THE KNEE SOCIETY | VIRTUAL FELLOWSHIP

Robotics in Knee Arthroplasty

Presented by:

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DISCLOSURES

- Royalties
  - Zimmer Biomet, Smith and Nephew
- Consultant
  - Zimmer Biomet, Smith and Nephew
- Speaker’ s bureau
  - Zimmer Biomet, Smith and Nephew
- Publishers:
  - Saunders, Lippincott Williams Wilkins, Springer
- Shareholder:
  - Blue Belt Technologies, CD Diagnostics

ROBOTS IN INDUSTRY

- Efficient
- Economical
- Exacting

"Robotics industry today is where the PC industry was 30 years ago." **

Bill Gates, Scientific American 2007

**(Especially healthcare)

EXPERIENCE WITH ORTHOPAEDIC ROBOTS

- Initial skepticism
- Early adopters showed value
  - Alignment
  - Soft tissue balance
  - Recovery
  - Blood loss
  - Safety (semi-autonomous)
- Increased utilization with pricing improvements

Lonner JH. Operative Techniques in Orthopaedics 2015

STORY OF ROBOTICS IN KNEE ARTHROPLASTY

- Study in patterns that define technological progress and innovation, in general
  - Newer companies/technologies
  - Declining capital and maintenance co
  - Smaller space requirements
  - Broadening access
  - Increased utilization
  - Expanding applications

Lonner JH. Operative Techniques in Orthopaedics 2015

STAKEHOLDERS WILL INFLUENCE FURTHER GROWTH OF ROBOTICS

Hindawi Publishing Corporation
Advances in Orthopedics
Volume 2013, Article ID 948360, 3 pages
http://dx.doi.org/10.1155/2013/948360

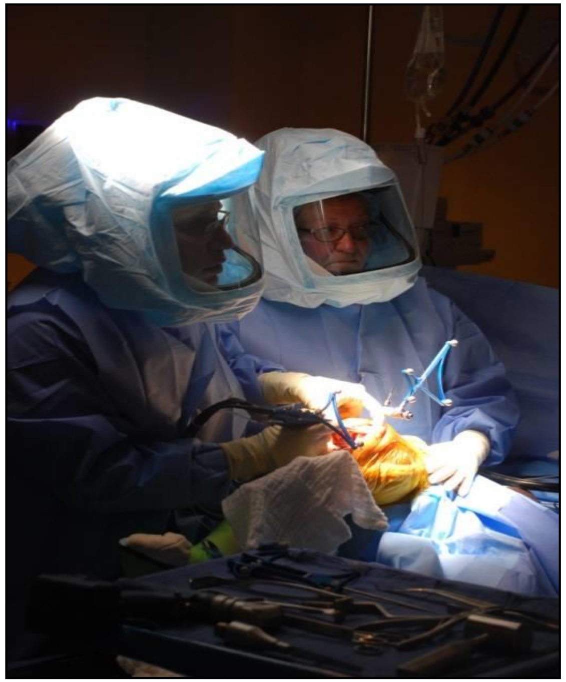
Editorial

Current Concepts in Robotics for the Treatment of Joint Disease

Michael A. Conditt,[1] William L. Bargar,[2] Justin P. Cobb,[3] Lawrence D. Dorr,[4] and Jess H. Lonner[5]

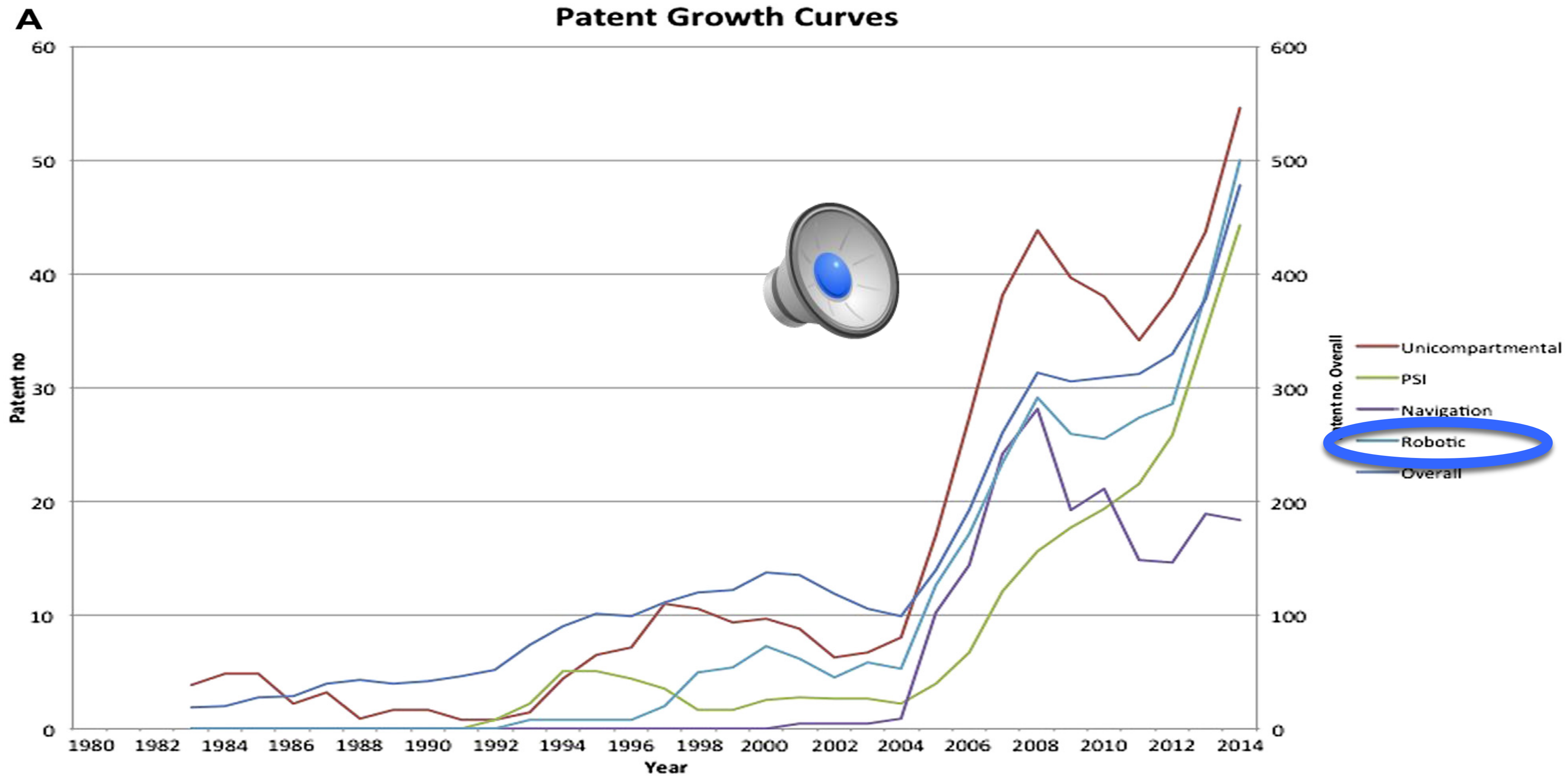
EXPANDING ROLE FOR ROBOTICS IN UKA

- 15% of UKA’s in US (2013)



www.OrthopedicNetworkNews.com. 2013

PATENTS AS A SURROGATE INDICATOR OF INNOVATION



Dalton DM et al. J Arthroplasty 2016

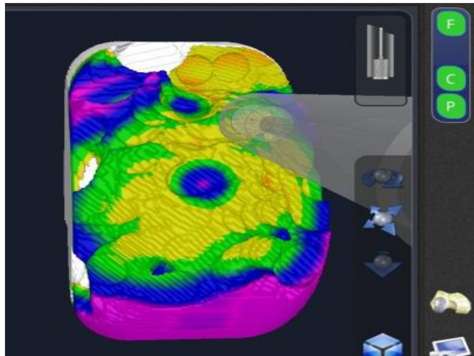
ROBOTIC LANDSCAPE: PROJECTED PENETRATION

- UKA
  - ~29% in five years
  - ~37% in 10 years
- TKA
  - ~10% in two years
  - ~18% in five years
  - ~23% in ten years

Medical Device and Diagnostic Industry, March 5, 2015
http://www.mddionline.com

KEY DISTINCTION IN ORTHOPAEDIC ROBOTICS

- Autonomous- robot operates independently
  - TCat (formerly Robodoc)– iThink Surgical
    - FDA approved for THA
    - Not FDA approved for TKA
- Semi-autonomous- surgeon guided; haptic or speed/exposure constraint
  - Mako (Stryker)
    - FDA approved for THA, UKA, PFA, TKA
  - Navio (Smith and Nephew)
    - FDA approved for UKA, PFA, TKA
  - OmniBot (Omni)
    - FDA approved for TKA



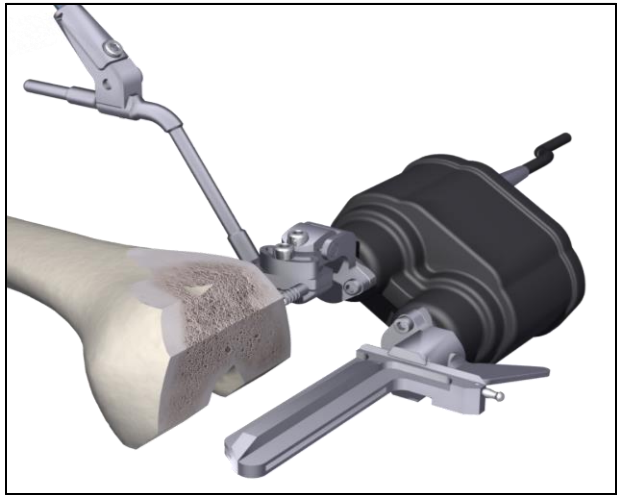
COMPLICATIONS WITH AUTONOMOUS SYSTEMS

- Complications THA
  - Soft tissue injuries, over-resectio
    - Severe abductor injuries/sciatic ve injuries
  - 18% revision due to instability (vs 4% control)
- Aborted cases TKA
  - 8% soft tissue injury

Honl et al JBJS 2003
Chun et al J Arthrop 2011

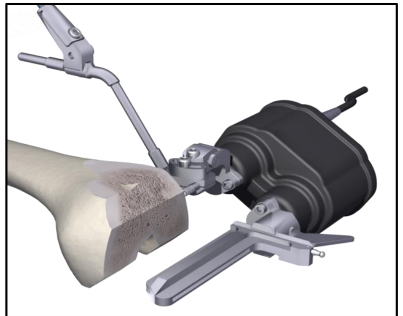
ADVANCEMENT OF SEMI-AUTONOMOUS ROBOTIC SYSTEMS

- Safety and avoidance of soft tissue complications has been key distinction



ROBOTICS FOR TKA?

- Unclear need for "precise" alignment
- Potential roles:
  - Optimizing soft tissue balance?
  - Bicruciate retaining TKA?
    - Access, balance
  - Facilitating efficiencies?
  - Reducing instrument storage/sterilization needs/costs?
    - Applicable for ASC's

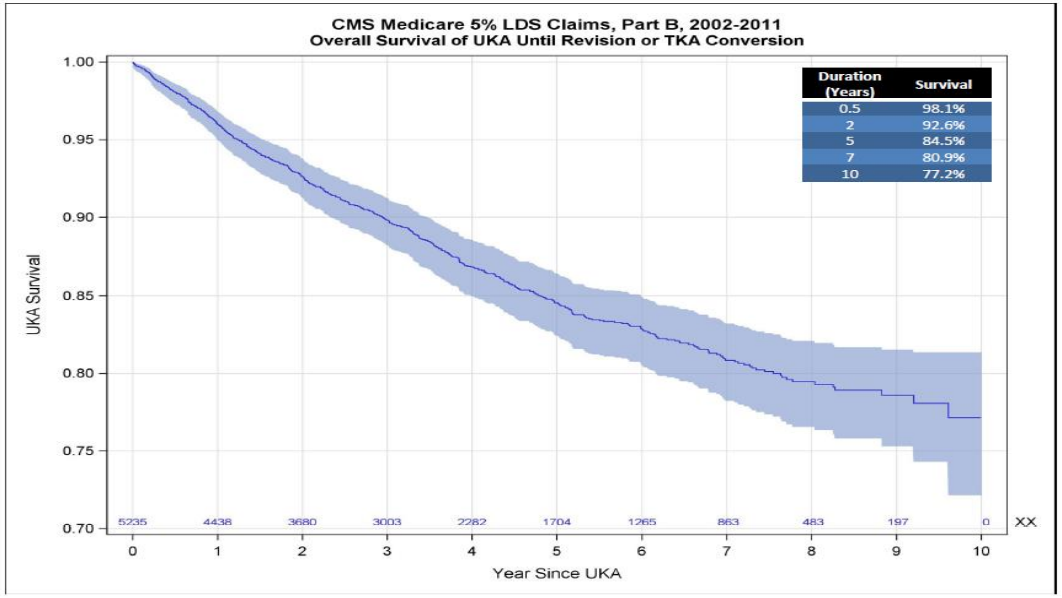


ROBOTICS FOR UKA?

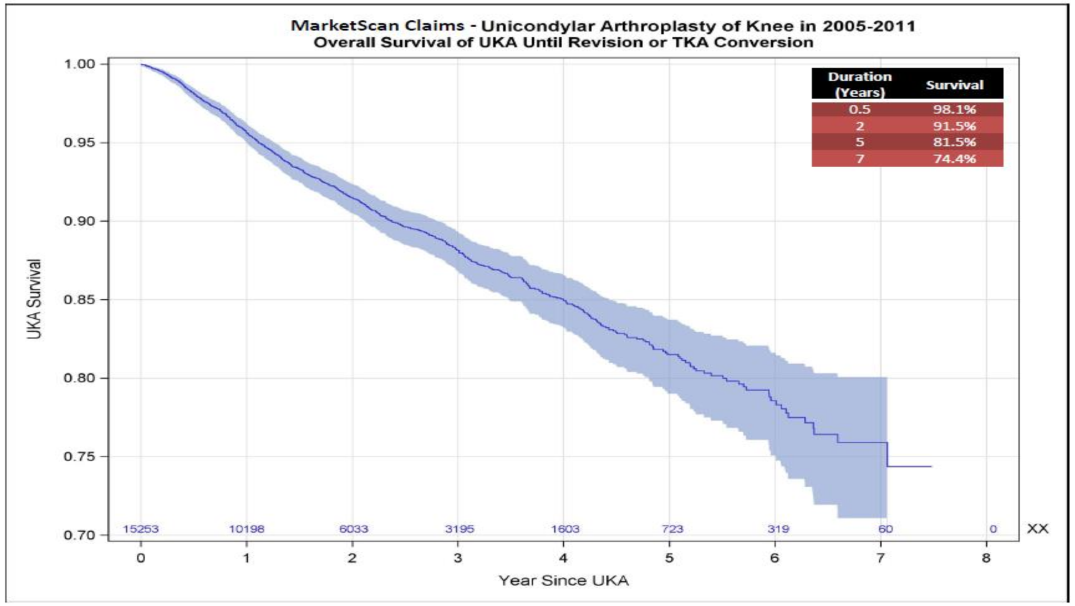
- 94% survivorship at 10-15 yrs in hands of high volume surgeons…

…BUT

> Age 65



< Age 65



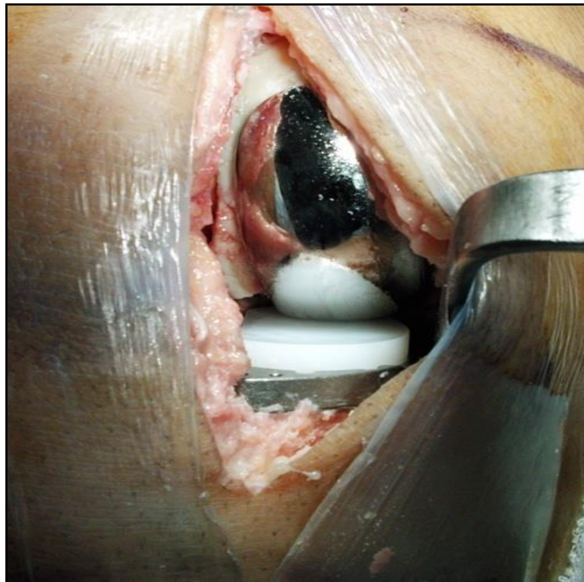
10-yr survivorship 77%

7-yr survivorship 74%

Ong, Kurtz, Hansen, Lonner AAHKS 2014

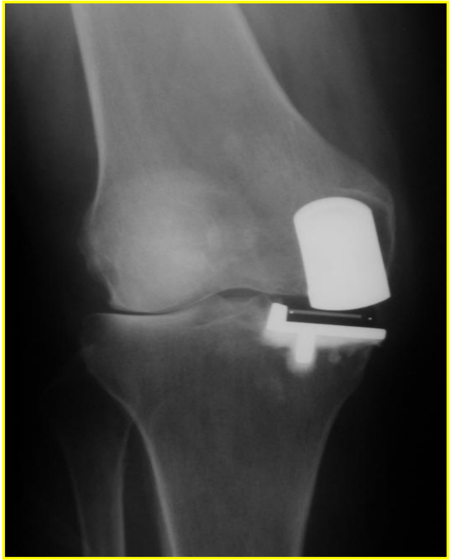
WHAT IMPACTS THE RESULTS OF UKA?

- Pathology/Disease
- Patient selection
- Component design
- Polyethylene quality
- Surgeon experience/volume
- Accuracy of implantation
- Soft tissue balance



MALALIGNMENT PREDISPOSES TO FAILURE

- Coronal malalignment of tibial component >3° varus
- Mechanical limb varus >8°
- Posterior tibial slope >7°



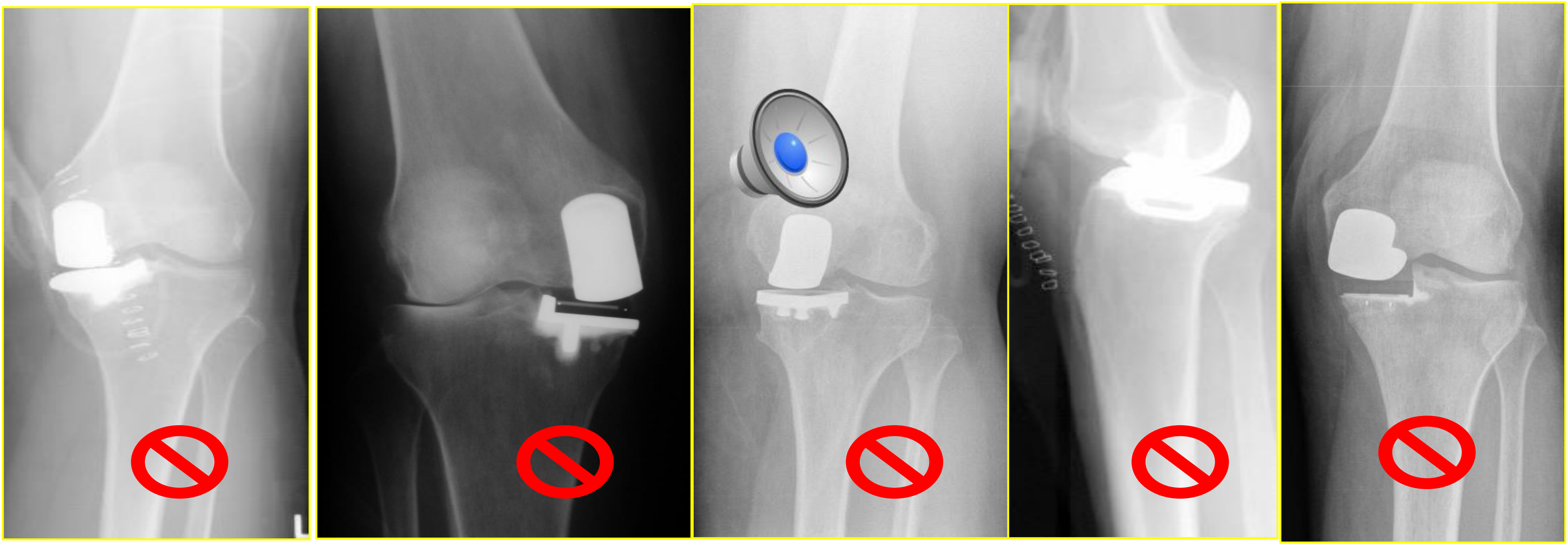
Collier /Engh et al. J Arthroplasty 2006; Hernigou JBJS 2004; Chatellard Orthop Traumatol Surg Res 2013

UKA MALALIGNMENT > IN MIS THAN OPEN WITH STANDARD INSTRUMENTATION

- Greater inaccuracy in tibial component alignment and limb alignment
  - Fisher DA et al. (J Arthrop 2003)
  - Hamilton WG et al. (J Arthrop 2006)

OUTLIERS IN ALIGNMENT IN UKA WITH CONVENTIONAL METHODS

- 40-60% of cases are malaligned beyond 2° of plan

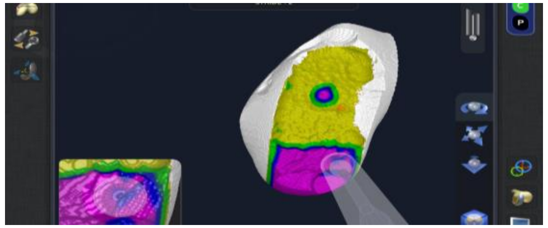


Keene G et al JBJS Br 2006;
Cobb J et al JBJS Br 2006

RATIONALE OF ROBOTICS FOR UKA

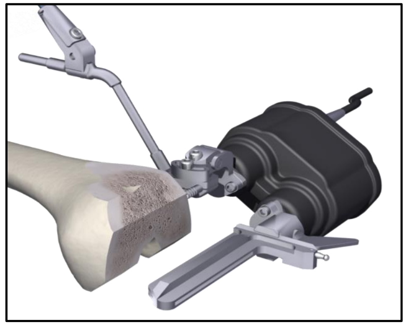
- Simplify the procedure
  - Reduce the amount of instrumentation
  - Eliminate surgical steps
- Enhance accuracy
  - Bone preparation/component alignment
  - Soft tissue balance
- Improve clinical results

Lonner JH. American Journal of Orthopedics 2009



SEMI-AUTONOMOUS ROBOTICS IN KNEE ARTHROPLASTY IN U.S.

- Virtual planning
  - Bone resection
  - Component sizing
  - Implant alignment
  - Soft tissue balancing



1ST GENERATION SYSTEM

- Image based CT planning and computer guidance
  - Balance & alignment
  - Implant positioning and sizing
- Intraop virtual gap balancing
- Bone prep with 6 mm burr attached to robotic arm

1ST GENERATION SEMI-AUTONOMOUS ROBOTIC ARM FOR UKA:

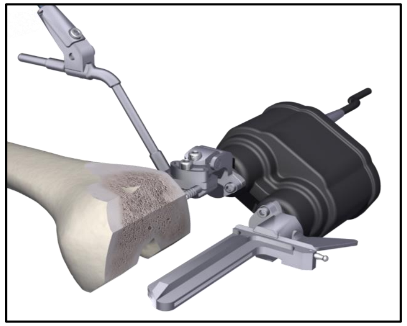
- Haptic constraint
- Efficient
- Accurate
- Safe
- Image-based (preop CT scan)

DOWNSIDES OF 1ST GENERATION SEMI-AUTONOMOUS ROBOTIC SYSTEM

- Capital expense
- Preop CT scan
  - Additional expense
    - Denials common; high copays; bundled payments
    - Hospitals "eat cost"
  - Time/Inconvenience
  - Radiation exposure

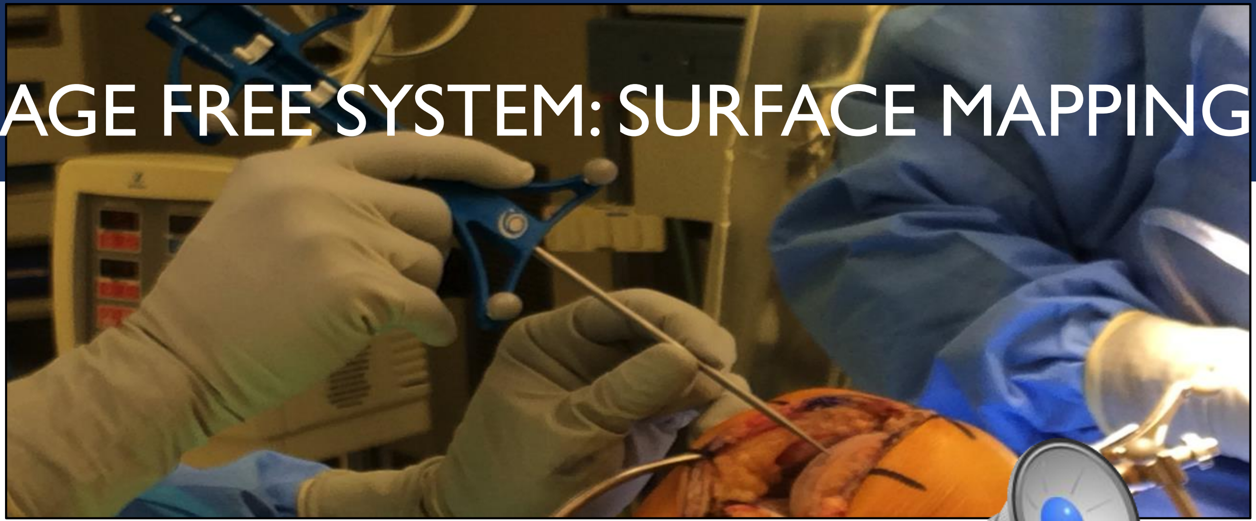
2ND GENERATION SEMI-AUTONOMOUS ROBOTIC SYSTEMS:

- Image-free (No CT scan)
- Intraop registration/mapping/planning
- Intraop gap balancing
- Burr Speed/Exposure control
- Cost favorable
  - 35% being used in ASC's for UKA



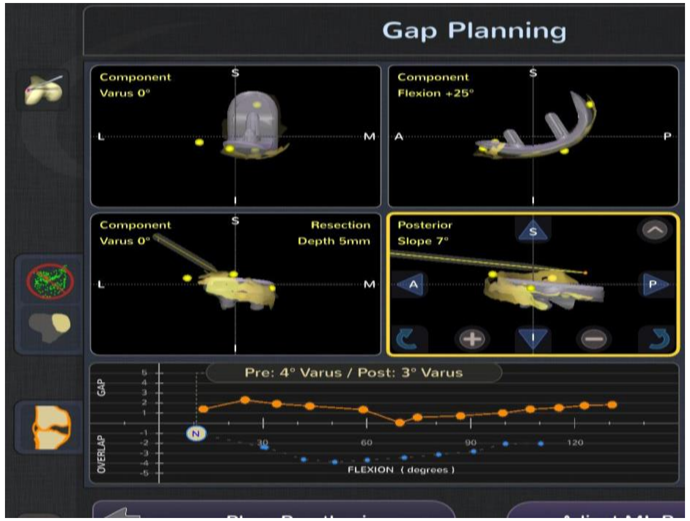
SURGICAL TECHNIQUES

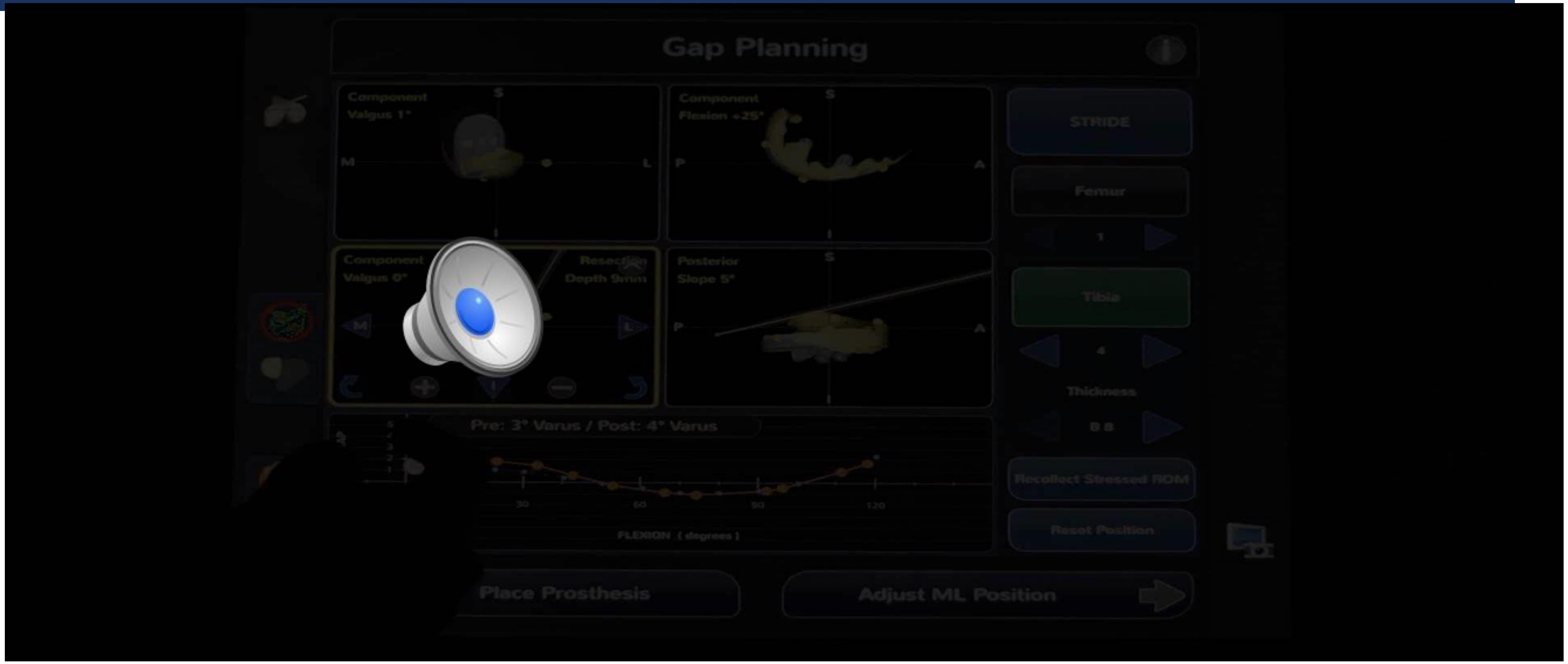
IMAGE FREE SYSTEM: SURFACE MAPPING



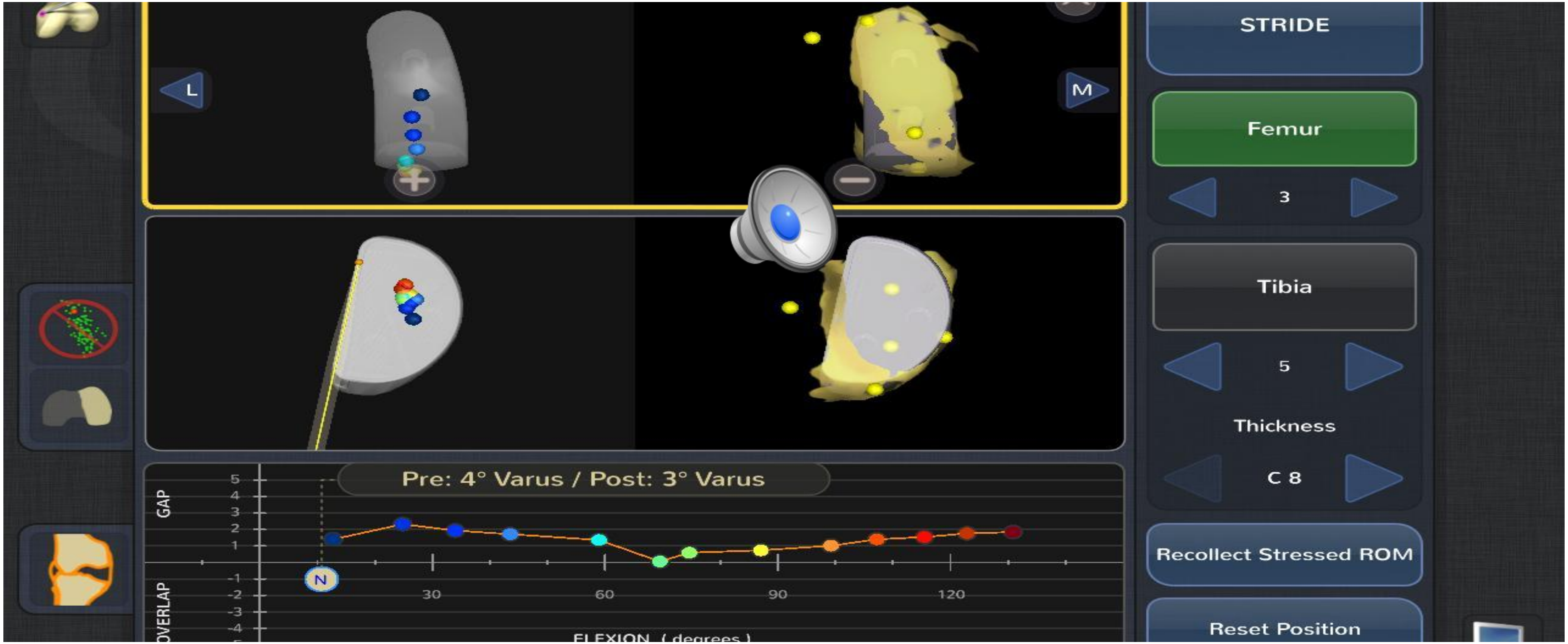
DYNAMIC INTRAOP GAP BALANCING

SELECTION OF IMPLANT SIZE/POSITION AND VIRTUAL GAP BALANCE

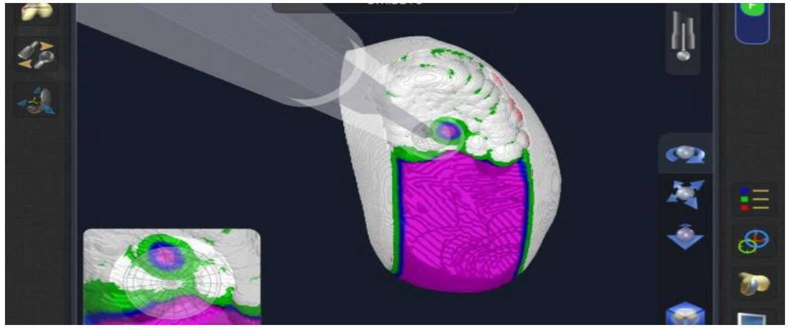


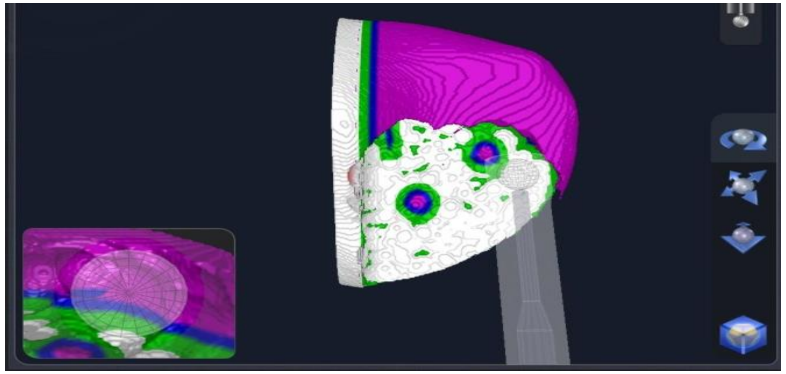


VIRTUAL TRACKING OF FEMUR ON TIBIA

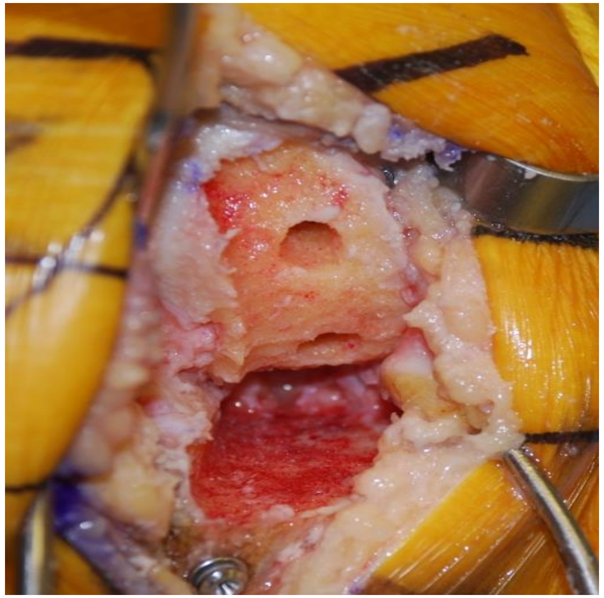


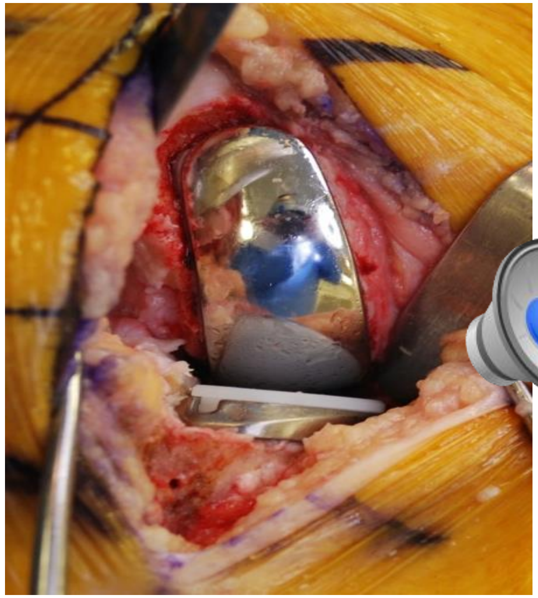
TECHNIQUE: BONE PREPARATION





PREPARED SURFACE





CT-BASED SYSTEM: PREOP PLANNING

IMAGE-BASED SYSTEM: DYNAMIC SOFT-TISSUE GAP BALANCING

- Remove osteophytes
- Tension MCL/LCL
- Capture tissue tension through ROM
- Adjust prn

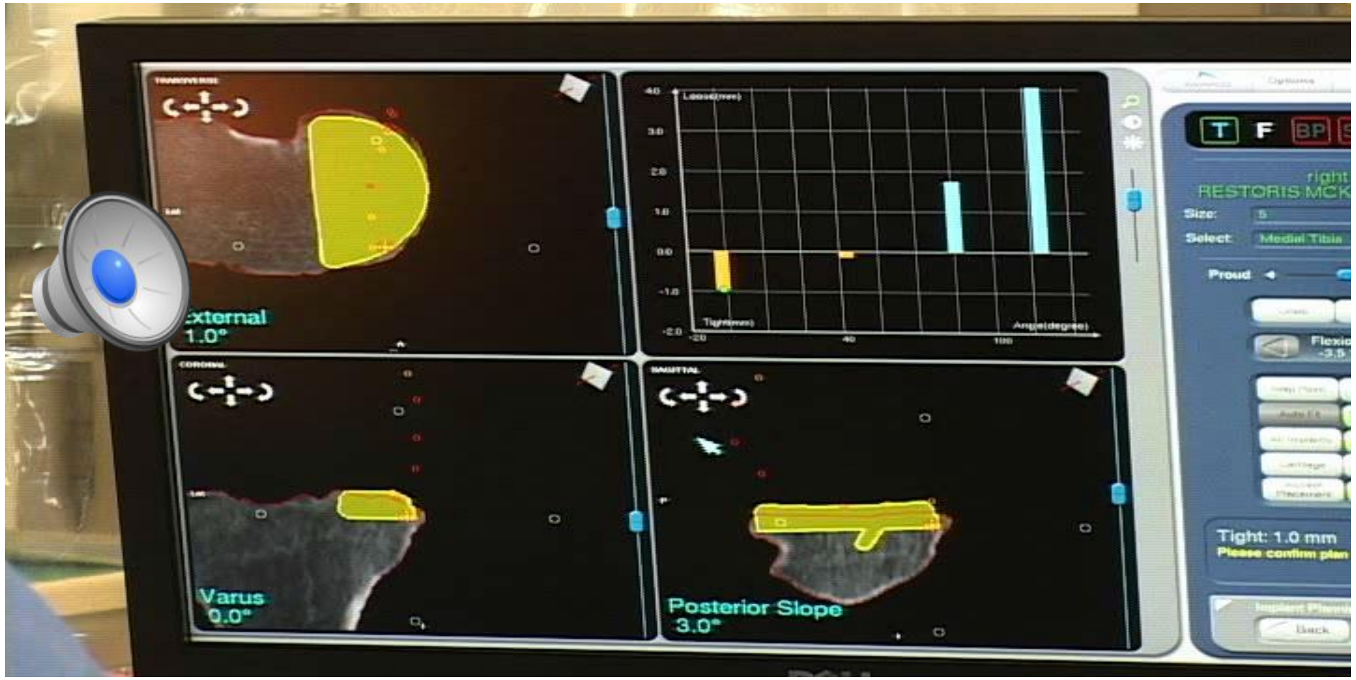
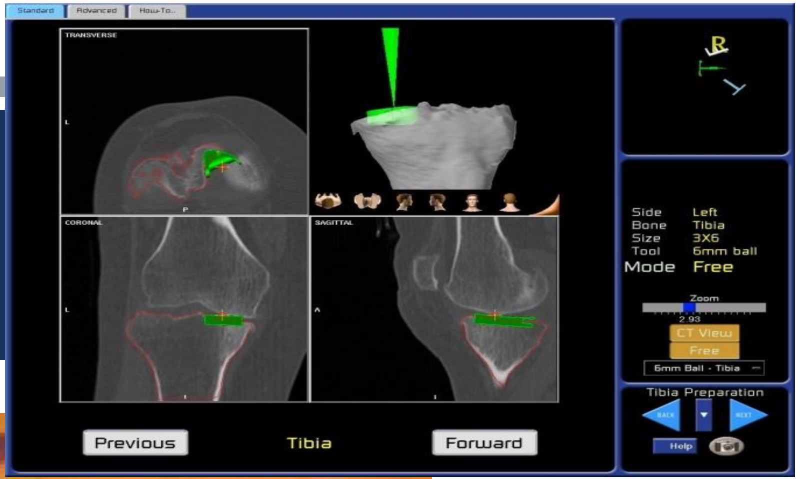
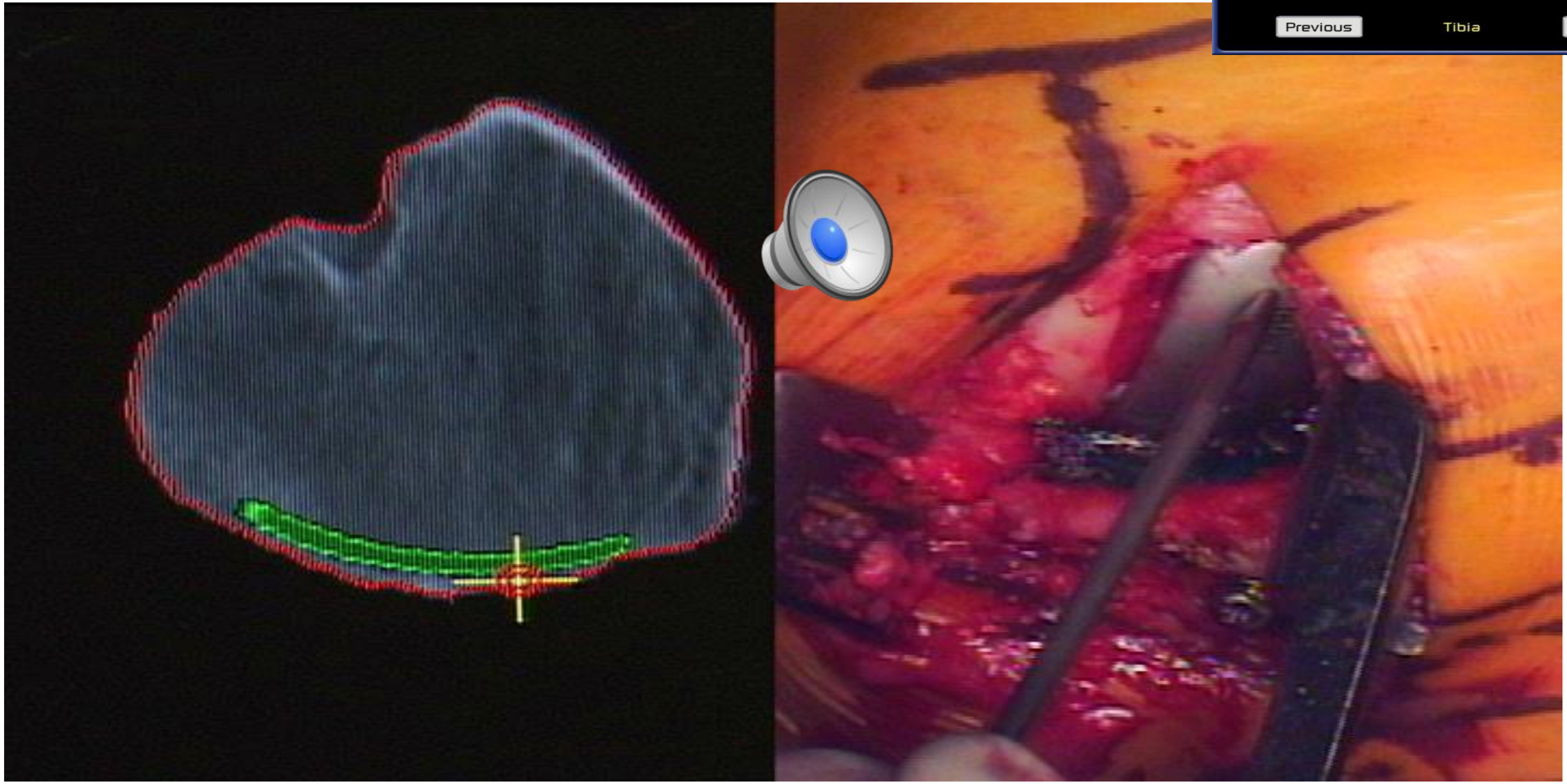


IMAGE BASED SYSTEM: HAPTIC CONSTRAINT

Bone resection volume based upon planned component placement and size

IMAGE-BASED SYSTEM: ASSESSING ACCURACY OF IMPLANT POSITION





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KEY STUDIES

- Accuracy of bone preparation
  - Pre-clinical (cadaveric specimens) and clinical studies
- Comparison of intraoperative plan for limb alignment with postop limb alignment
  - Clinical (navigated measures)
- Accuracy of tibial component alignment and volumetric bone preservation
  - Radiographic
- Learning Curve
- Safety
- Radiation avoidance by using image-free systems (eliminating preop CT scans)
- Survivorship and satisfaction

TIBIAL ALIGNMENT -- UKA

- Initial 31 robotic UKA's with Haptic, CT-based robotic system
- Matched group of preceding 27 conventional UKA
  - Height, weight, ROM, alignment
- Study parameter: Tibial alignment

(Lonner, John, Conditt CORR 2009)

TIBIAL ALIGNMENT -- UKA

- Variance: 2.6x greater with manual techniques ($p<0.05$)
- RMS error: 3.4° (manual) vs. 1.8° (rob
- Coronal alignment – Avg error:
  - Manual: 2.7 +/- 2.1° more varus
  - Robot: 0.2 +/-1.8 ° ($p<0.0001$)

(Lonner, John, Conditt CORR 2009)

ACCURACY OF COMPONENT POSITIONING IN UKA: SEMI-AUTONOMOUS ROBOT VS. CONVENTIONAL

- Prospective RCT, 120 patients
  - 62 robotic UKA (Robotic)
  - 58 conventional (Conventional)
- Component alignment and position determined by CT scan
  - Coronal, sagittal and axial positioning

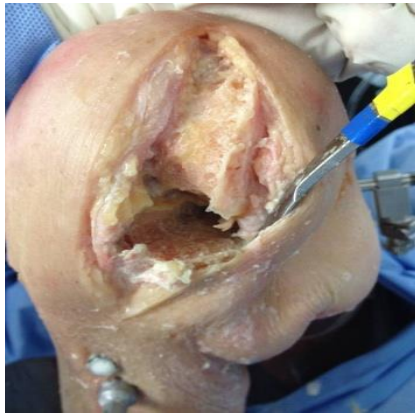
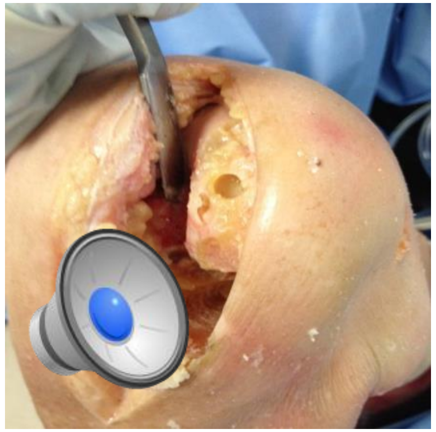
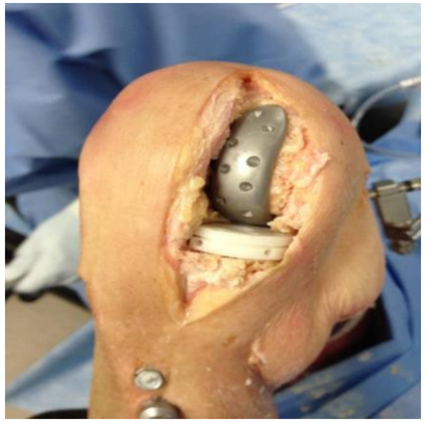
Bell SW et al. J Bone Joint Surg. 2016

ACCURACY OF COMPONENT POSITIONING IN UKA: SEMI-AUTONOMOUS ROBOT VS. CONVENTIONAL

- Robotic assistance had:
  - significantly lower component medi[illegible]plantation errors in all 3 component parameters ($p<0.01$)
  - Significantly fewer outliers >2° of target positions

Bell SW et al. J Bone Joint Surg. 2016

PRE-CLINICAL ACCURACY

- 25 cadaveric specimens
  - Image-free semi-autonomous system (2nd Generation robot)
  - Medial UKA
  - 3 surgeons

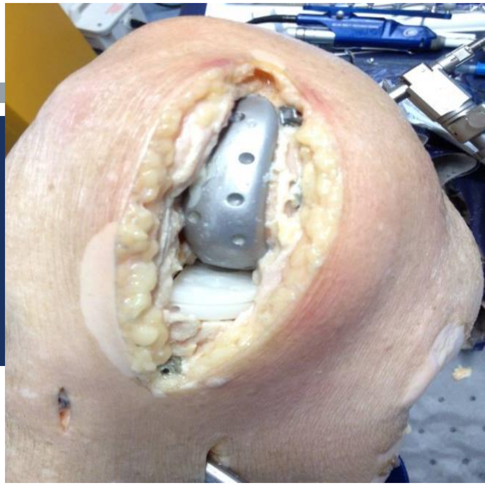
Lonner, Smith, Picard, Hamlin - Clin Orthop 2014

ANALYSIS METHOD

- Preop plan

- Postop analysis
  - Optical probe inserted into implant divots
  - Surface positions mapped
  - Postop position compared to plan

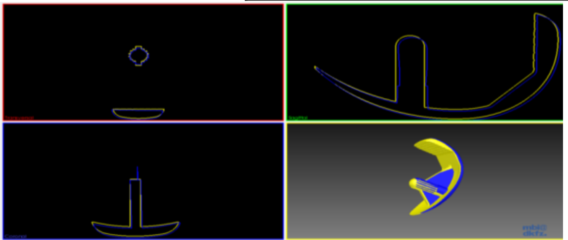
Lonner, Smith, Picard, Hamlin - Clin Orthop 2014



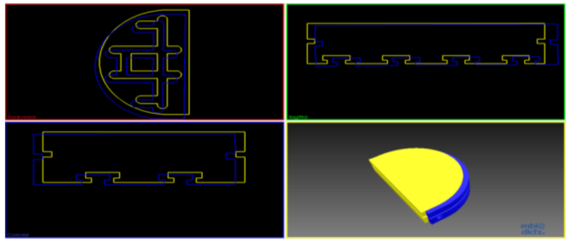
ALIGNMENT:
SEMI-AUTONOMOUS ROBOTS VS. MANUAL

2.6x less variability than manual techniques ($p<0.05$)

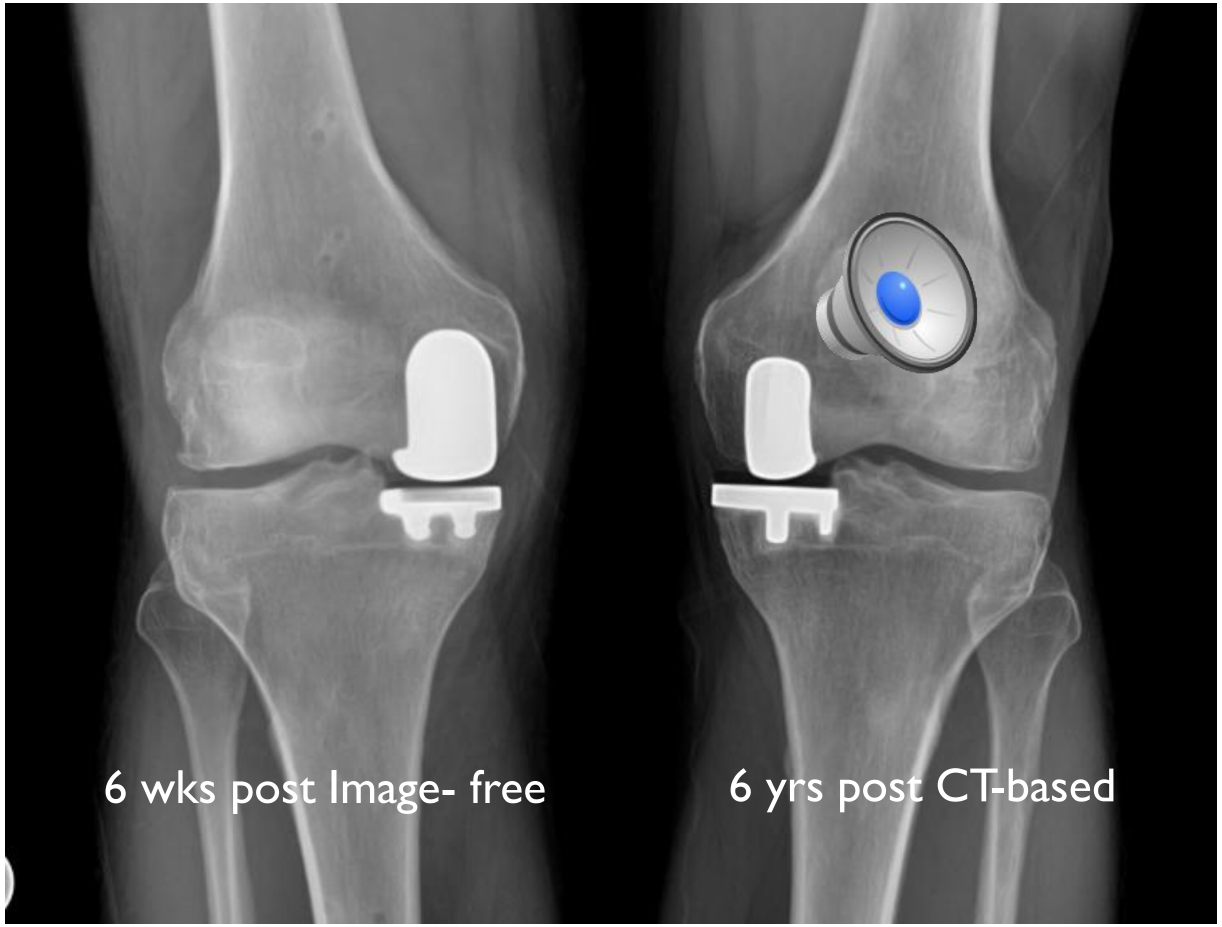
RMS Error	Image-Free	CT-Based	Manual
Flex/Ext (°)	1.6	2.1	4.1
Varus/Valgus (°)	2.3	2.1	6.0
Int/Ext (°)	1.7	3.0	6.3
Prox/Dist (mm)	1.3	1.0	2.8
Ant/Post (mm)	1.3	1.6	2.4
Med/Lat (mm)	0.9	1.0	1.6



Dunbar et al J Arthrop 2012
Jenny J Arthrop 2002
Lonner et al CORR 2014



ALIGNMENT: NO APPARENT DIFFERENCE -- CT-BASED VS IMAGE-FREE ROBOTIC SYSTEMS



PLANNED VERSUS ACHIEVED LIMB ALIGNMENT

- 65 cases, image-free robotic system
- Multiple surgeons
- Postop limb alignment ≤1° from plan 92% (60/65)

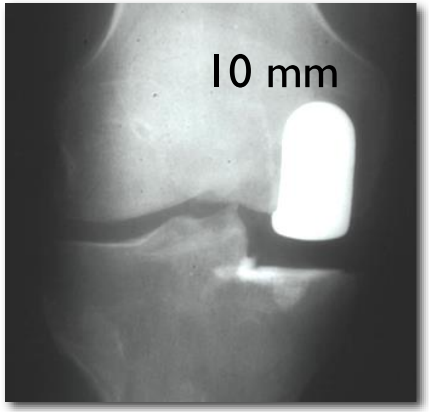
F Picard, A Gregori, J Bellemans, J Lonner, J Smith, D Gonzales, A Simone, B Jaramaz – CAOS July 2014

TIBIAL RESECTION (ROBOTIC VS. CONVENTIONAL)

- Industry Data
  - 27,989 conventional UKA's
  - 8421 semi-autonomous robotic UKA's
  - Studied variable: tibial poly thickness
- Implications for revision to TKA
  - Complexity, need for augments/stems

Robotic

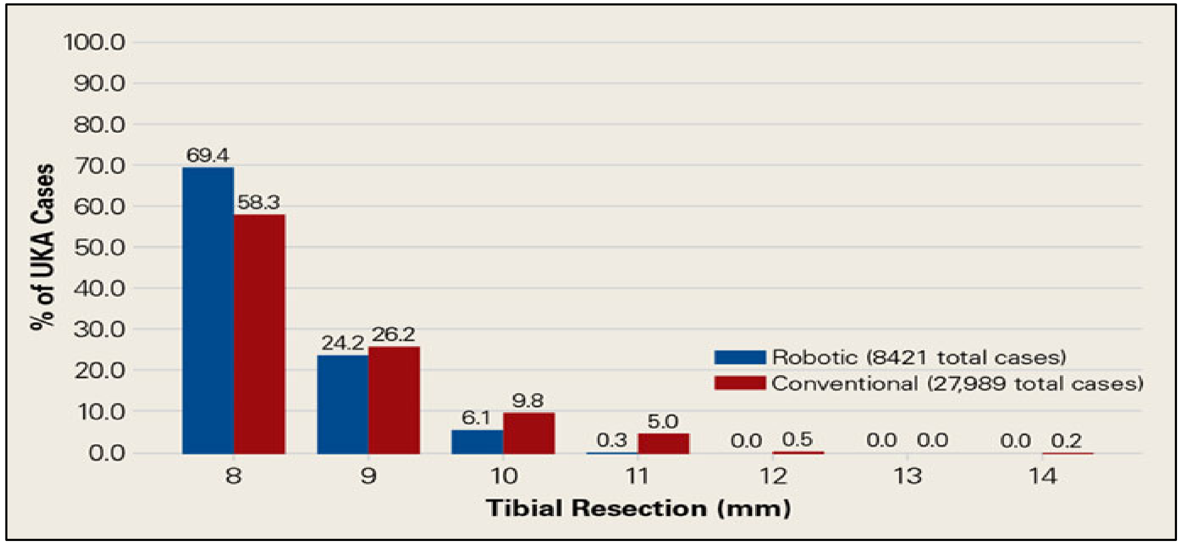
Conventional



Ponzio DY, Lonner JH. Am J Orthop 2016

TIBIAL RESECTION (POLY SIZES)

- 8-mm and 9-mm polyethylene inserts
  - Robotic group: 93.6%
  - Conventional group: 84.5% (*P* < .0001).
- Aggressive tibial resection, requiring tibial inserts m
  - Robotic group: 6.4%
  - Conventional group: 15.5%
- Tibial inserts >11 mm
  - Robotic group: 0.3%
  - Conventional group: 5.7%
- No differences between 2 semi-autonomous robots

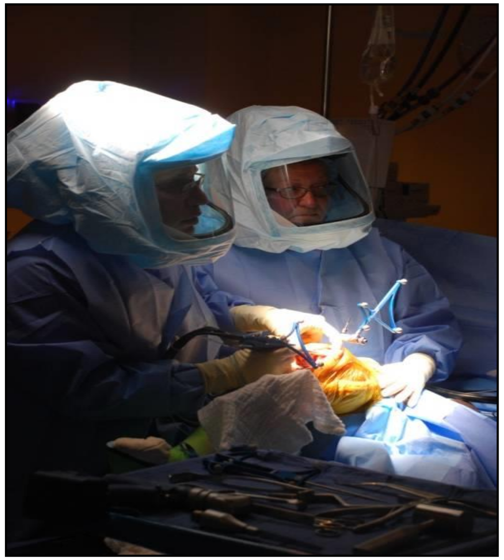


Ponzio DY, Lonner JH. Am J Orthop 2016

LEARNING CURVE

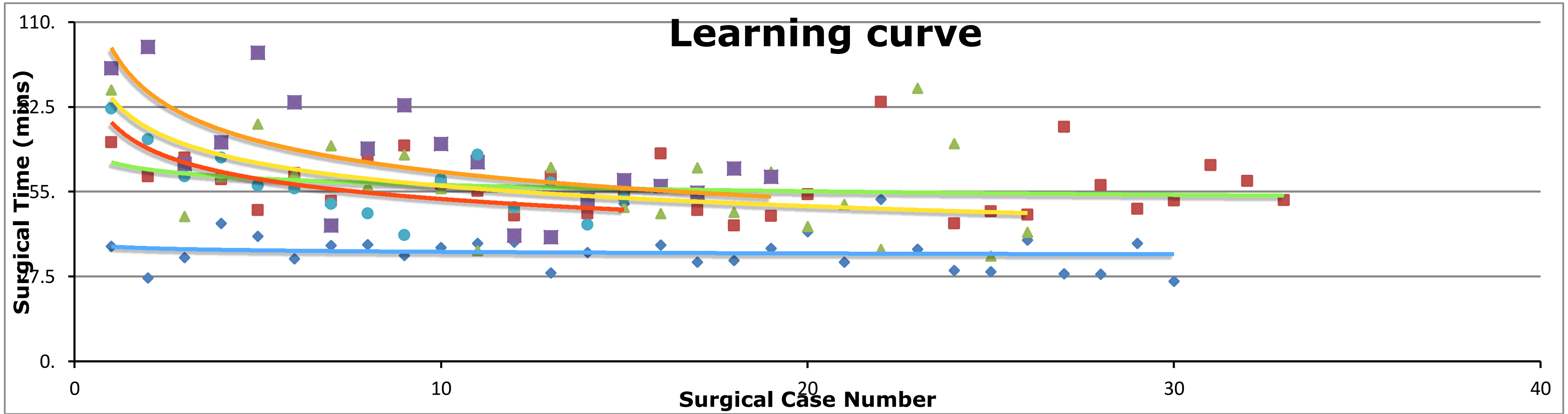
- Eleven novice users (2nd generation image-free system)
- Precision achieved immediately
- Mean of 8 procedures to reach a steady [illegible] surgical time (95% confidence interval 6-11)
- Avg. steady state surgical time 45 minutes (range 37-55 minutes)

A Gregori, F Picard, J Lonner, R Marquez, J Smith, A Simone, B Jaramaz - CAOS Abstract 2014



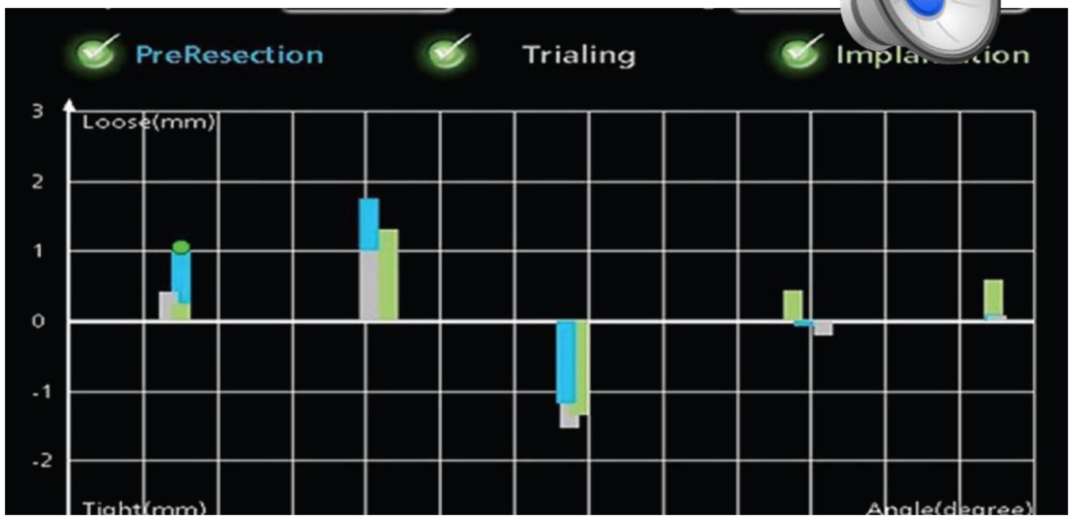
LEARNING CURVE

- Greatest improvement in “Cutting Phase”:
  - Average improvement from 42 to 24 minutes.
- Least improvement in “Anatomic Registration” and “Implant Planning”:
  - Average improvement from 14 minut 6 minutes.
- The mean steady state surgical time for all surgeons was 45 minutes (SE 4.3, p<0.001).



GAP BALANCING

- Final ligament balance after implantation accurate within 0.53 mm compared to dynamic plan



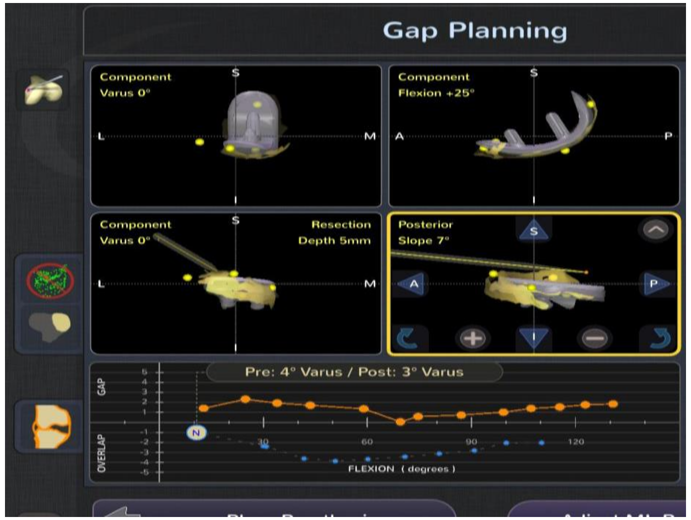
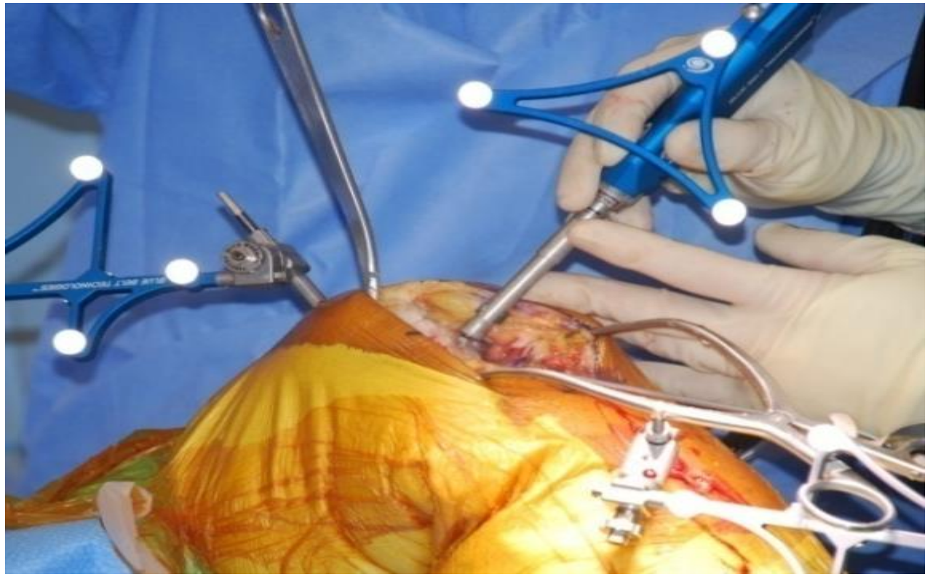


Plate JF et al Advances in Orthopedics 2013

SAFETY: SEMI-AUTONOMOUS ROBOTIC SYSTEMS

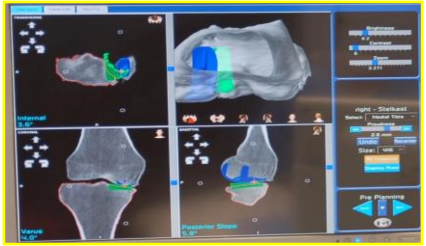
- Initial 1010 cases
- Single surgeon (JHL)
- No robot-related soft tissue complications



RADIATION FROM PREOP CT SCANS

- 236 scans 2011-2013
  - 1st generation image-based system
- ED of radiation from LE CT scan:
  - 4.8 +/- 3.0 mSv
- 25% had add'l CT scans (est cumulative ED of 6-103 mSv)
- Note: 10 mSv increases risk of fatal cancer by 1 in 2000

Ponzio DY, Lonner JH. J Arthroplasty 2015



SURVIVORSHIP AND SATISFACTION

- 909 consecutive semi-autonomous robotic UKA's
- 6 surgeons
- FB metal-backed implant
- Follow up: mean 30 mos [range, 22-52 mos]
  - Survivorship: 98.8% (96% if non-responders failed)
  - 92% satisfied in patients without revision

Pearle AD et al. Knee 2017

ROBOTICS FOR TKA?

- 100 TKA's
  - 50 conventional
  - 50 autonomous robotic-assisted (cur[illegible] not approved for use in U.S.)
- Mechanical axis outliers >3°:
  - Robotic: 0%
  - Conventional: 24%
- No differences in ROM or function scores

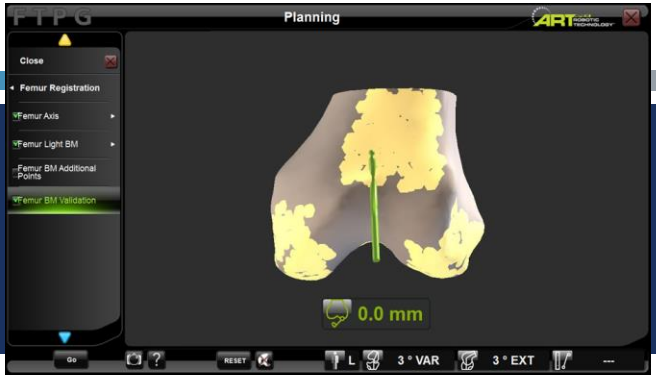
Song EK, Bargar WL et al. Clin Orthop 2013

ROBOTICS FOR TKA?

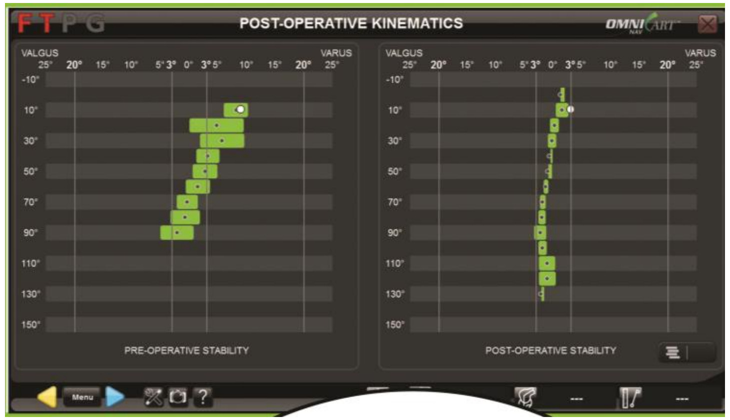
- Prospective RCT
- 60 TKA's
  - 29 conventional
  - 31 autonomous robotic-assisted (currently [illegible]roved for use in U.S.)
- Mechanical axis outliers >3°:
  - Robotic: 0%
  - Conventional: 19% (p=0.05)
- Joint line outliers (>5mm):
  - Robotic: 3.2%
  - Conventional: 20% (p=0.05)

Liow MHL et al. J Arthrop 2014

ROBOTICS FOR TKA



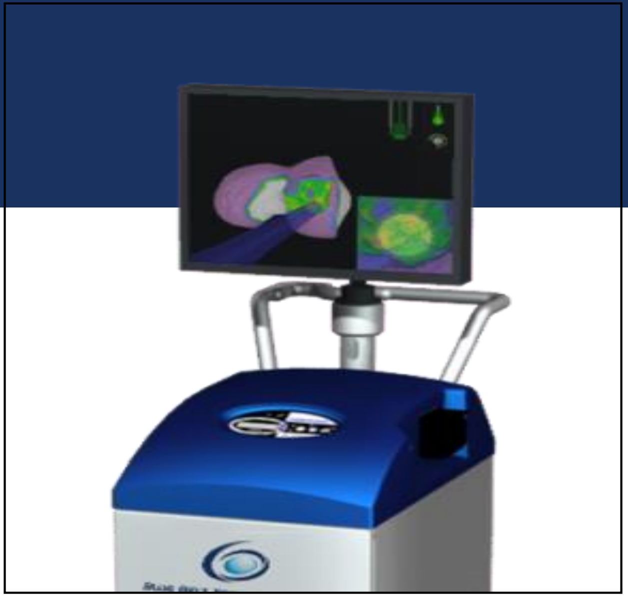
- Image-free semi-autonomous system (FDA approved)
- 108 initial cases
- Radiographic alignment data:
  - Mechanical axis within 3°: 91%*
  - Tibial component alignment within 3°: 99%
  - Femoral axis alignment within 3°: 99%



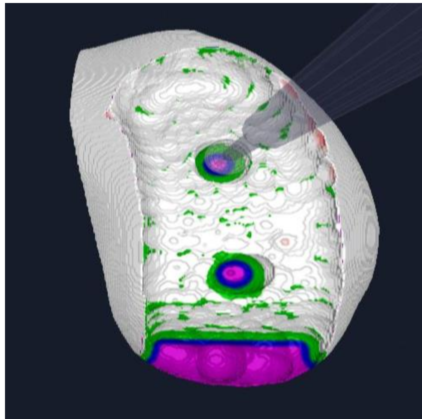
* Unpublished data suggests improved mechanical alignment with new kinematic balancing algorithm

Koenig JA, Plaskos C. Influence of Pre-Operative Deformity on Surgical Accuracy and Time in Robotic-Assisted TKA. Bone Joint J 2013;95-B (S-28) 62

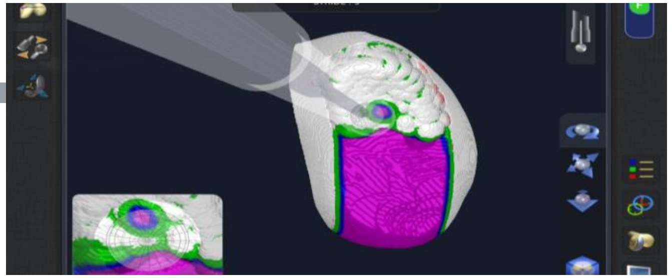
CONCLUSION: ROBOTICS



- Image-free vs CT based
- Autonomous vs. semi-autonomous
- Cost favorable?
- ASC-feasible?
- Expanding applications
  - UKA, PFA, BiKA
  - THA, TKA
  - Etc, etc.



CONCLUSION: ROBOTICS



- Semi-autonomous systems:
  - Accurate bone preparation, implant position, soft tissue gap balance
  - Safe
  - Further study needed to determine:
    - Functional outcomes
    - Impact on late results/durability

CONCLUSION: ROBOT

- Medicine is prime for a "disruption"
- Growing influence of smart technologies in knee arthroplasty
- Robotics fits into that paradigm
- Exponential utilization and development
- Stay tuned…

THANK YOU.

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