Robotic Joint Replacement Surgery

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Example: Robotic Joint Replacement Surgery
Patient-specific Information (Images, lab results, genetics, etc.)

General information (anatomic atlases, statistics, rules)

Preoperative
- Computer-assisted planning
- Patient-specific Model

Intraoperative
- Update Model
  - Computer-Assisted Assessment
- Update Plan
  - Computer-Assisted Execution

Postoperative
- Atlas
- Patient

Closed Loop Interventional Medicine

Statistical Analysis

Process Loop

Patient-specific Evaluation

Patient-specific loop
Demographics

- US
  - Total Hip Replacement > 300,000/year
  - Total Knee Replacement > 250,000/year
- Worldwide

• NOTE: Numbers need updating
Hip and Knee Implants

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)
  - 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
  - New name: Think Robotics
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
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ROBODOC® System

Conventional procedure (mallet and broach)

Computer-assisted planning and execution
Current Technique for THR

- Pre-operative planning using X-rays and acetate overlays
- Surgical preparation using mallet and broach or reamer
- Relies on surgeon’s “feel"
- Outcome depends on surgeon experience
THR Conventional Procedure

Planning (acetate templates on x-rays)  Execution (mallet and broach)

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
Conventional Total hip replacement

Placement?

Fit?
**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 Planning

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Robotic 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)
Pin-Based Registration

Q: How many pins are needed?

A: Need at least 3 "features"
   
   3 Pin Registration: uses center of each pin
   2 Pin Registration: uses center of each pin and axis of one pin
Robodoc total hip replacement

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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

Movies

Börner video – pins
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

ISS Video
Movies

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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• Process learning

Robodoc® Total Knee Replacement
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

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

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

• Gap

• Increase PE.

• Laxity in extension

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Ligament Balancing

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

Ligament Balancing

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

* Excessive constraint
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

- Misalignment (Varus or Valgus):

Manual Instrumentation (with navigation markers)
Surgical Navigation Systems

Navigated Cutting Guides

Thanks to Eric Stindel, MD, Ph.D.
Navigated Cutting Guides

Robodoc® Total Knee Replacement
Praxiteles Robotized Milling Guide

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

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

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


Fig. 1: Comparison of the robotic planning sketch for different prostheses in the same patient. 1 = S-ROM (DePuy, Leeds, United Kingdom), 2 = Ghentlock (Howmedica, Rutherford, New Jersey), and 3 = ABP (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 ABP prosthesis will not encroach as much on the insertion of the obturator muscles as on the greater trochanter.
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.