Computer Assisted Surgery (CAS)

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CAS Goals

- Clinical Background of Navigational Surgery
  - History
  - Relationship between Component Positioning Error and Outcome
  - Potential Impact of Error
    - Reoperation
    - Economic
    - Mortality

CAS - History

- Technologic Implementation
  - Historically
    - Combined CT Referencing, Electromechanical Positioning and Surgical Procedure Performance
      - RoboDoc

CAS - Today

- Technologic Implementation
  - Currently Referencing
    - CT Scan
    - Flouroscopic
    - Mechanical - Point Picking
  - Tracking
    - Optical
    - Electromagnetic
  - Surgical Instrument Guidance

CAS Goals

- Uncertainties
  - What do we need to maximize patient benefit?
  - Where are we now?
    - Does the Technology Work?
    - What are the current challenges?
  - What do we need to do to move from our current state to an improved state?
  - Can we justify the technology?

CAS – The Problem

- H_0: Component position Not associated with Complication
  - Knee Arthroplasty:
    - Six Degree of Freedom Problem
    - Three Prosthetic Components
      - Frontal Plane (Rotation and Translation)
      - Transverse Plane (Rotation and Translation)
      - Sagittal Plane (Rotation and Translation)

CAS - Background

- H_0: Component position Not associated with Complication
  - *Hip Arthroplasty:*
    - Six Degree of Freedom Problem
    - Two Prosthetic Components
      - Frontal Plane (Rotation and Translation)
      - Transverse Plane (Rotation and Translation)
      - Sagittal Plane (Rotation and Translation)

CAS - Knee

- Literature
- "Technical factors in performing surgery may influence both short- and long-term success rates. **Proper alignment of the prosthesis appears to be critical in minimizing long-term wear, risk of osteolysis, and loosening of the prosthesis.** Computer navigation may eventually reduce the risk of substantial malalignment and improve soft tissue balance and patellar tracking. However, the technology is expensive, increasing operating room time, and the benefits remain unclear."

  - **NIH Consensus Development Conference on Total Knee Replacement: December 8-10, 2003**

CAS

- "A number of investigators have demonstrated, in their hands, the potential for computer-assisted navigation to improve precision and accuracy in obtaining optimal knee alignment in the total knee arthroplasty construct. However, it will be difficult to demonstrate improvement in revision and loosening rates. In addition, there are concerns for computer glitches, training of personnel, extra time requirements, and cost and ability to demonstrate improvements in clinical results to warrant these concerns. Reproducibility of these improvements in precision and accuracy in the hands of the less experienced surgeon must be documented."

Callaghan JJ, Liu SS, Warth LC. Computer-assisted surgery: a wine before its time: in the affirmative. J Arthroplasty. 2006 Jun;21(4 Suppl 1):27-8.

CAS - Knee

- "5,760 knee arthroplasty procedures …. registered in a community joint implant registry…" (Twin Cities, Minnesota)
- Survival Rate at 11 years: 89 – 99%
- "Aseptic loosening or wear was the cause of revision in 40.8% of patients having total knee arthroplasty."

Gioe TJ et al, Clin Orthop Relat Res. 2004 Nov;(428):100-6

CAS – Knee (Alignment)

Author	Year	Varus (Mech)	Valgus (Mech)	Success	Prosthesis
Bargren JH	1983	-5	7	89%	Freeman -Swanson
Bargren JH	1983	14	-6	14%	Freeman -Swanson
Jeffery RS	1991	-3	3	97%	Denham
Jeffery RS	1991	-2 +	4 +	76%	Denham

CAS – Knee (Alignment)

Author	Year	Varus (Mech)	Valgus (Mech)	Outcome	Prosthesis
Jonsson B	1988	6	7	"Good"	Townley Bicondylar
Jonsson B	1988		> 7	"Poor"	Townley Bicondylar

Jonsson B et al: Clin Orthop Relat Res 226:124-8, Jan. 1988

CAS – Knee (Alignment)

Author	Year	Varus (Mech)	Valgus (Mech)	Failures	Prosthesis
Ritter MA	1994	-1	2	3	Cruciate Condylar
Ritter MA	1994	< - 2		8	Cruciate Condylar
Ritter MA	1994		> 3	0	Cruciate Condylar

Ritter MA et al: Clin Orthop Relat Res 299:153-6, Feb. 1994

CAS - Knee

- “The mechanical axis was used as a reference. The mean alignment was 0.99 degrees valgus with a standard deviation of 2.48 degrees. Some 72% of knees were within 3 degrees and 94% within 5 degrees of true alignment. Using two methods of assessing radiolucencies there was a non-significant relationship between the alignment and radiolucencies. The alignment tolerance with this prosthesis is, therefore, at least 5 degrees.”

Harvey IA et al: Med Eng Phys. 1995 Apr;17(3):182-7

CAS - Knee

Author	Year	“Sweet Spot – Range Tolerance” (Degrees)
Bargren J	1983	12
Jonsson B	1988	13
Jeffrey R	1991	6
Harvey I	1995	10
	Mean	10.25 (+/- 5)

CAS - Knee

- Absolute Control Limits – Quality Control
  - Literature Quality
    - Uncertain – Retrospective Case Series
    - Alignment Definitions Variable
      - Anatomic
      - Mechanical
    - Radiographic Techniques Incompletely Described
      - Knee Flexion
      - Anatomic Landmarks Used
      - Transverse Plane Positioning
    - Health Status Impacts Not Determined
    - Health Utilities Not Determined

CAS - Knee

- Alignment Control Limits
  - Probably About 5 Degrees
  - Reasonable to avoid extremes of Varus or Valgus
  - Differential Impact of Valgus Positioning Uncertain
  - May be Prosthesis Dependent
  - Health Status and Utilities are Not Available

CAS - Knee

- “..the 27 patients in the computer-assisted group showed radiologically superior mechanical alignment of the leg axis at 3-month follow-up compared with a group of 25 patients (matched for demographic data and preoperative scores) who received a TKA by conventional methods. Only one (4%) of the computer-assisted TKAs showed a deviation of more than 5 degrees from a straight mechanical alignment compared to 8 (32%) in the conventional group.”

Effects of Advanced Medical Technologies – Musculoskeletal Diseases: Duke Univ. Jan 2006: http://www.inhealth.org/MediaCenter/Duke_Final_Report_C__ _Musculoskeletal_Diseases.pdf

Decking et al, 2005

CAS - Knee

- “radiographic results were significantly better in the computer-navigated group with respect to component positioning in four axes. The percentage of excellent results was 42% in the computer-navigated group, compared to 17% in the conventional group, with no increase in complications ($p < .05$). Surgery took, on average, 10 minutes longer in the computer-navigated group”

Effects of Advanced Medical Technologies – Musculoskeletal Diseases: Duke Univ. Jan 2006: http://www.inhealth.org/MediaCenter/Duke_Final_Report_C__ _Musculoskeletal_Diseases.pdf

Haacker et al., 2005

HCUP Knee - 2004

	Primary Knee	Revision Knee
Total number of discharges	431,485	35,048 (8.1%)
LOS (length of stay) days (mean)	3.9 (+/- 0.1)	4.5 (+/- 0.1)
Charges ($ Mean)	33,722	41,656
Aggregate charges $ (the "national bill")	14,567 M	1,457 M
In-hospital deaths	527 (0.12%)	76 (0.22%)

HCUP Knee Revision - 2004

	Loosening + Wear = MF	Assume All MF Eliminated with Improved Positioning	Assume One Half MF Eliminated with Improved Positioning
Total number of discharges	0.408	143	71
Aggregate charges $ (the "national bill")	0.408	$5,944,560	$2,972,280
In-hospital deaths	0.408	0.3	0.16

HCUP Knee Revision - 2004

	Primary Knees	Assume One Half MF Eliminated with Improved Positioning	Total Incremental Cost / Primary
Total number of discharges	431,485	7150	
Aggregate charges $ (the "national bill")	14,567 M	$297.2 M	$688.85
In-hospital deaths	527	16	

CAS - Knee

- Validate Assumptions
  - Importance of Alignment
    - Current Prostheses
    - Health Status Impacts
  - "Steady State" (Revisions as a % of Primary KR)
  - Improve Economic Model
    - Discounting and Full Cost Accounting
    - Obtain Utilities to Support Comparison with Alternative Health Expenditure
  - Validate CAS Systems
    - Traceable Certification
    - Reliability Standards
  - CAS Usability
    - Continue to Reduce Usage Time
    - Reduce Capital Cost
  - "Average" Practitioner Can Duplicate Published Results
    - CAS System
      - Reproducibility Models and Protocols
    - Educational Models / Training Programs
  - Policy Maker / Insurance Reimbursement for Improved Primary Surgery

CAS - Hip

- The acetabular cup “safe zone”
  - 15 degrees of anteversion
  - 40 degrees of opening angle
  - The tolerance associated with optimal cup positioning was similar for both anteversion and opening angle at +/- 10 degrees.
  - The risk of dislocation increased from 1.5% to 6.1% if the cup was placed outside of the two degree of freedom, described “safe zone.”

Lewinnek, G. E.; Lewis, J. L.; Tarr, R.; Compere, C. L.; and Zimmerman, J. R.: Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg Am, 60(2): 217-20, 1978.

CAS - Hip

Reason for Revision

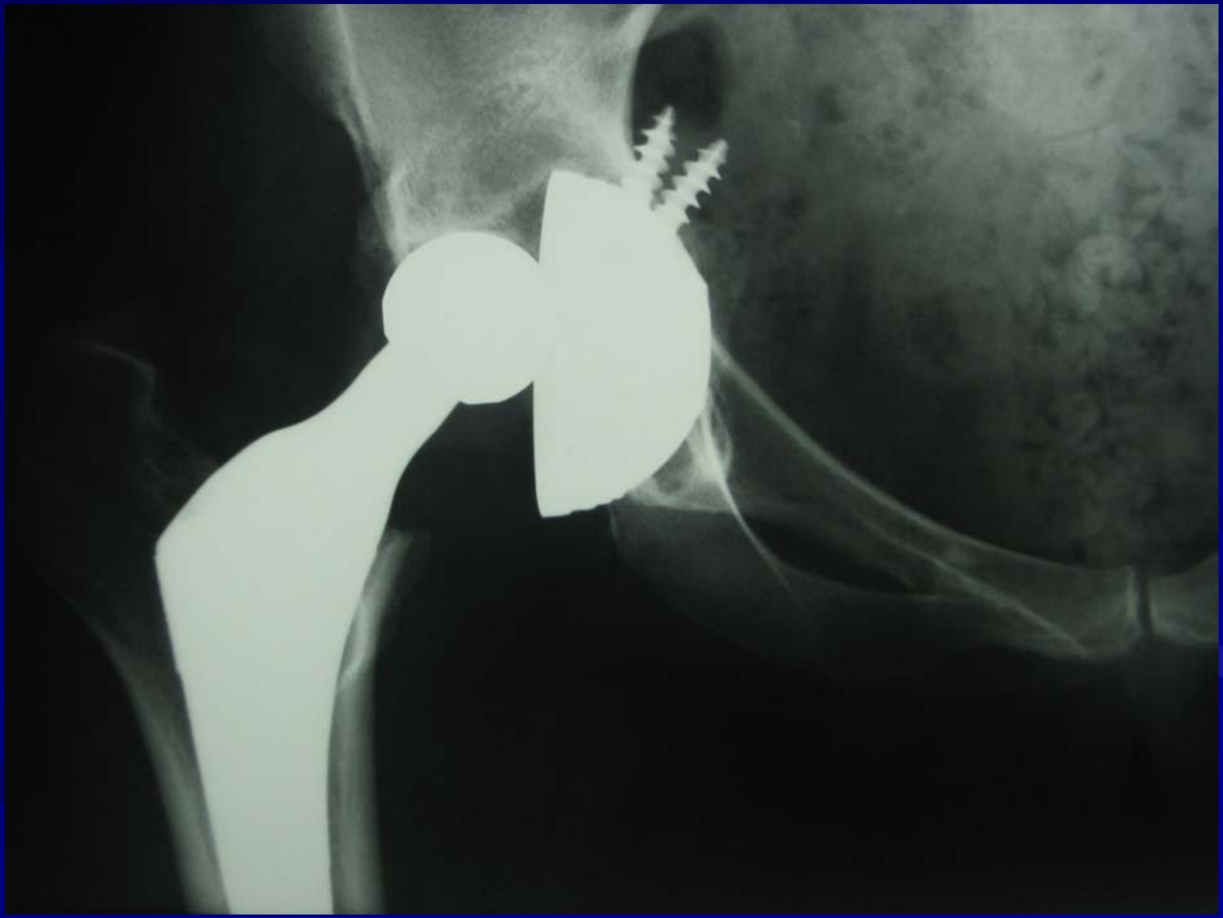
14,081 1st revision THR 1979-2000

Reason	N	Share
Aseptic loosening	10,610	75.3%
Primary deep infection	948	6.7%
Dislocation	810	5.8%
Fracture only	716	5.1%
Technical error	425	3.0%
Implant fracture	215	1.5%
Secondary infection	128	0.9%
Polyethylene wear	126	0.9%
Pain	46	0.3%
Miscellaneous	56	0.4%
Missing	1	<0.1%
Total	14,081	100%

"Table illustrating the reasons for revision in the 14,081 first revision total hip replacements (THRs) that were performed from 1979 to 2000. Aseptic loosening was the dominant reason, with a rate of 75.3%. Primary deep infection was the reason for 6.7% of the revisions. **Dislocation and technical error constituted the reasons for 8.8% of the revisions and could have been mainly related to malpositioning of the implants.** Periprosthetic fractures (5.1%), implant fractures (1.5%), and a number of less prevalent reasons constituted the balance of the reasons."

Swedish Registry, J. Bone Joint Surg. Am. 84:2-20, 2002

CAS - Hip



HCUPnet - 2004

	Primary Hip Replacement	Revision Hip	Revision %
Total number of discharges	225,900 (+/- 12,305)	37,115 (+/- 2,327)	16.4%
LOS (length of stay) days (mean)	4.1 (+/- 0.1)	5.4 (+/- 0.1)	
Charges ($ Mean)	36,846	45,621	
Aggregate charges $ (the "national bill")	8,316 M	1,684 M	
In-hospital deaths	607 (0.27%)	244	0.66%

HCUP Hip Revision - 2004

	Loosening Rate	Dislocation and Technical Error Rate (DTE)	Assume All Loosening and All DTE Eliminated with Improved Positioning	Assume One Half DTE Eliminated with Improved Positioning
Total number of discharges	0.753	0.088	31,200	1,630
Aggregate charges $ (the "national bill")			$1,420 B	$741,000 M
In-hospital deaths			205	11

HCUP Hip Revision - 2004

	Loosening Rate	Dislocation and Technical Error Rate (DTE)	Assume One Half DTE Eliminated with Improved Positioning	Incremental Cost / Primary Hip
Total number of discharges	0.753	0.088	16	
Aggregate charges $ (the "national bill")			$741 M	$328
In-hospital deaths			11	

CAS - Hip

- Validate Assumptions
  - Importance of Position
    - Current Prostheses
    - Current Surgical Technique
    - Uncertain Impact of Position on Loosening
    - Health Status Impacts
  - Improve Economic Model
    - Discounting and Full Cost Accounting
    - Obtain Utilities to Support Comparison with Alternative Health Expenditure
  - Validate CAS Systems
    - Traceable Certification
    - Reliability Standards

CAS - Hip

- Validate Assumptions
  - CAS Usability
    - Continue to Reduce Usage Time
    - Reduce Capital Cost
  - Prove that Practicing Surgeon Can Duplicate Published Results
    - CAS System
    - Reproducibility Models and Protocols
  - Educational Models / Training Programs
  - Policy Maker / Insurance Reimbursement for Improved Primary Surgery

CAS Systems Needs

- Standardized Artifacts and Protocols
  - Allow Comparison between Systems
  - Phantoms That Support Traceability to Standard Organizations are Needed
    - Confirm Basic Metrology
  - Phantoms That Replicate Standard and Outlier Patients
    - Geometry – Range Validation
      - Size
        - "Dwarf" – "Giant"
      - Soft Tissue
        - Asthenic – Morbidly Obese
    - Representative Anatomic Referencing Landmarks
    - Radiographic Characteristics Comparable to "Normal" Human

CAS Systems Needs

- Standardized Artifacts and Protocols
  - Standard Testing Protocols
    - Replicate OR Environment
      - EM Interference
      - Lighting Conditions
      - Temperature
      - Usability
        - Performance Time
        - Contamination
    - Support Reproducibility Testing
    - Support Field Calibration

CAS Systems Needs

- Standardized Artifacts and Protocols
  - Process Monitoring Protocols
    - Six Sigma
      - Dimensional Change over Time
      - Vibration
      - Temperature Change
      - Product History
    - Summary Measure(s)
      - Offset Process Capability Index
      - Relevant Degrees of Freedom
  - Educational Models
    - Training Programs

Summary

- Validate Assumptions
  - Expand and Refine Relationships between Component Positions and Clinical Outcomes through Longer term investigations.
  - Confirm Lack of Clinical Complications from real world Usage (eg: pin fracture, bone fracture, soft-tissue complications, etc.)
  - Support Joint Registry
- Technology Can Work!
  - Innovators have Demonstrated Positioning Capability with CT Referencing and Optical Technology
  - EM Technology Validation - Pending
  - Need to Prove Generalizability of the Technology to the Practicing Surgeon

Summary

- Improve Economic Model
  - Discounting and Full Cost Accounting
  - Obtain Utilities - Comparison with Alternative Health Expenditure

Summary

- CAS Systems Needs
- Standardized Artifacts and Protocols
  - Allow Comparison between Systems
  - Phantoms That Support Traceability to Standard Organizations are Needed
    - Confirm Basic Metrology
  - Phantoms That Replicate Patient
    - Geometry
    - Anatomic Landmarks
    - Radiographic Characteristics
  - Standard Testing Protocols
    - Replicate OR Environment
    - Support Reproducibity Testing
    - Support Field Calibration
  - Process Monitoring Protocols
    - Six Sigma
  - Educational Models
    - Training Programs

Thank

You