Robotic Joint Replacement Surgery

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My introduction to medical robotics: Robotic Hip and Knee Replacement

1988 1990 1992

2015

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

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

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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  - Mako robotics
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ACROBOT surgical robot

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

Blue Belt Technologies: http://www.bluebelltech.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

Conventional Total hip replacement

Integrated Surgical Systems marketing video
Issues with conventional method

Placement?

Fit?

Information

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

General information (anatomic atlases, statistics, rules)

Robodoc® THR

Model → Plan

Patient-specific loop

Patient-specific Evaluation

Process Loop

Statistical Analysis

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)

Patient-specific loop
- Patient-specific Evaluation
- Process Loop
- Statistical Analysis

Model → Plan → Action

Robodoc total hip replacement

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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)
**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**

(Blank space for movies)

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Engineering Research Center for Computer Integrated Surgical Systems and Technology
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
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

• Better planning

• Ability to carry out the plan
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• Process learning
Robodoc® Total Knee Replacement

Photos: Think Robotics and Integrated Surgical systems

Illustrations: Zimmer, Inc.
Manual Practice

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.**

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**Ligament Balancing**

- Lift-off = wear
- Instability
Ligament Balancing

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

Ligament Balancing

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

- Well align knee (HKA ~ 180°): Excessive cuts
  - Gap
  - Increase PE.
  - Laxity in extension

Ligament Balancing

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

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

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

Ligament Balancing

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

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

- Misalignment (Varus or Valgus):

- Retraction

- Release

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

Thanks to Eric Stindel, MD, Ph.D.
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Engineering Research Center for Computer Integrated Surgical Systems and Technology
Manual Instrumentation (with navigation markers)

Surgical Navigation Systems

Images → Workstation → Tracking device → Tool
Navigated Cutting Guides
Robodoc® Total Knee Replacement

Robot follows preplanned cutting path after registration

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
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

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)
           Company now operates in the US
           as Think Surgical
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.