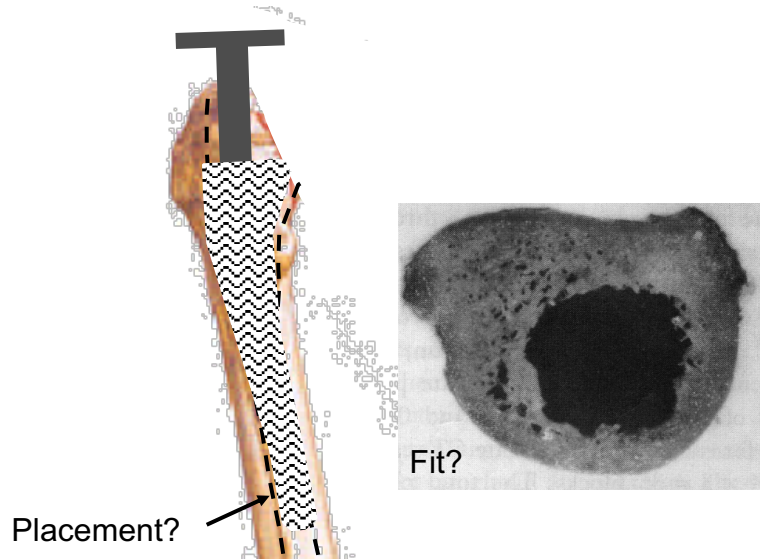
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## Issues with conventional method

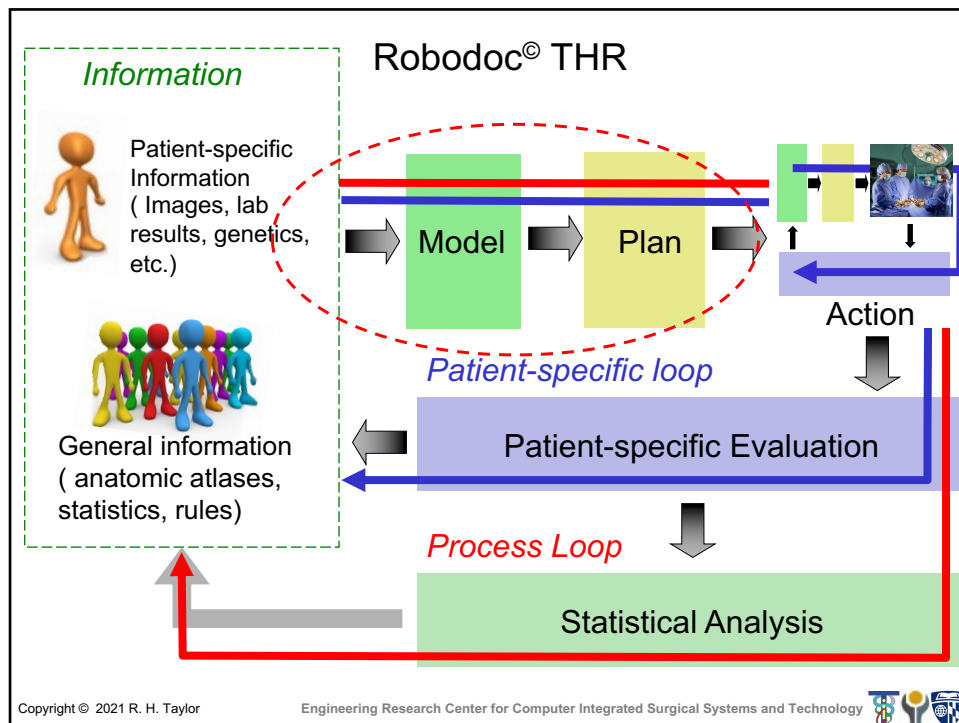


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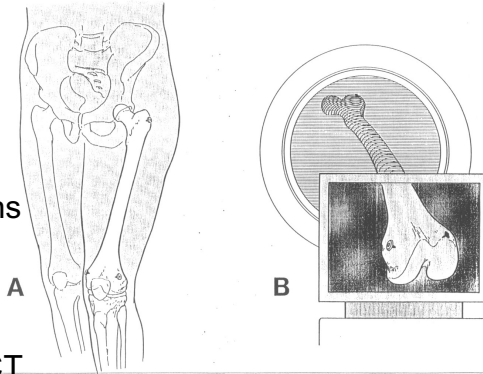


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## Robodoc THR Planning

- 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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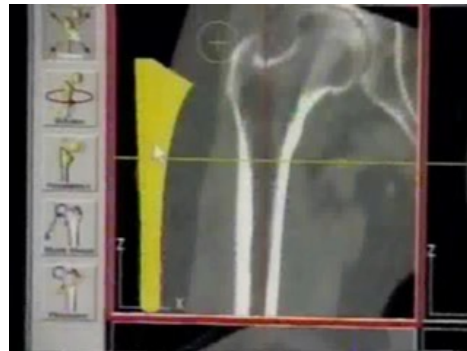
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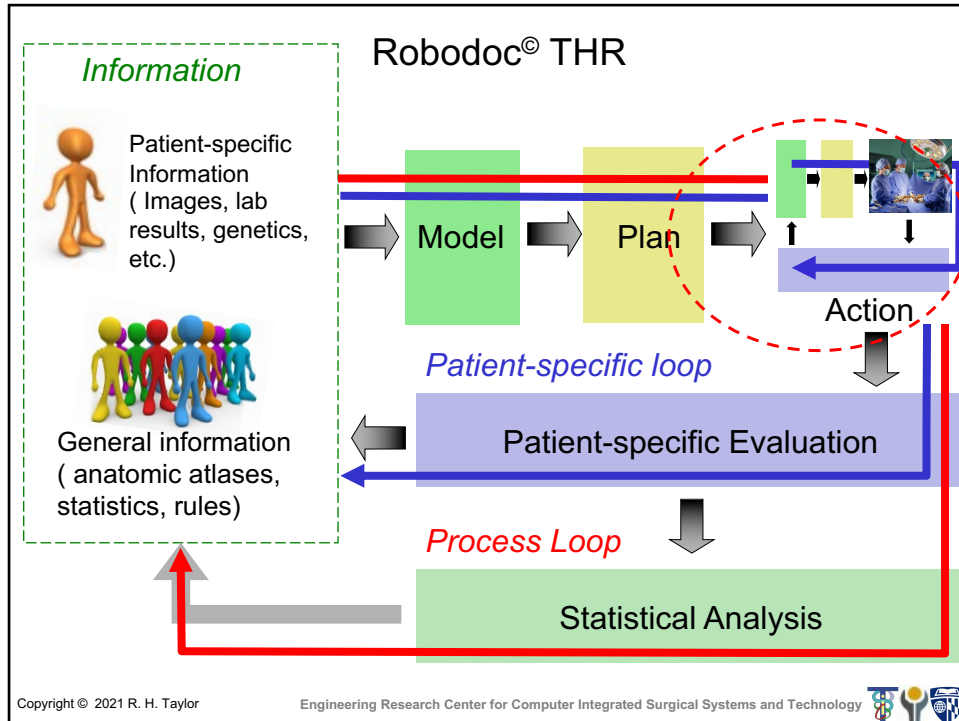


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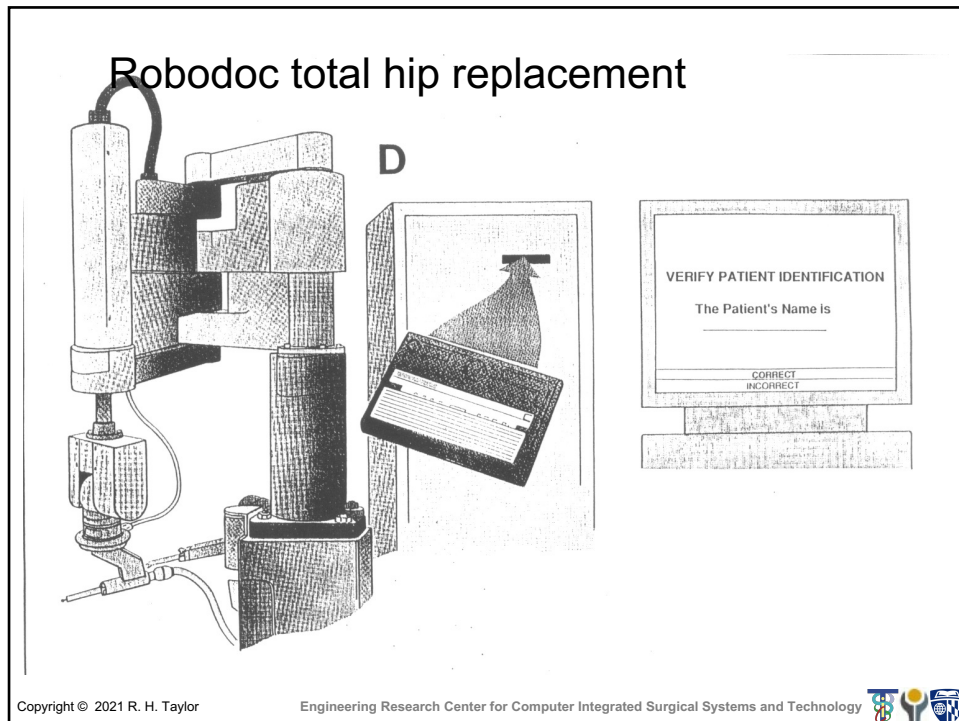
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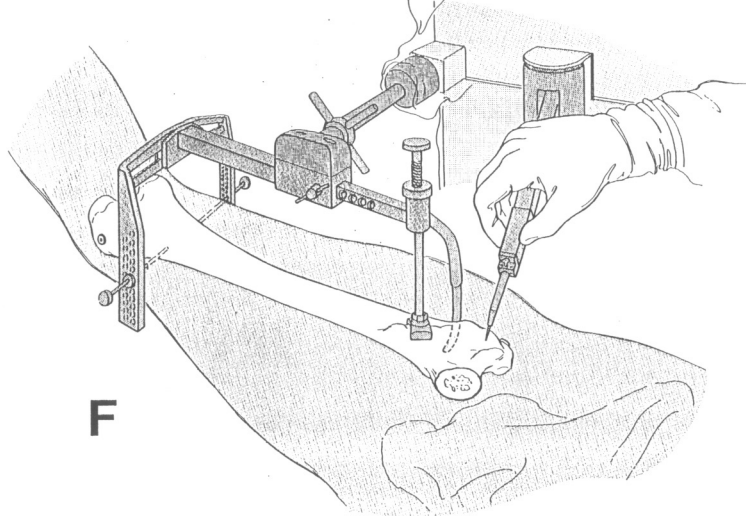


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## Robodoc total hip replacement



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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)

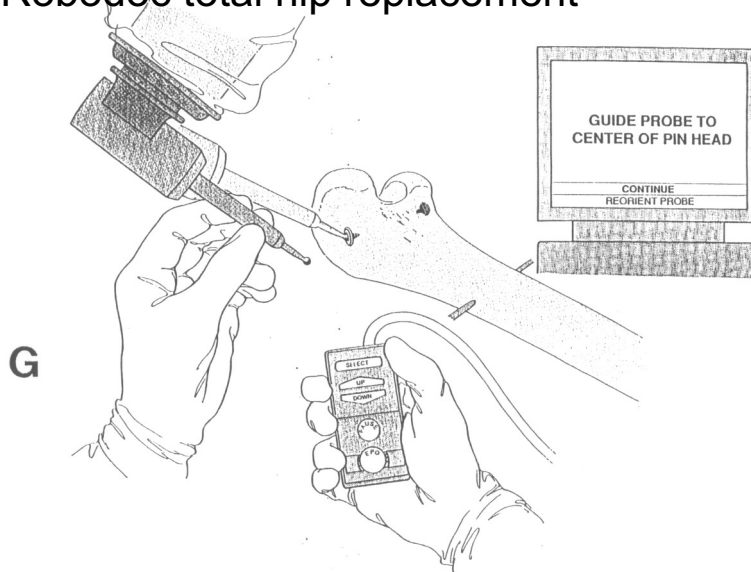
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## Robodoc total hip replacement



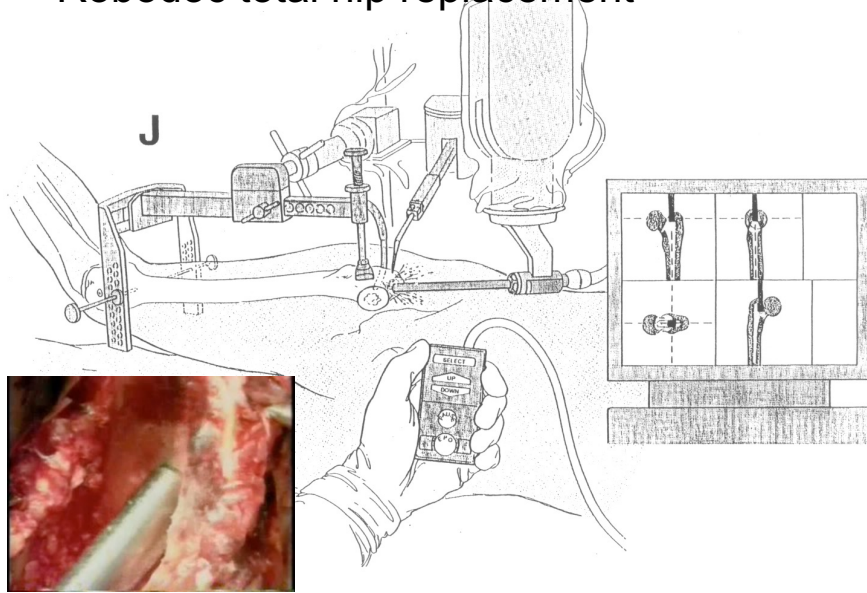
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## Robodoc total hip replacement



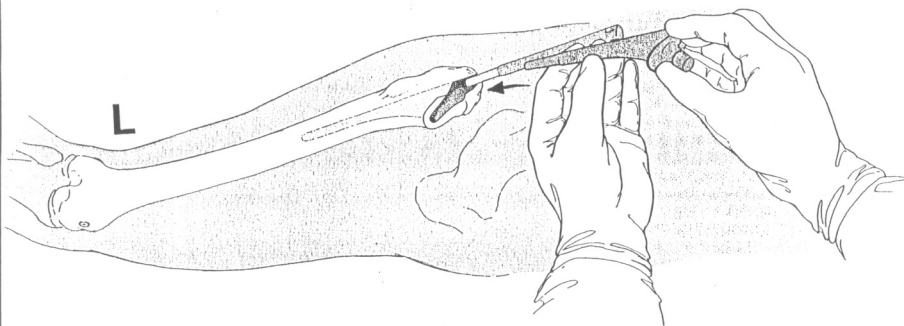
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## Robodoc total hip replacement



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## 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

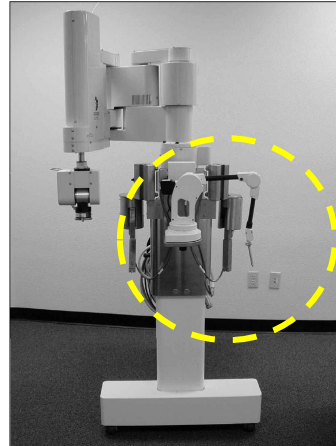


## Movies



## 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



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## Movies



Pinless Registration Step

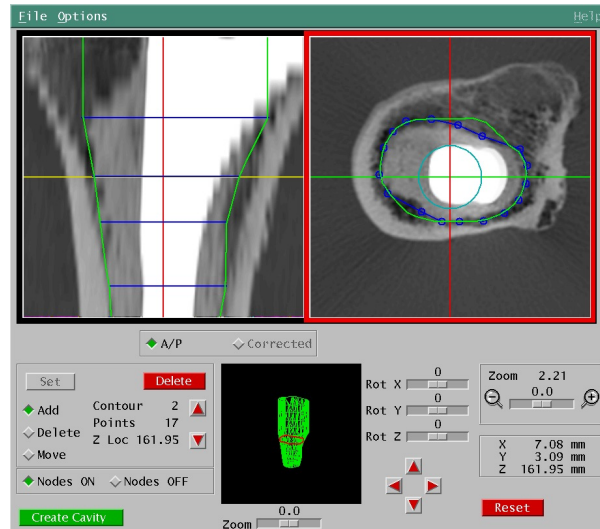
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## Revision THR (cement removal)



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## 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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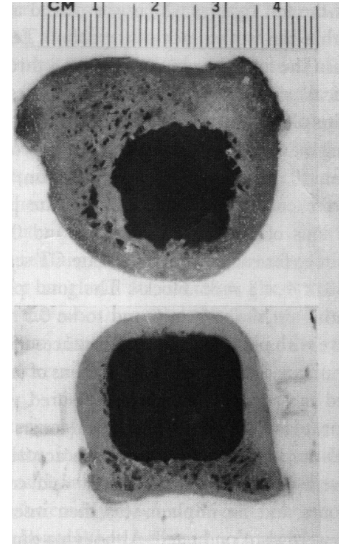


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## Leverage from Surgical CAD/CAM in Robotic THR

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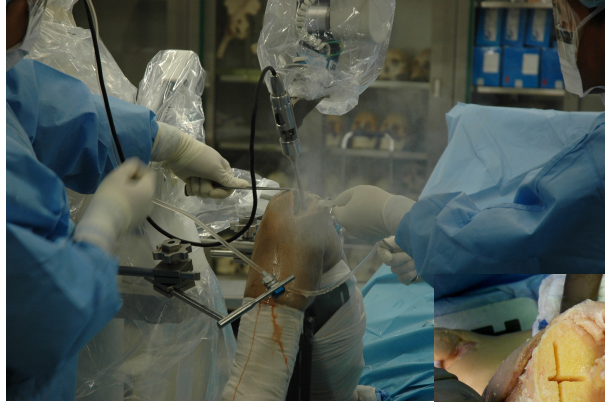
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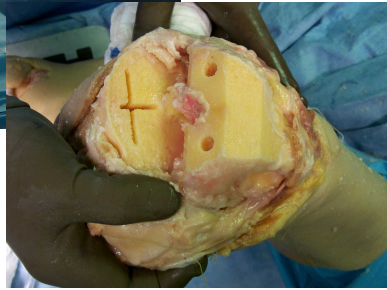


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# Robodoc® Total Knee Replacement



Photos: Think Robotics and Integrated Surgical systems



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Fig. 24



CR-Flex Femur



CR-Flex Provisional

Illustrations: Zimmer, Inc.

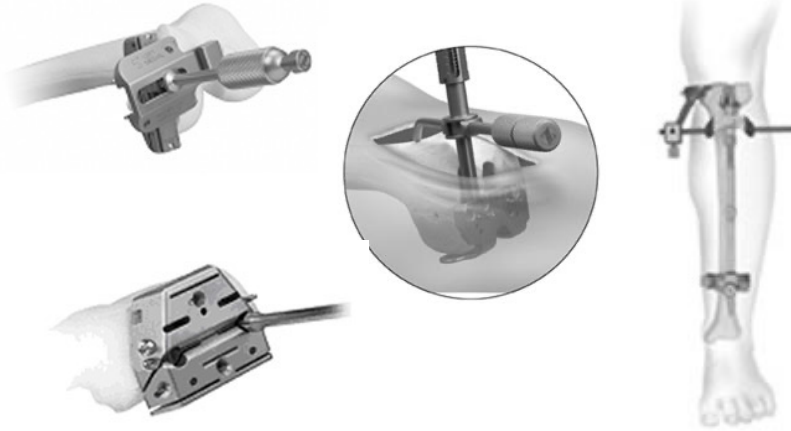
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## Manual Practice



<http://www.zimmer.com/z/ct/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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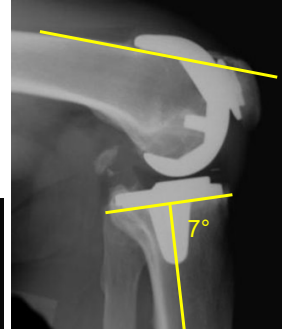
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## Fundamental Challenges

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



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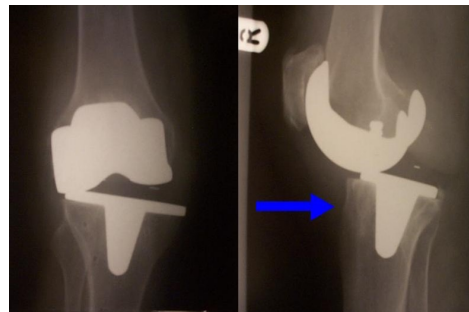


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## Ligament Balancing



•Lift-off = wear



•Instability

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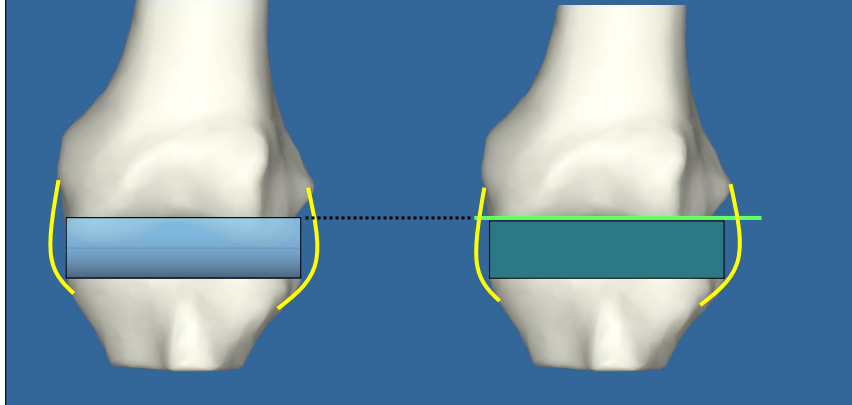
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## Ligament Balancing

• Well align knee (HKA ~ 180°): Good cuts



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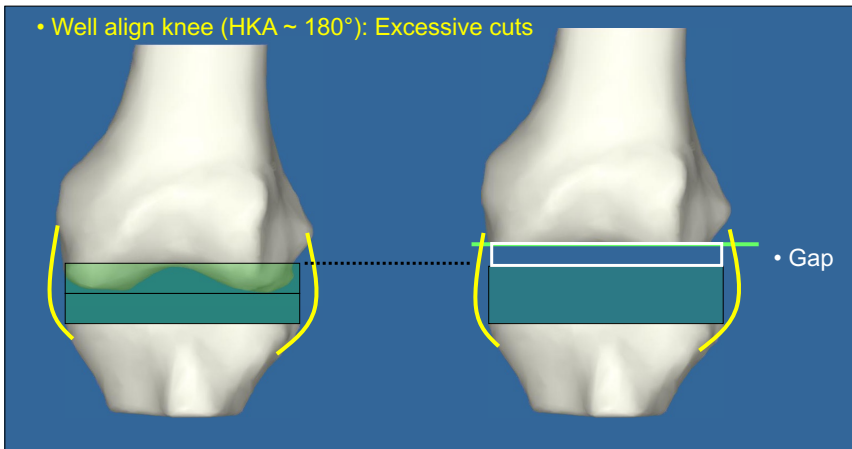
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## Ligament Balancing

• Well align knee (HKA ~ 180°): Excessive cuts



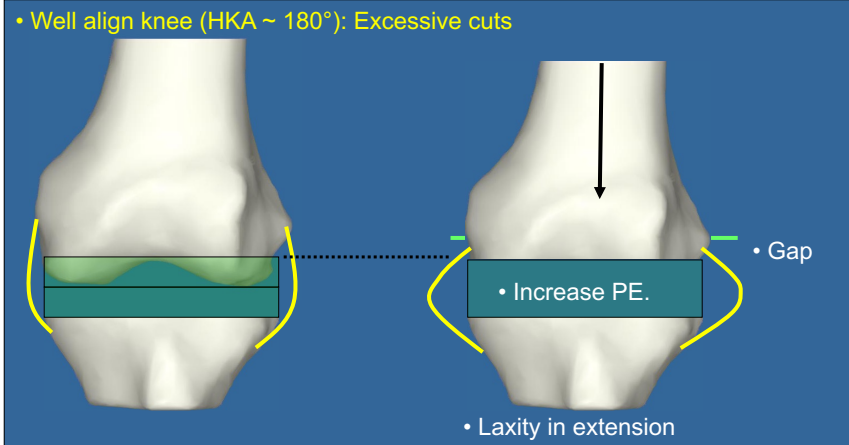
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## Ligament Balancing



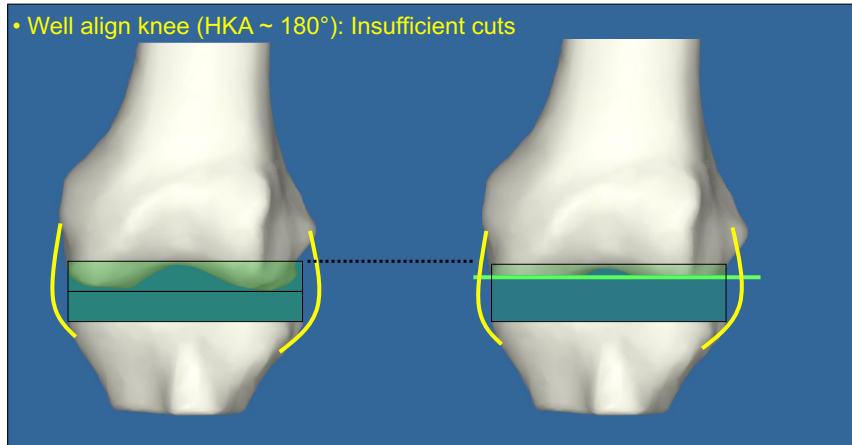
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## Ligament Balancing



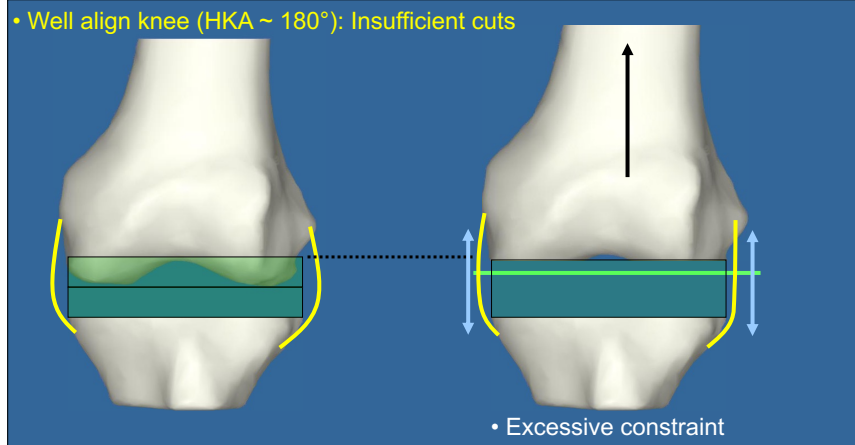
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## Ligament Balancing



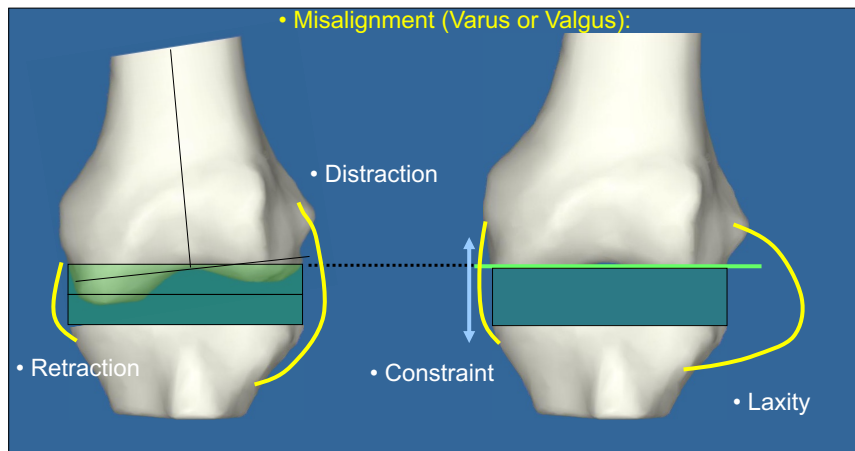
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## Ligament Balancing



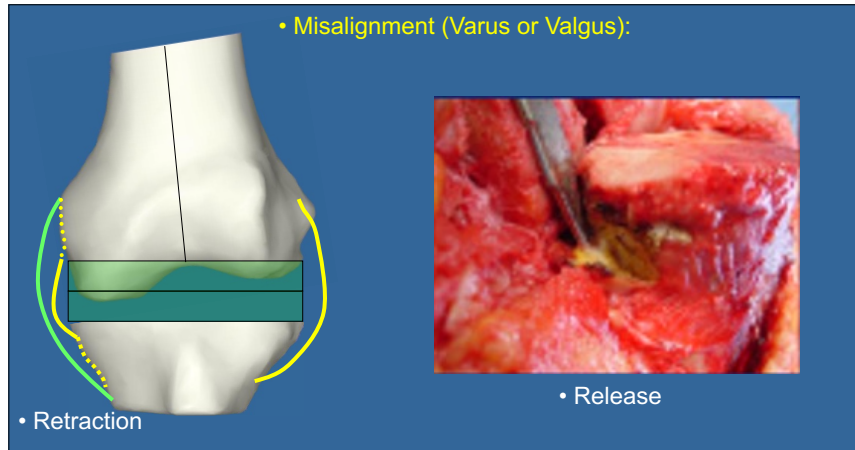
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## Ligament Balancing



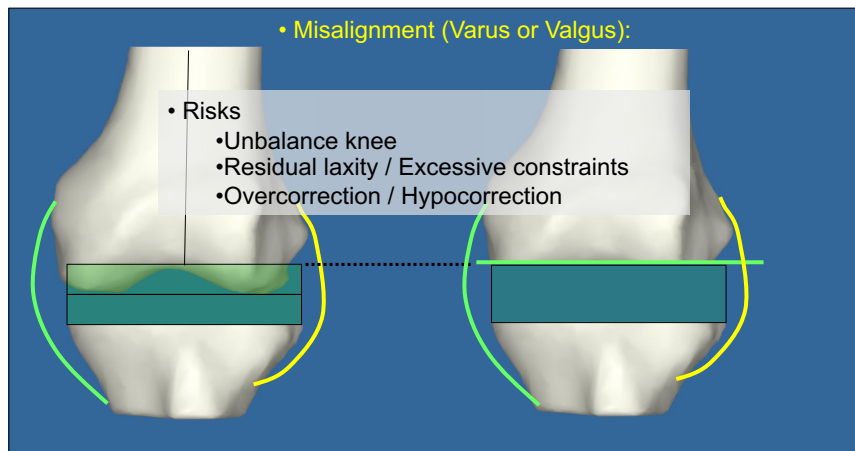
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## Ligament Balancing



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## Manual Instrumentation (with navigation markers)



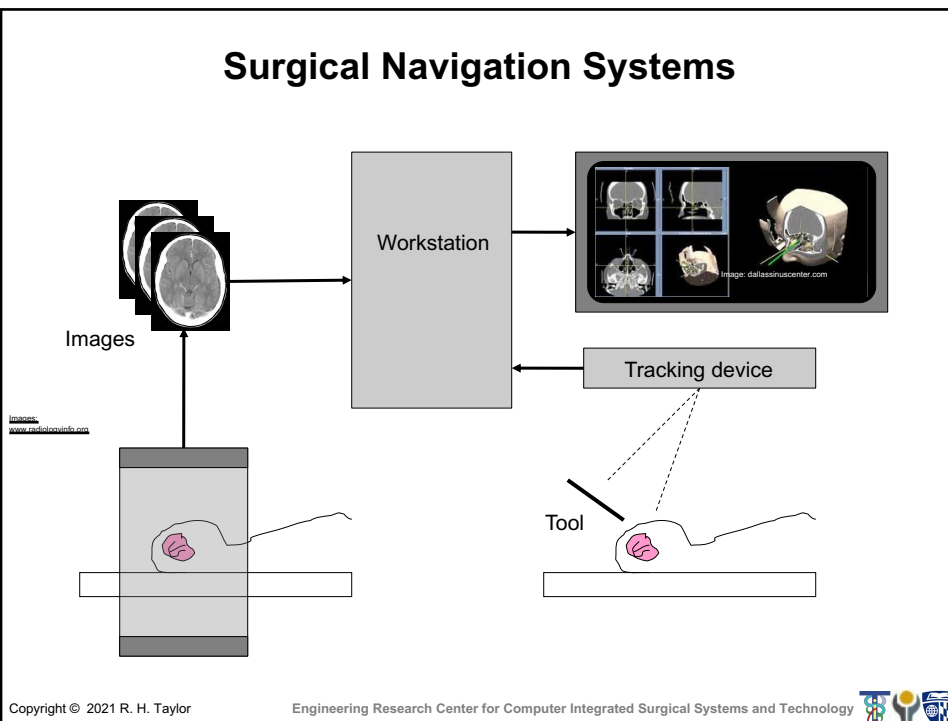
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## Surgical Navigation Systems



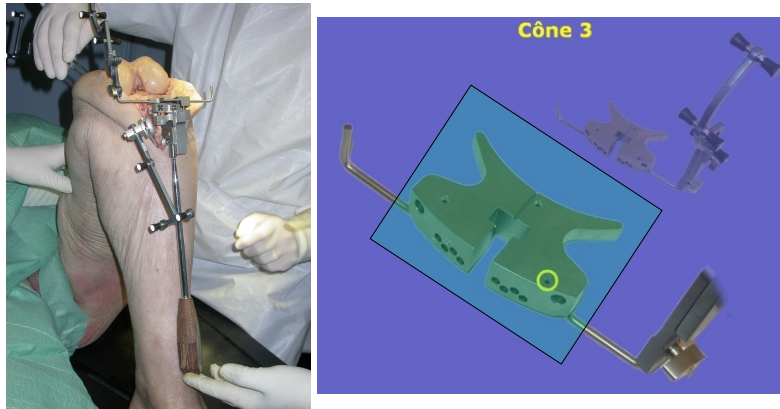
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## Navigated Cutting Guides



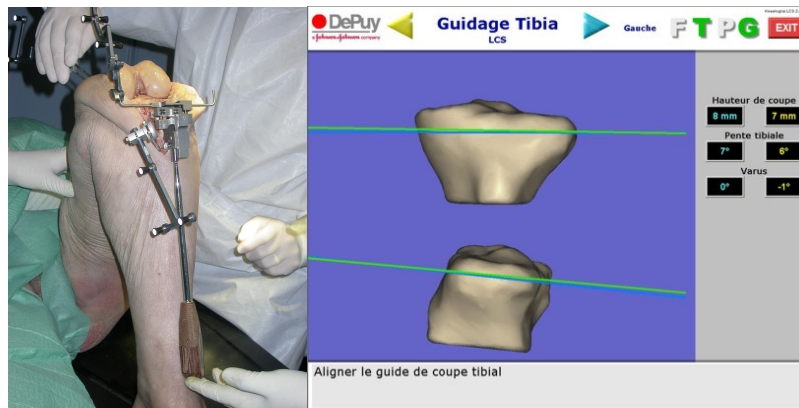
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## Navigated Cutting Guides



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## Robodoc® Total Knee Replacement



Robot follows preplanned cutting path after registration

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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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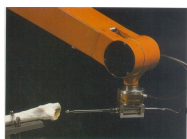
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## Case Study: Robodoc Early History

- 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

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## 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



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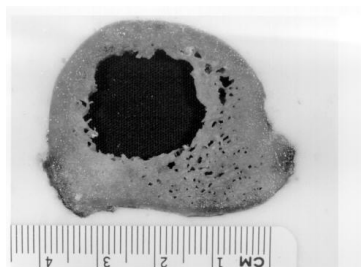
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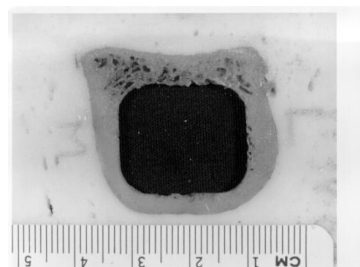
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## ROBODOC Benefits

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



Broach



Robot

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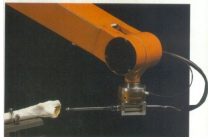
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## ROBODOC History

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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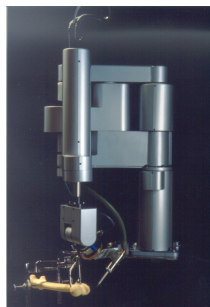
## ROBODOC History

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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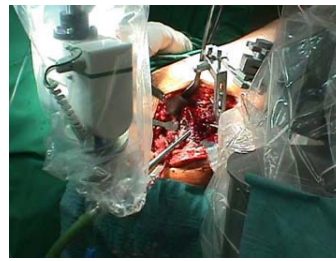
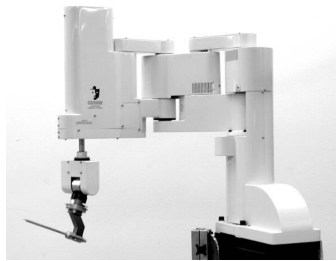


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## ROBODOC History

### 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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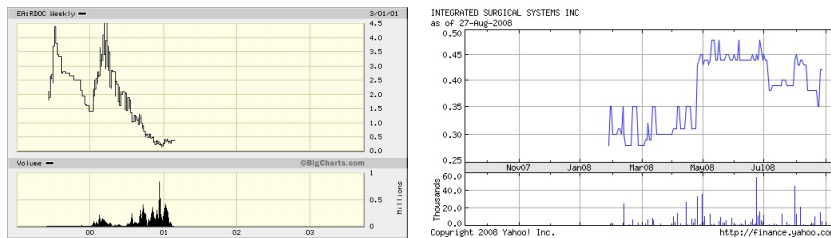
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## ROBODOC Status

- 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

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## 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

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## German Clinical Trial

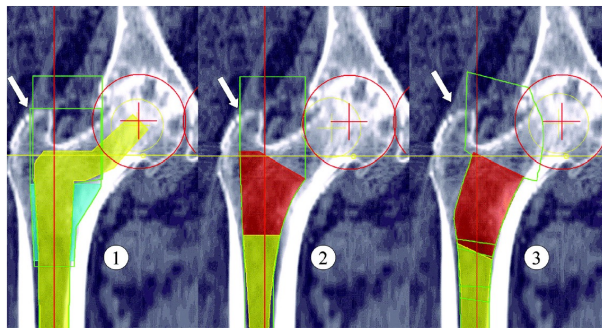


Fig. 5  
Comparison of the robotic planning sketches for different prostheses in the same patient. 1 = S-ROM (DePuy, Leeds, United Kingdom), 2 = Osteolock (Howmedica, Rutherford, New Jersey), and 3 = ABG (Howmedica). The arrow indicates the muscle insertion area. The areas framed by the thin green line 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.

Hohl 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



## 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.

