ROBODOC® System for Total Hip and Knee Replacement

Application Overview

- Total Hip and Knee Replacement Surgery
  - replace damaged articulating surfaces with implants
    - cemented - use cement to attach to bone
    - cementless - rely on bone ingrowth
  - position/orientation is important
  - proper fit can be important (cementless)

Total Hip Replacement Surgery

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

PLAY MOVIE

ROBODOC THR Procedure

- Pre-operative planning using 3-D CT scan data and implant models (ORTHODOC®)
- Surgical preparation of bone by robot using milling tool
  - Increased dimensional accuracy
  - Increased placement accuracy
- Outcome more consistent
Manual Broach vs. Robot

ROBODOC Procedure Overview

• Perform orthopedic procedures (hip and knee replacement):
  – Preoperative CT scan
  – Preoperative planning
  – Intraoperative registration
  – Robotic machining of bone

ROBODOC 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

ROBODOC 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

PLAY Pinless Video (1998)
ROBODOC Procedures

- Primary Total Hip Replacement (THR)
  - Pin-based and pinless
- Primary Total Knee Arthroplasty (TKA)
  - Pin-based and pinless
- Revision THR (cement removal)
  - Pin-based only

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

1995-2002 ROBODOC as a Medical Product
  March 1996 CE Mark (C System)
  April 1996 First 2 installations (Germany)
  Nov 1996 ISS initial public offering (NASDAQ)
  Sept 1997 IMMI acquisition (Neuromate)
  March 1998 First pinless hip surgery
  April 1999 New electronics design (D System)
  Feb 2000 First knee replacement surgery

First Surgery - Nov 7, 1992

The Press Reacts...
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

PLAY Total Knee Surgery Movie (2000)

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)

STILL NOT A PRODUCT IN NORTH AMERICA 😞 😞 😞