Robotic Joint Replacement Surgery

Russell H. Taylor, Peter Kazanzides

Center for Computer-Integrated Surgical Systems and Technology
The Johns Hopkins University
3400 N. Charles Street; Baltimore, Md. 21218
rht@jhu.edu

My introduction to medical robotics:
Robotic Hip and Knee Replacement

Image: http://thinksurgical.com
Total Hip Replacement Surgery

- femur
- femoral stem
- acetabular cup to be installed here
- pelvis
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

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*Images and text representing various robotic systems and techniques.*
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D. Glozman & M. Shoham

ACROBOT surgical robot

Mako Robotics Rio (Stryker)
http://www.makosurgical.com/
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- Freehand Navigation-Assisted
  - Smith and Nephew (Blue Belt)

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
Issues with conventional method

Placement?

Fit?

Robodoc® THR

Patient-specific Information
- Images, lab results, genetics, etc.

General information
- Anatomical atlases, statistics, rules

Information

Model → Plan

Patient-specific loop

Process Loop

Statistical Analysis

Patient-specific Evaluation

Action
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)
Robodoc® THR

Information

Patient-specific Information (Images, lab results, genetics, etc.)

General information (anatomic atlases, statistics, rules)

Process Loop

Patient-specific Evaluation

Statistical Analysis

Model → Plan → Action

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 from each other)
+ 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

Movies

Pinless Registration Step
ROBODOC: Feature-Based Registration

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

New Approach: Feature-Based Registration with Tracked Ultrasound

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

Distal Incision with ICP

Ultrasound with ICP

Ultrasound with P-IMLOP

Slide credit: Seth Billings


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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• Ability to carry out the plan
  – Accurate shape
  – Accurate placement
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• Process learning

Robodoc® Total Knee Replacement

Photos: Think Robotics and Integrated Surgical systems
Manual Practice

http://www.zimmer.com/zi/cit/pressroom/library/view?item=9403

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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

Fundamental Challenges

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

Thanks to Eric Stindel, MD, Ph.D.
Ligament Balancing

- Lift-off = wear
- Instability

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

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

• Gap

Thanks to Eric Stindel, MD, Ph.D.
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Ligament Balancing

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

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Ligament Balancing

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

• Excessive constraint

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Ligament Balancing

- Retraction
- Laxity
- Constraint
- Distraction
- Misalignment (Varus or Valgus)

Ligament Balancing

- Retraction
- Release
- Misalignment (Varus or Valgus)
Ligament Balancing

- Risks
  - Unbalance knee
  - Residual laxity / Excessive constraints
  - Overcorrection / Hypocorrection

Robodoc® Total Knee Replacement

Robot follows preplanned cutting path after registration
Manual Instrumentation (with navigation markers)

Surgical Navigation Systems

Images

Workstation

Tracking device

Tool
Navigated Cutting Guides

Thanks to Eric Stindel, MD, Ph.D.
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Mako Rio System (Stryker)

Hand-over-hand cooperative control with constraints

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

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
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

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

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>2003-2007</td>
<td>ROBODOC RIP</td>
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<tr>
<td>Oct 2003</td>
<td>Class action lawsuit in Germany</td>
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<tr>
<td>June 2005</td>
<td>ISS “ceases operations”</td>
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<tr>
<td>June 2006</td>
<td>German high court ruling against plaintiff</td>
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<tr>
<td>Sept 2006</td>
<td>ISS resumes operations</td>
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<tr>
<td>June 2007</td>
<td>ISS sells assets to Novatrix Biomedical</td>
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<tr>
<td>2007-present</td>
<td>ROBODOC reborn</td>
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<tr>
<td>Sept 2007</td>
<td>Curexo Technology formed (Novatrix)</td>
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<td>Sept 2007</td>
<td>Curexo files 510(K) with FDA</td>
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<td>Aug 2008</td>
<td>Robodoc receives FDA approval (for hip replacement surgery)</td>
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<td>Company now operates in the US as Think Surgical</td>
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</tbody>
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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
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


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.