Robotic Joint Replacement Surgery

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Closed Loop Interventional Medicine

Information

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

General information (anatomic atlases, statistics, rules)

Patient-specific Evaluation

Process Loop

Statistical Analysis

Action

Model → Plan

Patient-specific loop

Preoperative

Computer-assisted planning

Patient-specific Model

Intraoperative

Update Model

Update Plan

Computer-Assisted Execution

Postoperative

Patient

Computer-Assisted Assessment

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Engineering Research Center for Computer Integrated Surgical Systems and Technology
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
  – Robodoc is marketed by Curexo (Novatrix subsidiary)
  – FDA Approval – 2008
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
  - C. Plaskos (Praxiteles)
  - Mitsuishi et al. (U. Tokyo)
  - Cutting tool
  - Femur bone
  - Opening area
Other Robotic THR & TKR Systems
(Partial List)

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D. Glozman & M. Shoham

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Mako Robotics Rio
http://www.makosurgical.com/
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Hip and Knee Implants
Total Hip Replacement Surgery

- Femoral stem
- Acetabular cup to be installed here

Total hip replacement

- Placement?
- Fit?
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
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)
Planning

Patient-specific Evaluation

Statistical Analysis

Interventional Medicine

Closed Loop

Model → Plan → Action

Patient-specific loop

Process Loop

General information (anatomic atlases, statistics, rules)

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

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
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
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

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

Thanks to Eric Stindel, MD, Ph.D.

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

Thanks to Eric Stindel, MD, Ph.D.

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Engineering Research Center for Computer Integrated Surgical Systems and Technology
Ligament Balancing

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

Thanks to Eric Stindel, MD, Ph.D.

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Engineering Research Center for Computer Integrated Surgical Systems and Technology
Ligament Balancing

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

Thanks to Eric Stindel, MD, Ph.D.

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Engineering Research Center for Computer Integrated Surgical Systems and Technology
Ligament Balancing

• Misalignment (Varus or Valgus):

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

Manual Instrumentation
(with navigation markers)

Thanks to Eric Stindel, MD, Ph.D.

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Engineering Research Center for Computer Integrated Surgical Systems and Technology
Surgical Navigation Systems

Images → Workstation → Tracking device → Tool

Navigated Cutting Guides

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

Robodoc® Total Knee Replacement
Praxiteles Robotized Milling Guide

Thanks to Eric Stindel, MD, Ph.D.

Mako Rio System

http://www.youtube.com/watch?v=Wun4AjcFZSw
Blue Belt PFS system

PFS Knee Resurfacing
http://www.bluebelttech.com/videos.php

Robodoc 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 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 (cont.)

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 (cont.)

1995-2002 ROBODOC as a Medical Product

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 1996</td>
<td>CE Mark (C System)</td>
</tr>
<tr>
<td>April 1996</td>
<td>First 2 installations (Germany)</td>
</tr>
<tr>
<td>Nov 1996</td>
<td>ISS initial public offering (NASDAQ)</td>
</tr>
<tr>
<td>Sept 1997</td>
<td>IMMI acquisition (Neuromate)</td>
</tr>
<tr>
<td>March 1998</td>
<td>First pinless hip surgery</td>
</tr>
<tr>
<td>April 1999</td>
<td>New electronics design (D System)</td>
</tr>
<tr>
<td>Feb 2000</td>
<td>First knee replacement surgery</td>
</tr>
</tbody>
</table>

### ROBODOC Generations

- **Alpha:** Canine System (1990)
- **Beta:** Human clinical prototype
  - Version 1: 10 patient study (1992)
  - Version 2: Multi-center trial (1993)
- **Commercial Product**
  - D System: Custom electronics (1999)
Canine System Goals

- Proof of concept
  - procedural flow
  - high accuracy (small bones)
  - operating room compatibility (sterility)
- Focus on application, not system design
  - Use primarily off-the-shelf hardware
- Rely on engineering supervision in OR
- Research mode: no formal design process

Canine System Design
Canine System Design

• Prototype appearance (external cables, etc.)
  – Custom pitch axis added to robot
  – Wiring panel on side of cabinet
• Primitive (text-based) user interface
  – Keyboard and 32-button pendant
  – Engineer operated robot for all 26 surgeries
  – Force controlled guiding (fast/slow modes)
  – ORTHODOC for CT display during cutting
Canine System Design

• Software written in AML
  – IBM robot programming language (interpreted)
• Primitive computer hardware
  – 80286 for Robot Control Computer
  – 80386 for ORTHODOC/RTM
• Did not use some safety systems in surgery

Canine System Safety

• Force sensor to detect collisions
• Optical tracking system (Optotrack) to independently track robot end-effector
  – not used clinically
• Bone motion monitor
  – design not completed
• Visualization of cutting procedure (RTM)
  – display cut paths on CT cross-sections
Canine System Lessons

• The procedure works!
• The user interface needs improvement
• Error recovery can be complex
  – Raise exception and “start over” can work well
• Bone motion detection is critical
• Avoid special power requirements
Beta System Goals

• Re-design system for production
  – Create specifications, risk analysis, etc.
  – Improve system appearance
  – Rewrite software in industry-standard language
• Create user interface for surgeon use
  – graphical user interface and simple pendant
• Support longer tools (higher stiffness)
• Reduce cost
Beta System Design

• Customized industrial robot (Sankyo Seiki)
  – Integrated pitch axis
  – Integrated redundant encoders
  – Improved stiffness (roll axis)
  – Reduced force and speed for safety
  – High accuracy specifications
• Adjustable base to increase workspace
Beta System Design

• Three physical units
  – Surgical Robot
  – Control Cabinet
  – Operating Room Display
• Improved user interface
  – Large menus (visible from a distance)
  – Simple hand-held pendant (5 buttons)
  – Better force guiding (nonlinear gains)

Beta System Design

• Software written in C and C++
• Additional safety features
• Simple, yet powerful, error handling design
  – Local error recovery for “simple” errors
  – Jump to “top level” otherwise
Safety Design Overview

• Driven by risk analysis (FMECA)
  – Eliminate single points of failure
• Fail Safe design
  – System fails to a safe state (robot powered off, finish procedure manually)
• Limited Fault Tolerance
  – System can continue without RTM graphics
• Completely different from industrial robots

Beta System Safety Design

• Force sensor to detect collisions
• Redundant joint encoders
  – primary encoders on motor shaft
  – redundant encoders at joint
• Bone motion monitor (intraoperative)
• Visualization of cutting procedure (RTM)
• Bone motion detection during CT scan
Beta System Safety Design

• Safety Volume
  – Independent check that tool is in implant cavity

• Startup Diagnostics
  – Verify force sensor, robot, BMM

• Mechanical changes to robot
  – higher gear ratios to reduce speed
  – smaller motors to reduce torque

• Low-level software speed limit

First Surgery - Nov 7, 1992
Beta System Lessons

- Did not meet EMC requirements
  - Emissions marginal
  - Susceptible to interference (cautery mode)
- Required larger vertical workspace
  - Version 2 system had base encoder
- Difficult to move robot
- System too large for OR
Commercial System Goals

• Meet regulatory requirements
  – CE Mark
  – UL/CSA
• Improve maneuverability
• Reduce size
• Improve system appearance
• Support local languages

Quality Systems

• “Design controls” are now required
  – By FDA (GDP)
  – For ISO9000 certification
• Regulatory agencies do not prescribe QS
  – Company defines Quality System
  – Regulatory agency certifies Quality System and monitors compliance (Quality Records)
Quality System Documents

- Project Plan
- Software Development Procedure
- Software Quality Assurance Plan
- Risk or Hazard Analysis
- Requirements Specifications
- Verification and Validation Plan
- Change Control Procedures

Commercial System Design
Commercial System Design

[Image of a commercial system design]

Commercial System Design

[Image of another commercial system design]
Commercial System Design

- Distributed architecture
  - EMC compliance
- Two units (Robot and Control Cabinet)
- More attractive robot and base
  - Force sensor cable inside robot arm
- Base easier to maneuver
  - Steering system

Commercial System Safety Design

Safety design reviewed by notified body (TUV) for CE mark

- Electrical safety requirements
- Electromagnetic emissions/susceptibility
- Checksums/CRCs on all data
- Remove motor power for tool change
Commercial System Surgery

Commercial System Lessons

- Robot should either save time (money) or provide substantial clinical benefit (enable new procedures).
- Robot must interface with other devices in the operating room of the future.
- Registration should not require an additional surgery.
- Further size reduction is necessary.
ROBODOC Status

- Approximately 50 systems installed worldwide
  - Europe (Germany, Austria, Switz., France, Spain)
  - Asia (Japan, Korea, India)
  - U.S. (Clinical trial for FDA approval)
- Over 10,000 hip replacement surgeries
- Several hundred knee replacement surgeries

Summary

- The ROBODOC System has evolved over the past 15+ years:
  - Laboratory prototype
  - Canine system
  - Clinical prototype
  - Commercial product
Summary

• Experience has led to changes in:
  – System architecture (distributed)
  – Safety design (risk analysis)
  – User interface (ease of use)
  – Ergonomics (OR compatibility)