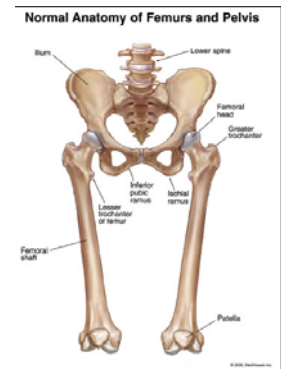


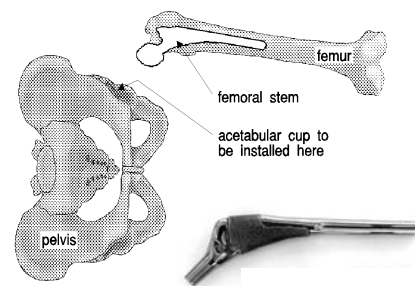
## ROBODOC® System for Total Hip and Knee Replacement



### 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

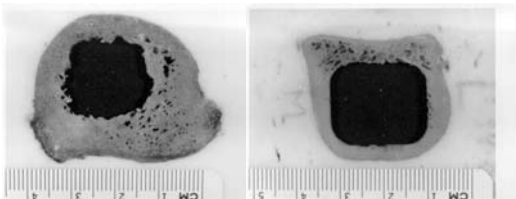
- Pre-operative planning using X-rays and acetate overlays
- Surgical preparation using mallet and broach or reamer
- Relies on surgeon's "feel"
- Outcome depends on surgeon experience

**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

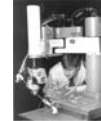
- Primary Total Hip Replacement (THR)
  - Pin-based and pinless
- Primary Total Knee Arthroplasty (TKA)
  - Pin-based and pinless
- Revision THR (cement removal)
  - Pin-based only

## 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

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

|            |                                      |
|------------|--------------------------------------|
| 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**

