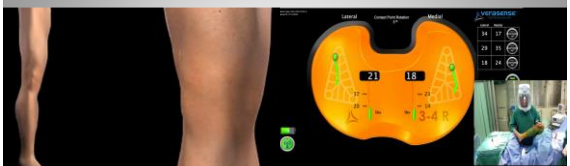
SENSOR ASSISTED SURGERY

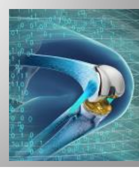
A Universal Solution to Customized Soft Tissue Balance



"You can't change what you can't measure"

Martin W. Roche, MD

Holy Cross Hospital Orthopedic Institute

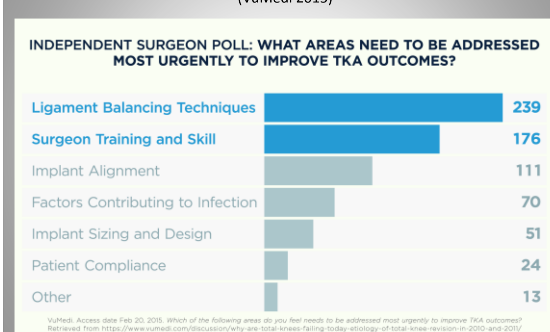


DISCLOSURES

- OrthoSensor Inc: (Royalties, Board Member)
- Stryker-MAKO, Inc: (Royalties)

SURGEON POLL

(VuMedi 2015)



WHAT DO WE WANT TO CHANGE ?

- Reduce Rev TKA Burden
- Mal-rotation
- Mal-alignment
- Soft tissue Imbalance
- Patient Dissatisfaction

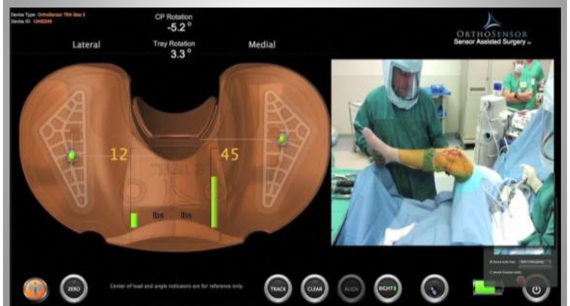
DRIVE TOWARDS A DEFINITION of " KNEE BALANCE"

SENSOR MULTIFUNCTIONALITY allows DYNAMIC INTRA-OP KINETIC ASSESSMENT

INTRA-OP SCENERIOS

- Soft Tissue Asymmetry and Imbalance
- Selective Soft Tissue Releases
- Implant Congruency and Mal-rotation
- Relation of "Balance" and Alignment Adjustments
- Effects of Cementing Techniques

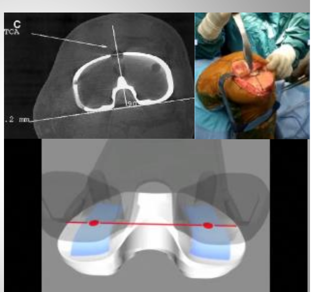
PIE-CRUSTING MCL



ROTATION

Importance of Proper Tray Rotation

- Retrospective analysis (n=170): 53% exhibited asymmetrical tibiofemoral congruency (68% IR, 32% ER)
- 1000+ CT scans: exhibited the mid-medial 1/3 of the tibial tubercle can vary by (± 25°)
- Inter-compartmental balance can be achieved by adjusting tibio-femoral congruency



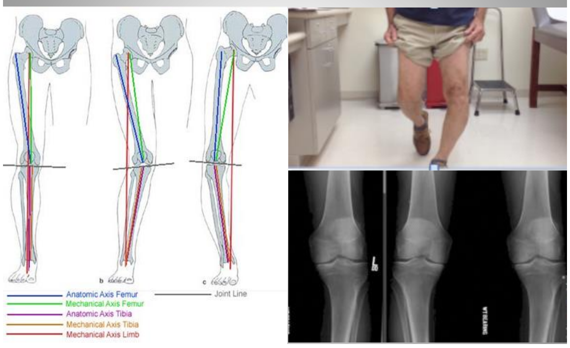
Roche M et al. The Relationship of the Medial 1/3 of the Tibial Tubercle to the Posterior Aspect of the Tibia, Holy Cross Hospital, Ft. Lauderdale, FL

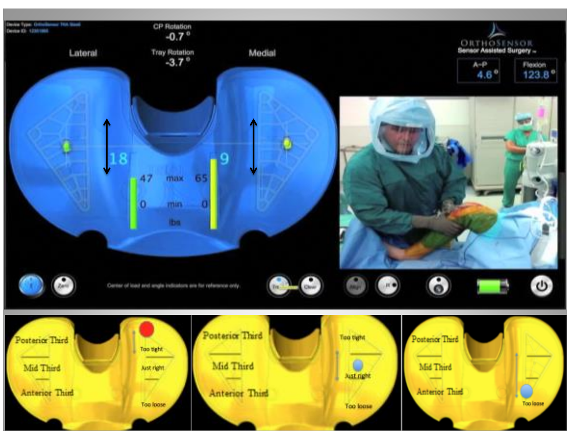
VALGUS KNEE

Concerns:

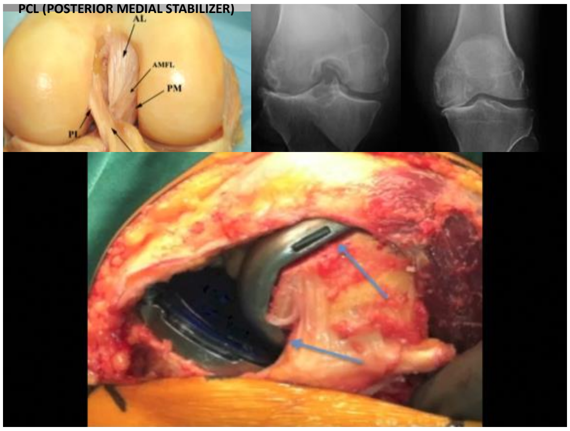
- Contracture / Recurvatum
- MCL Stability
- Femoral Rotation
- Extra-articular Deformity

EFFECTS OF ALIGNMENT



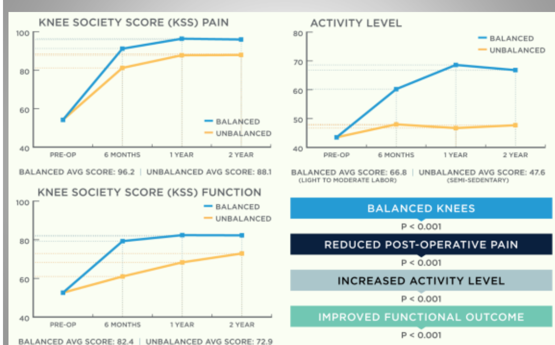


PCL (POSTERIOR MEDIAL STABILIZER)



CEMENTING TECHNIQUES

PATIENT REPORTED OUTCOMES



*Gustke et al. Primary TKA Patients with Quantifiably Balanced Soft-Tissue Achieve Significant Clinical Gains Sooner than Unbalanced Patients. *Advan Orthop.2014*

PATIENT SATISFACTION

Prospective Data Collection	Meta-Analysis
Balanced satisfaction: **96.7%** Unbalanced satisfaction: **82.1%**	• 12 papers met inclusion criteria (B-F = 3.048; homogeneity < 0.001; df = 11) • 81% average ("satisfied" to very satisfied")

CONCLUSIONS

- Ligament Balance continues to be the most significant factor impacting patient outcomes
- Functional improvement and satisfaction scores for unbalanced patients at 1-year were inferior to those achieved by balanced patients at 6-months
- Sensor-assisted TKA patients are statistically more likely to achieve reduced pain, improved function, and greater activity levels than unbalanced patients
- Patient Satisfaction scores for balanced patients show much larger improvement than unbalanced patients

Improving Accuracy & Intelligence with Navigation in Total Knee Arthroplasty

VuMedi Webinar Advancing TJA with Computer Technologies

Paul K. Gilbert, MD
Clinical Assistant Professor
Keck Medical Center of USC
Huntington Memorial Hospital, Pasadena, California

Keck Medical Center of USC

March 3, 2015

General Ortho/subspecialty in joints
25 years in community private practice
Recently joined USC part time
Started doing CAS for hips and knees in 2004
400 robotic unicompartmental knees
Accelerometer based tools

Keck Medical Center of USC

Disclosures

- Teaching/research consultant for Stryker/Mako Orthopaedics

Keck Medical Center of USC

3

Why did I start?

- Accuracy, the biomechanical sweet spot
- Better functional outcomes
- Happier patients
- Less bleeding, fat emboli
- Less revisions

Keck Medical Center of USC

The Literature

- Implant malalignment and malposition are associated with decreased function and/or higher revision rates
- Navigated TKA results in better alignment and position
- Navigated TKA data does not show improved functional outcomes

Keck Medical Center of USC

Pros and Cons

- Less blood loss
- Less thromboembolism
- Less cognitive changes
- Promotes teamwork and staff satisfaction

- Fractures associated with pin sites
- Pin site infections
- Cost
- Time
- Learning curve
- Vascular injury

Keck Medical Center of USC

Patient Satisfaction

80%

What makes a good TKA?

Keck Medical Center of USC

Pre-op: evaluate, optimize, educate, educate, educate
Surgery:
Post-op: rehab, hand holding, rehab, rehab

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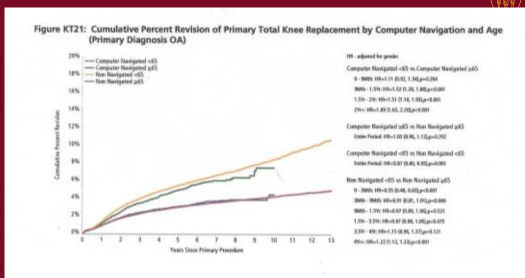
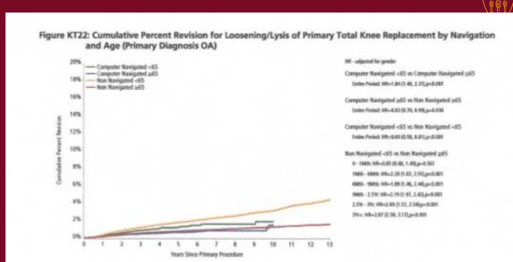
Physical Therapists
Pain management docs
Patients feel they got the best
Surveys

Keck Medical Center of USC



2014 Australian Joint Registry

Keck Medical
Center of USC



2014 Australian Joint Registry

Keck Medical
Center of USC

Accuracy and Intelligence

Thank you very much

Keck Medical
Center of USC

Patient Specific Instruments: Where Are We Now?

Adolph V. Lombardi, Jr., MD, FACS
Joint Implant Surgeons, Inc.; White Fence Surgical Suites; The Ohio State University; Mount Carmel Health System
New Albany, Ohio

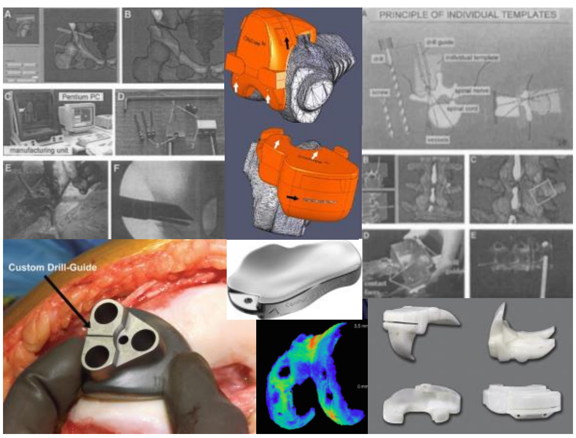
Adolph V. Lombardi, Jr. Disclosure

- Consultant, Speaker's Bureau:
  - Biomet, Inc.; Pacira
- Royalties:
  - Biomet, Inc.; Innomed, Inc.
- Research Support:
  - Biomet, Inc.; Stryker; Pacira; Kinamed
- Publications Editorial Boards:
  - Journal of Arthroplasty; Journal of Bone and Joint Surgery - American; Clinical Orthopaedics and Related Research; Journal of the American Academy of Orthopaedic Surgeons; Journal of Orthopaedics and Traumatology; Surgical Technology International; The Knee
- Boards:
  - Operation Walk USA; The Hip Society; The Knee Society; Mount Carmel Education Center at New Albany

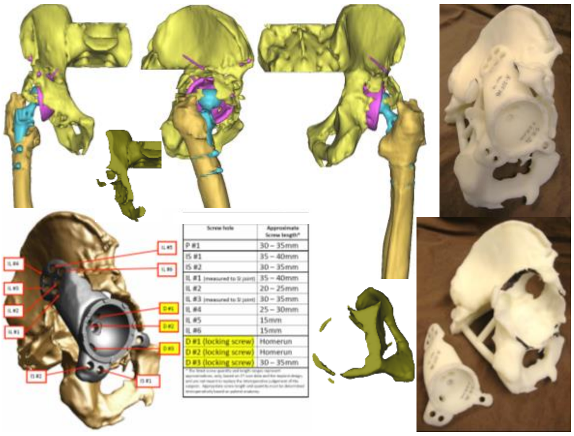
1. PSI has a 2-decade history.

History of Technology

- Radermacher 1994
- Materialise, founded 1990
  - Mimics and Magics software released 1991, 1992
- Kinamed, since 1995
- ConforMIS, founded 2004
- OtisMed, founded 2005



2. PSI are based on a proven technology – Rapid Prototyping.



Studies of Custom Triflange Components in Revision THA

Authors (Country)	# of Patients (Hips)	Males: Females	Mean Age (years)	Type of Acetabular Defect	Observation Time	Results
Christie et al. (US) [6]	76 (78)	20:56	59	AAOS types III/IV	Surgeries 1992-1998; Mean f/u 53 months	6 reoperations for recurrent dislocation (7.8%); no removal of triflange components. Pre-op HHS: 33; Post-op HHS: 82
Colen et. al (Belgium) [7]	6 (6)	3:3	69	AAOS types III/IV	Surgeries 2007-2011; Mean f/u 28 months	0 revisions. Post-op HHS: 61
DeBoer et al. (US) [10]	18 (20)	3:15	56	Pelvic discontinuity	Surgeries 1992-1998; Mean f/u 123 months	6 revisions (30%); no removal of triflange components. Pre-op HHS: 41; Post-op HHS: 80
Holt et al. (US) [12]	26 (26)	8:18	69	Paprosky type 3B; AAOS types III/IV	Mean f/u 54 months	3 failures of triflange components (11.5%). Pre-op HHS: 39; Post-op HHS: 78
Joshi et al. (US) [13]	27 (27)	9:18	68	AAOS type III	Surgeries 1993-1996; Mean f/u 58 months	2 revisions with removal of triflange components (7.4%).
Taunton et al. (US) [25]	57 (57)	6:51	61	Pelvic discontinuity	Surgeries 1992-2008; Mean f/u 76 months	20 revisions for any reason (35%); 3 failures of triflange components (5.3%). Post-op HHS: 75
Wind Jr. et al. (US) [27]	19 (19)	7:12	58	Paprosky types 3A/3B; AAOS types III/IV	Surgeries 2001-2005; Mean f/u 31 months	2 revisions for failure of triflange components (10.5%). Pre-op HHS: 38; Post-op HHS: 63
Lombardi et al. CORR (in submission)	26 (28)	7:19	68	Paprosky type 3B	Surgeries 2003-2012; Mean f/u 47 months	4 revisions for any reason (14%); 2 failures of triflange components due to infection (7.1%). Pre-op HHS: 42; Post-op HHS: 64

US=United States; f/u=follow-up.

3. PSI are offered by multiple orthopaedic manufacturers.

Current TKA Platforms for Patient Specific Alignment Guides

Manufacturer	Product	Imaging	US Launch
Biomet	Signature™	MRI CT	10/2007 01/2010
ConforMIS	iTotal®	CT	2011-2012
DePuy	Trumatch™	CT	04/2009
Medacta	MyKnee®	CT or MRI	04/2010
Smith & Nephew	Visionaire™	MRI & X-ray	11/2008
MicroPort*	Prophecy™	CT or MRI	03/2009
Zimmer	PSI	MRI CT	11/2009 06/2012

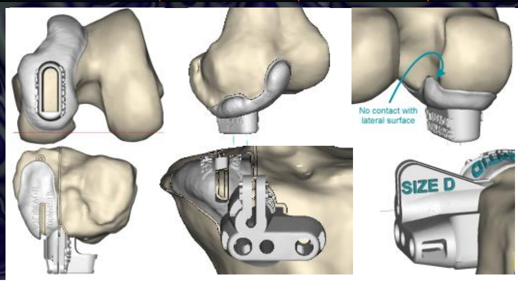
formerly Wright Medical

4. PSI are expanding:

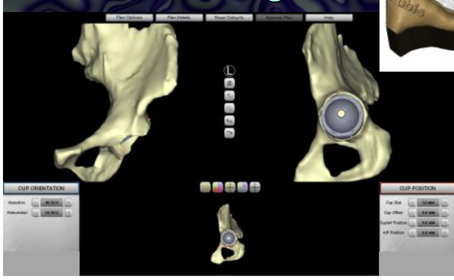
- UKA
- THA
- TSA
- TA
- Osteotomy alignment correction

Current PSI Platforms for UKA

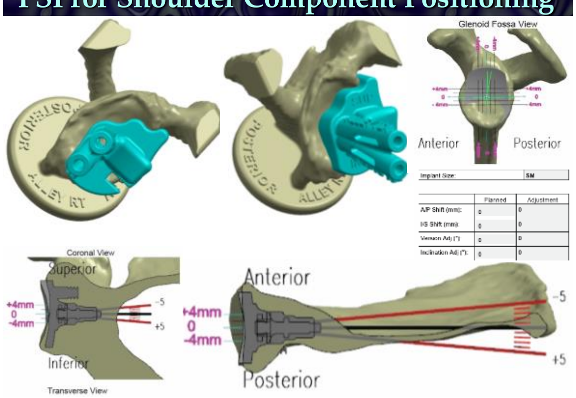
Manufacturer	Product	Imaging	US Launch
Biomet	Signature™	MRI	10/2011
Zimmer	PSI	MRI CT	02/2012 10/2012

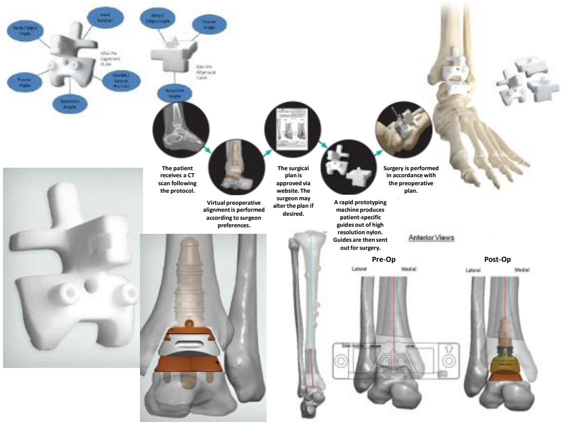


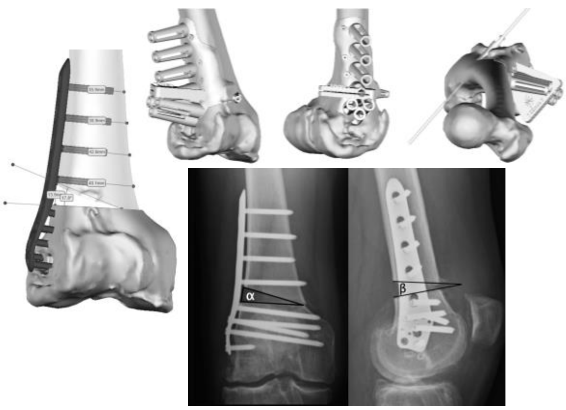
PSI for Acetabular Positioning



PSI for Shoulder Component Positioning







Victor & Premanthana, BJJ 2013

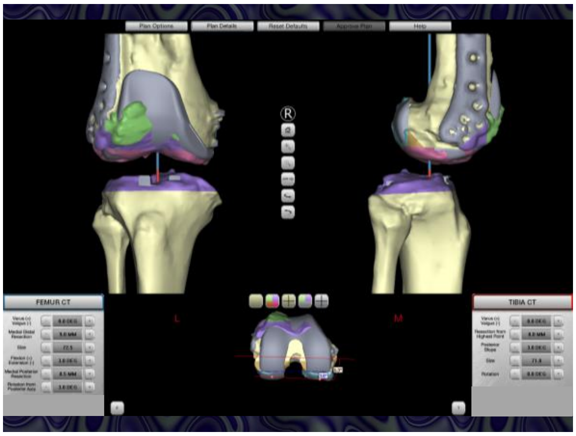
5. PSI utilization is increasing throughout the world

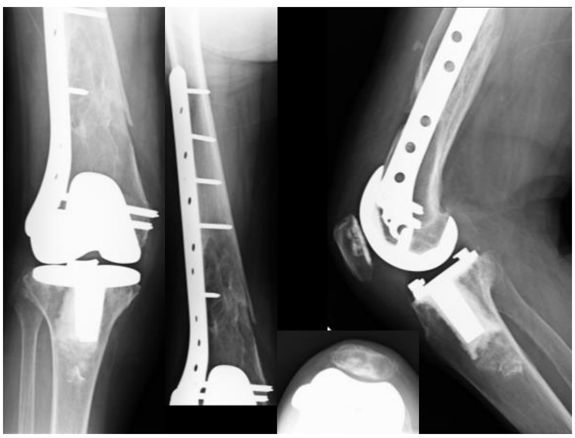
Numbers of PSI TKA, 2011-2012

Manufacturer	Global 2011	Europe 2011	Global 2012	Europe 2012
Biomet	11,192	3,169	22,506	6,501
DePuy-Synthes	6,000	700	16,000	1,100
Medacta	4,600	3,400	6,200	4,600
Smith & Nephew	19,500	1,825	22,000	2,614
Wright Medical	1,600	400	2,000	550
Zimmer	9,800	1,250	13,850	2,150

Thienpont et al., KSSTA 2013

6. PSI are extremely useful in patients with extra-articular deformity or retained hardware.





7. PSI have been used successfully in revision knee arthroplasty.

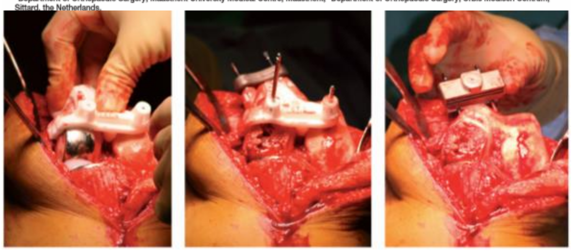
Acta Orthopaedica 2013; 84 (2): 165–169 165

Patient-specific guide for revision of medial unicondylar knee arthroplasty to total knee arthroplasty

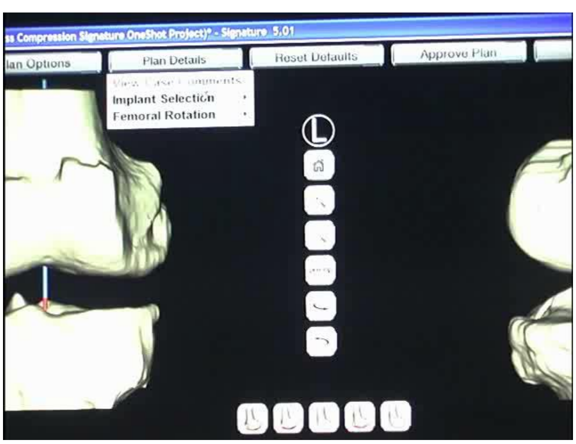
Beneficial first results of a new operating technique performed on 10 patients

Bart Kerens[1], Bert Boonen[2], Martijn Schotanus[2], and Nanne Kort[2]

[1]Department of Orthopaedic Surgery, Maastricht University Medical Centre, Maastricht; [2]Department of Orthopaedic Surgery, Orbis Medisch Centrum, Sittard, the Netherlands.



8. PSI facilitate preoperative planning.



9. PSI offer distinct advantages to lower volume surgeons.

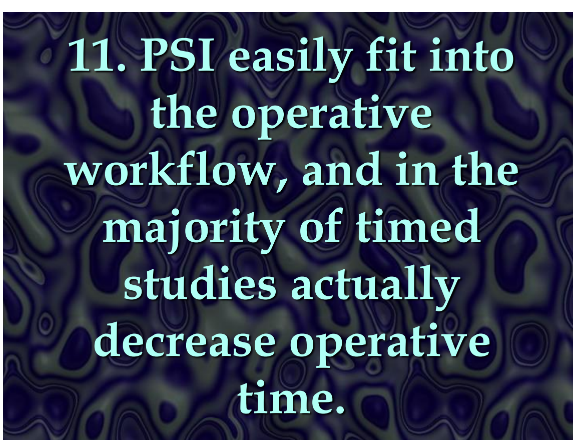
With a 6-fold increase in the incidence of TKA projected over the next 2 decades, an increasing burden on lower volume/inexperienced arthroplasty surgeons, who tend to have longer operative times and increased complication rates compared with high-volume surgeons, is expected. Improved efficiency and reproducibility in implant positioning and limb alignment is paramount to decreasing complications, improving outcomes, and meeting the increasing demand. Patient-customized cutting guides that are being developed by most major manufacturers of total knee prostheses are an emerging technology that will allow the lower-volume surgeon to meet many of these demands. One of the primary drivers of increased surgical times for lower-volume surgeons is the significant number of steps and complexity of instrumentation required to perform a TKA. The use of CPI eliminates numerous steps in the surgical technique and eliminates the need for as many as 80 instruments, which allows for significantly improved surgical efficiency. The elimination of this instrumentation also allows for significant improvement in processing and operating room efficiency with decreased incidence of processing error. The 31-minute decrease in operating room set-up and breakdown in the study reported here was realized by an operating room staff who is very experienced with TKA. A greater improvement in efficiency may be realized by a lower volume operating room staff.

Johnson, AJO 2011

10. PSI require less instrumentation resulting in less OR time setup and breakdown, a decrease in the number of instruments requiring sterile processing.


Traditional Setup


PSI Setup


11. PSI easily fit into the operative workflow, and in the majority of timed studies actually decrease operative time.

Value of PSG in TKA

- Significant reduction in:
  - Processing and sterilization time
  - Turnover time
  - OR time
  - Number of trays used
  - Hospital stay

Noble et al., J Arth 2012
Johnson, Am J Orthop 2011
Duffy, Am J Orthop 2011
Lionberger et al., AAHKS 2011
Nunley et al., CORR 2011
Tibesku et al., AOTS 2013

12. PSI has more supportive literature than negative literature.

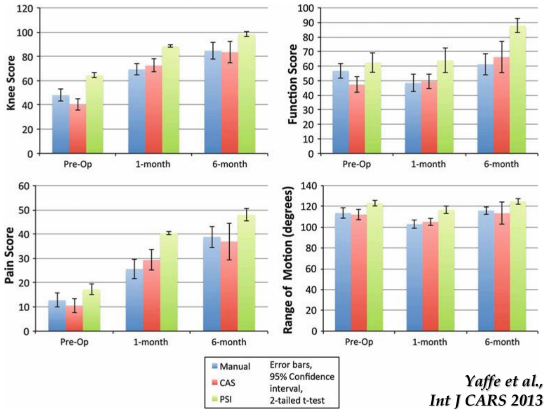
Patient Specific Guides - *Pro*

- Barrett et al., J Arth 2014
- Boyd et al., Clin Sports Med 2014
- Cenni et al., J Ortho Res 2014
- Ensini et al., KSSTA 2014
- Marimuthu et al., J Arth 2014
- Silva et al., KSSTA 2014
- Bonicoli et al., Eur J OST 2013
- Chareancholvanich et al., BJJ 2013
- Daniilidis & Tibesku, Int Orthop 2013
- Issa et al., J Knee 2013
- Kerens et al., Acta Orthop 2013
- Koch et al., KSSTA 2013
- MacDessi et al., The Knee 2013
- Thienpont et al., The Knee 2013
- Thienpont et al., KSSTA 2013
- Tibesku et al., AOTS 2013
- Volpi et al., KSSTA 2013
- Yaffe et al., Int J CARS 2013
- Ast et al., OCNA 2012
- Bali et al., J Arth 2012
- Boonen et al., Acta Orthop 2012
- Heyse & Tibesku, The Knee 2012
- Johnson, Am J Orthop 2012
- Lombardi & Frye, CRMSM 2012
- Nam et al., JKS 2012
- Mayer et al., J Arth 2012
- Ng et al., CORR 2012
- Noble et al., J Arth 2012
- Slammin & Parsley, CRMSM 2012
- Yaffe et al., Biomed Tech 2012
- Yeo et al., ISRN Orthop 2012
- Stulberg et al., KS IM 2012
- Mont et al., KS IM 2012
- Duffy, Am J Orthop 2011
- Johnson, Am J Orthop 2011
- McGovern, Am J Orthop 2011
- Watters et al., JSOA 2011
- Lombardi et al., Orthopedics 2008

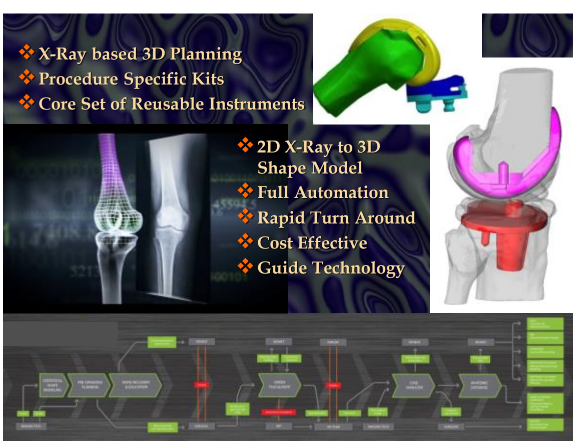
Patient Specific Guides – *Con / Questionable*

- Chen et al., KSSTA 2014
- Conteduca et al., Int Orthop 2014
- Scholes et al., KSSTA 2014
- Victor et al., CORR 2014
- Hamilton et al., J Arth 2013
- Nam et al., The Knee 2013
- Parratte et al., KSSTA 2013
- Roh et al., CORR 2013
- Stronach et al., CORR 2013
- Barrack et al., JBJS Br 2012
- Conteduca et al., KSSTA 2012
- Conteduca et al., Int Orthop 2012
- Lustig et al., J Arth 2012
- Nam et al., J Arth 2012
- Nunley et al., CORR 2012
- Stronach et al., CORR 2012
- Bellemans et al., KS IM 2012

13. PSI has been reported to be associated with significant improvement in Knee Society Functional Score in short-term follow-up.



14. PSI technology is in a state of constant evolution – Now based on preoperative CT/MRI and moving in the direction of preoperative x-rays only.



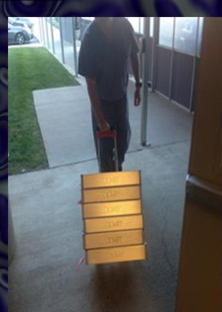
15. PSI are part of the future delivery of implants.

Traditional Instrument/Implant Delivery System

1. Orthopaedic Assessment
2. Surgery Scheduled
3. Orthopaedic Rep Contacted
4. Physician/Rep Template Case
5. Plan Developed
6. Instruments/Implants Delivered to Hospital
7. Instruments Signed into Central Sterile
8. Implants Stored
9. Washer/Sterilizer Decontamination
10. Instruments Wrapped/Labeled

Traditional Instrument/Implant Delivery System

11. Instruments Autoclaved
12. Case Cart Loaded
13. Delivered to OR
14. Trays Opened and Checked
15. Implants Inventory to Field
16. Trays Removed from Field Loaded on Cart
17. Preliminary Decontamination
18. Returned to Decontamination
19. Load Washer/Sterilizer
20. Organize Trays/Wrap/ Label
21. Autoclave Trays



Traditional Re-Usable Cutting Blocks & Trials

Mont et al., J Arth 2013

Sterile-Packed Single-Use Cutting Blocks & Trials

The Future of Orthopaedic Implant Delivery

- Marrying PSG with single-use instruments streamlines the delivery of orthopaedic products
- Decreased number of instruments with SUI reduces:
  - OR setup time
  - OR turnover time
  - Overall surgical time
  - Infection?
- PSG and SUI increase efficiency

Patient Specific Instrumentation and Implants: Do They Significantly Impact Patient Satisfaction and Outcome?

Brian S. Parsley, MD
Clinical Associate Professor
Director- Adult Reconstruction Fellowship

Ryan Palmer, DO
Adult Reconstruction Fellow
Baylor College of Medicine
Houston, Texas

Disclosures

- Consultant for Nimbic Air Barrier System
- Royalties from Conformis Inc.
- AAHKS Board

Orthopaedist Love New Toys!

Amphibious bicycle

New Technology for TKA- PSI

- Rapid growth in the offerings of Patient Specific Guidance
  - Customized cutting blocks for knee replacements
  - Computer based guidance for hip and knee replacements
    - From simple to complex
    - Both imageless and image based
    - Individual vs robotically guided
  - Custom made implants for knee replacements
- What is the justification?
  - Cost reduction?
  - Time Efficiency?
  - Patient outcomes?

Let's Look at Function

No Benefit of Patient-specific Instrumentation in TKA on Functional and Gait Outcomes: A Randomized Clinical Trial

Matthew P. Abdel MD, Sébastien Parratte MD, PhD, Guillaume Blanc MD, Matthieu Ollivier MD, Vincent Pomero PhD, Elke Viehweger MD, PhD, MHA, Jean-Noël A. Argenson MD, PhD

- Patient Specific Instrumentation (PSI) vs. Conventional
  - 40 patients randomized into 2 groups; 20 each group
  - All pts received Zimmer NexGen LPS-Flex mobile cemented implants
- Patients evaluated pre-operatively and 3 months post-operatively
  - New Knee Society Score [KSS], KOOS, SF-12, & Gait Analysis
- Results:
  - In the PSI group, 25% of cases required intra-operative modifications
  - Overall, there were no differences in the new KSS, KOOS, or SF-12 between the PSI and conventional TKA groups (see graft)
  - Overall, there were no differences in the analyzed gait parameters between the two groups

Clin Orthop Relat Res (2014) 472:2468–2476

Score (points)	Patient-specific instrumentation			Conventional instrumentation		
	Preoperative	3 months postoperative	p value	Preoperative	3 months postoperative	p value
New Knee Society Knee Score						
Objective knee score (/100)	53 ± 13	80 ± 7	< 0.0001*	51 ± 13	82 ± 7	< 0.0001*
Satisfaction score (/40)	18 ± 6	27 ± 7	< 0.0001*	18 ± 7	[illegible]	< 0.0001*
Expectation score (/15)	8 ± 3	10 ± 3	0.157	[illegible]	[illegible]	0.008*
Functional activity score (/100)	35 ± 14	61 ± 12	[illegible]	[illegible]	[illegible]	< 0.0001*
KOOS						
Pain (/100)	22 ± 11	35 ± 12	[illegible]	23± 10	34 ± 12	0.001*
Symptoms (/100)	21 ± 8	[illegible]	[illegible]	22 ± 6	37 ± 8	< 0.0001*
ADL (/100)	[illegible]	[illegible]	0.004*	33 ± 12	48 ± 13	0.0004*
Sports (/100)	[illegible]	[illegible]	0.119	17 ± 13	25 ± 17	0.128
QOL (/100)	[illegible]	28 ± 13	0.075	20 ± 8	27 ± 10	0.003*
SF-12						
Physical subscale (/100)	29 ± 7	35 ± 8	0.015*	28 ± 12	35 ± 6	0.001*
Mental subscale (/100)	50 ± 9	57 ± 8	0.017*	51 ± 10	58 ± 10	0.062

Values are mean ± SD; * statistically significant findings; KOOS = Knee Injury and Osteoarthritis Outcome Score; ADL = activities of daily living; QOL = quality of life.

No Difference

Comparison of Pre & Post Op Function

Parameter	Patient-specific instrumentation			Conventional instrumentation		
	Preoperative	Postoperative	p value	Preoperative	Postoperative	p value
Spatiotemporal						
Double limb support (%)	49 (38–90)	45 (28–90)	0.2	[illegible]	43 (28–58)	
Single limb support (%)	40 (30–70)	44 (34–74)	0.2	[illegible]	43 (30–54)	0.02
Walking speed (m/second)	0.65 (0.18–0.9)	0.75 (0.28–1)	[illegible]	[illegible]	0.76 (0.5–0.11)	0.004
Cadence (steps/m)	64 (35–90)	[illegible]	[illegible]	[illegible]	95 (75–122)	< 0.0001
Stride length (m)	0.83 (0.5–1)	[illegible]	[illegible]	0.81 (0.5–1)	0.96 (0.1–1.16)	0.003
Kinematics/kinetics						
Knee varus angle (degrees)	[illegible]	[illegible]	0.03	9.25 (−3 to 20)	6 (−3 to 16)	0.07
Knee valgus angle (degrees)	[illegible]	−4.5 (−17 to 5)	0.2	−7.95 (−13 to 0)	−5.8 (−12 to 4)	
Knee varus moment (Nm/kg)	[illegible]	0.4 (0.2–0.7)	0.004	0.48 (0.3–0.8)	0.38 (0.1–0.7)	0.13
Knee valgus moment (Nm/kg)	[illegible]	−0.05 (−0.2 to 0)	0.34	−0.12 (−0.25 to 0.01)	−0.1 (−0.2 to 0)	0.51
Knee power generation (W/kg)	0.13 (0.02–0.8)	0.2 (0.02–0.5)	0.29	0.163 (0.02–0.8)	0.2 (0.01–0.7)	0.48
Ankle power generation (W/kg)	1.56 (0.06–2.8)	2.3 (0.4–3.6)	0.005	1.85 (0.06–4)	2.2 (0.9–4.1)	0.28

Values are represented as mean (range).

No Difference

Comparison of Pre & Post Op Gait

- 3 complications in the PSI group
  - 2 patients had post-operative flexion contractures of 5 and 10 degrees
    - Both patients had pre-operative flexion contractures
  - 1 patient had pre-operative patellar subluxation that continued post-operatively
- No complications in the conventional TKA group

Complications

Custom Cutting Guides Do Not Improve Total Knee Arthroplasty Outcomes at 2 Years Follow-up

D. Nam, A. Park, J. Stambough, S. Johnson, R. Nunley, R. Barrack

- 95 custom cutting guides vs. 95 conventional cutting guides for TKA by same surgeon
- Patient self selection into either group
- UCLA Score, SF-12, Oxford Knee & Forgotten Joint scores collected pre & postoperatively
- Rotational alignment, Patient Satisfaction scores post-operatively,

AAHKS AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

Presented at AAHKS Annual Meeting Nov. 2014

- No differences for range of motion, UCLA, SF-12, Oxford Knee, or Forgotten Joint scores between the two cohorts (p=0.09 to 0.76)
- No differences were present for the incremental improvement in these scores from preoperatively to postoperatively (p=0.1 to 0.9)
- No difference in mean tourniquet time (59.1 + 13.2 mins in CCG vs. 59.7 + 14.7 mins in standard cohort; p=0.75)
- Percentage of outliers for overall mechanical alignment (31% in CCG versus 23% in standard cohort with HKA outside of 0° + 3°; p=0.2).

Results

Presented by Nam at AAHKS Annual Meeting Nov. 2014

- At two years follow-up, custom cutting guides fail to demonstrate any advantages in clinical outcomes versus the use of standard instrumentation in total knee arthroplasty.
- The benefit of CCGs must be proven prior to continued implementation of this technology.

Conclusions

Presented by Nam at AAHKS Annual Meeting Nov. 2014

Systematic Review of Patient-specific Instrumentation in Total Knee Arthroplasty: New but Not Improved

Adam Sassoon MD, Denis Nam MD,
Ryan Nunley MD, Robert Barrack MD

- Do patient specific cutting blocks **achieve neutral mechanical alignment** more reliably during TKA when compared with conventional methods?
  - 16 studies, Level I-III evidence
- Does patient-specific instrumentation (PSI) provide financial benefit through **improved surgical efficiency**?
  - 13 studies, Level I-III evidence
- Does the use of patient-specific cutting blocks translate to **improved clinical results** after TKA when compared with conventional instrumentation?
  - 2 studies, Level III evidence

Clin Orthop Relat Res (2015) 473:151–158

Do Patient Specific Instrumentation Achieve Neutral Mechanical Alignment More Reliably?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	No difference in overall alignment, no difference in femoral component alignment, small difference in tibial component alignment unlikely to be significant (89.8° versus 90.5°)
Hamilton et al. [13]	52	I	No difference in mechanical alignment with PSI
Noble et al. [20]	29	I	Mechanical alignment closer to neutral with PSI (1.7° versus 2.8°)
Barrack et al. [2]	200	II	Equivalent coronal plane alignment
Barrett et al. [3]	66	II	Mechanical alignment comparable between groups
Chen et al. [8]	60	II	Increased rate of mechanical axis outliers (± 3°) with PSI
Silva et al. [30]	45	II	Decreased rate of tibial component internal rotation with PSI
Parratte et al. [25]	40	II	PSI does not improve component rotation in TKA
Daniilidis and Tibesku [11]	170	II	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI
Ng et al. [19]	724 (160*)	III	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
Heyse and Tibesku [14]	94	III	PSI reduced the number of femoral component rotation outliers
Barke et al. [1]	89	III	No difference in mechanical alignment with PSI
Vundelinckx et al. [32]	62	III	No difference in mechanical alignment, posterior slope of tibial component more accurate with PSI
Boonen et al. [5]	40	III	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI

* Only 160 patients of the total patients had data pertaining to mechanical alignment; PSI = patient-specific instrumentation.

Variable Results From Improvement in Reduction in Outliers When PSI Used

---

Do Patient Specific Instrumentation Achieve Neutral Mechanical Alignment More Reliably?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	No difference in overall alignment, no difference in femoral component alignment, small difference in tibial component alignment unlikely to be significant (89.8° versus 90.5°)
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Parratte et al. [25]	40	II	PSI does not improve component rotation in TKA
Daniilidis and Tibesku [11]	170	[illegible]	...quivalent, fewer outliers (± 3°) with PSI
Ng et al. [19]	724 (	[illegible]	...quivalent, fewer outliers (± 3°) with PSI
Nunley et al. [22]	150	III	Equivalent number of mechanical axis outliers with standard instrumentation and PSI
Yaffe et al. [33]	122	III	No difference in mechanical alignment with PSI
Heyse and Tibesku [14]	94	III	PSI reduced the number of femoral component rotation outliers
Barke et al. [1]	89	III	No difference in mechanical alignment with PSI
Vundelinckx et al. [32]	62	III	No difference in mechanical alignment, posterior slope of tibial component more accurate with PSI
Boonen et al. [5]	40	III	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI

* Only 160 patients of the total patients had data pertaining to mechanical alignment; PSI = patient-specific instrumentation.

To No Difference In Benefit

Do Patient Specific Instrumentation Achieve Neutral Mechanical Alignment More Reliably?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	No difference in overall alignment, no difference in femoral component alignment, small difference in tibial component alignment unlikely to be significant (89.8° versus 90.5°)
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Noble et al. [20]	29	I	Mechanical alignment closer to neutral with PSI (1.7° versus 2.8°)
Barrack et al. [2]	200	II	Equivalent coronal plane alignment
Barrett et al. [3]	66	II	Mechanical alignment comparable between groups
Chen et al. [8]	60	II	Increased rate of mechanical axis outliers (± 3°) with PSI
Silva et al. [30]	45	II	Decreased rate of tibial component internal rotation with PSI
Parratte et al. [25]	40	II	PSI does not improve component rotation in TKA
Daniilidis and Tibesku [11]	170	II	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI
Ng et al. [19]	724 (160*)	III	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI
Nunley et al. [22]	150	III	Equivalent number of mechanical axis outliers with standard instrumentation and
Yaffe et al. [33]	122		nt with PSI
Heyse and Tibesku [14]	94	III	PSI reduced the number of femoral component rotation outliers
Barke et al. [1]	89	III	No difference in mechanical alignment with PSI
Vundelinckx et al. [32]	62	III	No difference in mechanical alignment, posterior slope of tibial component more accurate with PSI
Boonen et al. [5]	40	III	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI

* Only 160 patients of the total patients had data pertaining to mechanical alignment; PSI = patient-specific instrumentation.

To The Reverse Effect with PSI

Do Patient Specific Instrumentation Achieve Neutral Mechanical Alignment More Reliably?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	No difference in overall alignment, no difference in femoral component alignment, small difference in tibial component alignment unlikely to be significant (89.8° versus 90.5°)
Hamilton et al. [13]	52	I	No difference in mechanical alignment with PSI
Noble et al. [20]	29	I	Mechanical alignment closer to neutral with PSI (1.7° versus 2.8°)
Barrack et al. [2]	200	II	Equivalent coronal plane alignment
Barrett et al. [3]	66	II	Mechanical alignment comparable between groups
Chen et al. [8]	60	II	Increased rate of mechanical axis outliers (± 3°) with PSI
Silva et al. [30]			with PSI
Parratte et al. [25]			
Daniilidis and Tibesku [11]			ers (± 3°) with PSI
Ng et al. [19]			ers (± 3°) with PSI
Nunley et al. [22]			standard instrumentation and PSI
Yaffe et al. [33]	122	III	No difference in mechanical alignment with PSI
Heyse and Tibesku [14]	94	III	PSI reduced the number of femoral component rotation outliers
Barke et al. [1]	89	III	No difference in mechanical alignment with PSI
Vundelinckx et al. [32]	62	III	No difference in mechanical alignment, posterior slope of tibial component more accurate with PSI
Boonen et al. [5]	40	III	Overall mechanical alignment equivalent, fewer outliers (± 3°) with PSI

* Only 160 patients of the total patients had data pertaining to mechanical alignment; PSI = patient-specific instrumentation.

Conclusion:
No Significant Difference Overall in Ability to Achieve Overall Alignment

Does PSI Provide Financial Benefit Through Improved Surgical Efficiency?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	PSI decreased OR time by 5 minutes
Hamilton et al. [13]	52	I	PSI was 4 minutes longer than standard instrumentation but decreased number of instrument trays
Noble et al. [20]	29	I	PSI decreased OR time by 7 minutes and decreased instrument trays
Barrack et al. [2]	200	II	PSI decreased OR time and instrument processing time, overall increase in cost of procedure after accounting for preoperative scan and cutting guide
Iss			
Bar			
Str			
Ch			
Sch			d
Co			d carefully intraoperatively
Nunley et al. [21]	114	III	No difference in tourniquet time but decreased total time in OR by 12 minutes
Barke et al. [1]	89	III	No difference in operative time
Pietsch et al. [27]	50	III	Changes in the technician plan needed preoperatively to generate an accurate preoperative plan
Boonen et al. [5]	40	III	PSI decreased OR time by 10 minutes

PSI = patient-specific instrumentation; OR = operating room.

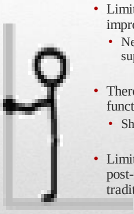
Minimal decrease in OR Time if any except one study (12min) and one at 10 min
Frequent need to recut despite PSI
Decrease in # of trays and cost associated
Increase in cost associated with Custom Cutting Blocks and CT or MRI

Does The Use of PSI Translate to Improved Clinical Results?

Study	Total number of patients	Level of evidence	Conclusion
Yaffe et al. [33]	122	3	No difference in pain, motion, Knee Society knee scores; PSI had higher Knee Society function scores pre- and postoperatively
Vunderlinckx et al. [32]	62	3	No difference in pain, patient satisfaction, or functional outcomes (KOOS, Lysholm score)

PSI = patient-specific instrumentation; KOOS = Knee Injury and Osteoarthritis Outcome Score.

No Difference in Functional Scores at Short Term Follow-up
Limited number of studies available

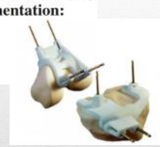


- Limited data exist with regard to the effect of PSI on post-operative function, improvement in pain, and patient satisfaction
  - Neither of the 2 studies evaluating clinical results provided strong evidence to support an advantage favoring the use of PSI
- There is a need for Mid- and long-term data regarding PSI's effect on functional outcomes and component survivorship
  - Short-term data scarce
- Limited available literature does not clearly support any improvement of post-operative pain, activity, function, or ROM when PSI is compared with traditional instrumentation

Conclusions

Clinical, functional, and radiographic outcomes following total knee arthroplasty with patient-specific instrumentation, computer-assisted surgery, and manual instrumentation: a short-term follow-up study

Mark Yaffe · Michael Luo · Nitin Goyal · Philip Chan · Anay Patel · Max Cayo · S. David Stulberg



- Retrospective case-control study
- 122 Total Knee Arthroplasties by one surgeon
  - 44 with (PSI) vs 38 with Computer Assisted Surgery (CAS) vs 40 with manual instrumentation
  - Groups were identical with regard to age, gender, diagnosis, BMI, and perioperative management but had significantly different starting points

Int J CARS (2014) 9:837–844

Table 2 Clinical, functional, and radiographic findings

	Patient-specific instruments group	Computer-assisted surgery group	Manual instrumentation group	p value (ANOVA)
Knee score (points)[a]				
Preop.	64.5 ± 7.0 (45 to 70)	40.4 ± 14.5 (18 to 75)	48.0 ± 15.0 (17 to 77)	<0.0001
1 month postop.	88.4 ± 3.8 (79 to 100)	72.4 ± 16.5 (27 to 100)	69.3 ± 14.0 (40 to 100)	<0.0001
6 months postop.	98.3 ± 5.3 (70 to 100)	83.4 ± 18.0 (32 to 100)	84.7 ± 16.7 (23 to 100)	0.0001
Change in Score Pre to Post	33.8	43.0	36.7	NS

Pre-operative and post-operative knees scores were higher in the PSI group.

Similar improvements from pre to post-op.

Bias? Lack of randomization? Skewed results?

Table 2 Clinical, functional, and radiographic findings

	Patient-specific instruments group	Computer-assisted surgery group	Manual instrumentation group	p value (ANOVA)
Function score (points)[a]				
Preop.	62.3 ± 20.9 (17 to 97)	47.3 ± 15.1 (5 to 80)	56.7 ± 12.4 (35 to 80)	0.0014
1 month postop.	63.9 ± 22.3 (5 to 100)	49.3 ± 14.6 (20 to 85)	48.4 ± 17.9 (20 to 100)	0.0010
6 months postop.	87.8 ± 13.3 (59 to 100)	66.2 ± 20.7 (30 to 100)	61.3 ± 17.2 (20 to 90)	<0.0001

Pre and post-operative knee function scores were higher in the PSI group.

PSI showed a higher function score improvement when compared to manual instrumentation (24.5 pts vs 3.8 pts)

Bias? Lack of randomization? Skewed results?

Table 2 Clinical, functional, and radiographic findings

	Patient-specific instruments group	Computer-assisted surgery group	Manual instrumentation group	p value (ANOVA)
Range of motion (deg)				
Preop.	123.3 ± 9.3 (98 to 138)	112.1 ± 15.1 (70 to 140)	113.7 ± 15.7 (70 to 140)	0.0004
1 month postop.	116.7 ± 11.6 (65 to 135)	105.1 ± 10.2 (80 to 125)	103 ± 13.4 (65 to 135)	<0.0001
6 months postop.	124.8 ± 7.7 (105 to 140)	113.4 ± 21.4 (35 to 135)	116.1 ± 9.4 (95 to 135)	0.0047
Change in ROM	1.5	1.3	2.4	

Pre and post-operative range of motion was higher in the PSI group. The change in ROM between groups was no different.

Table 2 Clinical, functional, and radiographic findings

	Patient-specific instruments group	Computer-assisted surgery group	Manual instrumentation group	p value (ANOVA)
Pain score (points)[b]				
Preop.	17.2 ± 7 (0 to 20)	10.5 ± 9.1 (0 to 30)	12.8 ± 9.1 (0 to 30)	0.0017
1 month postop.	40.5 ± 2.1 (40 to 50)	29.3 ± 13 (0 to 50)	25.6 ± 12.5 (10 to 50)	<0.0001
6 months postop.	47.9 ± 7.9 (10 to 50)	36.9 ± 15.3 (0 to 50)	38.8 ± 10.8 (20 to 50)	0.0003
Change in pain score	30.7	26.4	26	

Pre to post-operative knees pain score improvement was higher in the PSI group but the improvement within groups was similar.

Table 2 Clinical, functional, and radiographic findings

	Patient-specific instruments group	Computer-assisted surgery group	Manual instrumentation group	p value (ANOVA)
Mechanical axis (deg)[c]				
Preop.	7.4 ± 6.2 (−9 to 15)	7.7 ± 8.9 (−14 to 20)	5.2 ± 11.5 (−27 to 22)	0.4478
Postop.	0.98 ± 2.3 (−4 to 6)	2.0 ± 2.5 (−3 to 7)	−0.24 ± 3.5 (−6 to 8)	0.0053
Postoperative sagittal femoral alignment (deg)[c]	1.4 ± 4.8 (−6 to 13)	1.9 ± 2.2 (−2 to 7)	2.7 ± 3.2 (−6 to 9)	0.3729
Postoperative sagittal tibial alignment (deg)[c]	87.2 ± 5.0 (80 to 100)	88.1 ± 1.9 (83 to 92)	88.1 ± 1.8 (83 to 91)	0.7928

CAS showed a more varus mechanical axis compared to manual (2.00 degrees varus vs. 0.24 degrees valgus)

No difference found in post-operative mechanical axis between PSI and CAS, or PSI and manual groups

Conclusions

- The PSI group showed greater improvement in Knee Society function scores over 6 months when compared to manual TKA
  - But the PSI group also had higher pre-operative function scores
  - Lack of randomization limits conclusions
- No statistical differences seen in knee score, ROM, or pain score improvement from pre-operative to the 6-month post-operative period among all groups
- No difference in mechanical alignment

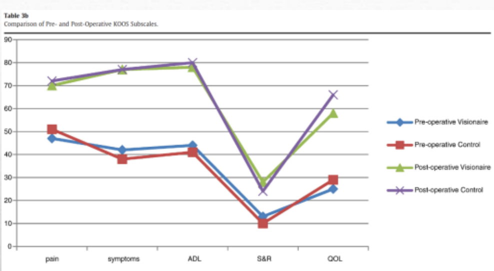
Int J CARS (2014) 9:837–844

Functional and Radiographic Short-Term Outcome Evaluation of the Visionaire System, a Patient-Matched Instrumentation System for Total Knee Arthroplasty

Bart J. Vundelinckx MD [a,c], Liesbeth Bruckers Msc [b], Kris De Mulder MD [c], Jo De Schepper MD [c], Gert Van Esbroeck MD [c]

- 62 patients Smith and Nephew Genesis II TKA Visionaire(31) vs Conventional(31)
- Randomized in 1:1 linear fashion
- Mean follow up: short- 200+days
- **Results:**
  - No statistical difference in Satisfaction
  - No statistical differences between pre-operative and post-operative KOOS scores
    - Total KOOS scores (see graft)
    - KOOS subscales (see graft)
  - No statistical differences in VAS scores

The Journal of Arthroplasty 28 (2013) 964–970



The Journal of Arthroplasty 28 (2013) 964–970

Results

- Flexion Contracture
  - Visionaire
    - 13/31 (43%) unable to obtain full extension post-operatively
  - Conventional
    - 6/31 (19%)
- Strict adherence to pre-operative plan and cutting blocks as a cause of residual flexion deformity
  - Did not recut distal femur, followed planned resection
- No statistically significant differences between groups for
  - Satisfaction, Pain scores, or Functional outcome scores
  - Gait, Flexion, EBL & transfusion needed, or alignment

The Journal of Arthroplasty 28 (2013) 964–970

Biomet Signature PSI System

- Average $4000 per standard Vanguard TKA hospital contract
  - General number in Houston, TX Medical Center region
- Add approximately $950 upcharge for PSI creation with Signature system
- Cost of MRI to create instrumentation-?? Cost

Hospital Outcomes and Cost for Patients Undergoing a Customized Individually Made TKA vs Off-The-Shelf TKA.

Gregory Martin, MD; Alyssa Swearingen; Steven Culler, PhD

- 248 TKA's by one surgeon: 126 ConforMIS TKA vs. 122 Off-the-shelf (OTS) TKA
- Retrospective review
- Data collected:
  - Length of procedure,
  - LOS,
  - Transfusions,
  - Cost,
  - Disposition

Presented at ICJR Pan-Pacific Meeting 2014

Results

- Demographics, LOS: No statistical differences
- Transfusion rates
  - Conformis showed significantly less (2.4% ConforMIS vs 10.7% OTS)
- Adverse event rate
  - Conformis showed significantly less (1.6% ConforMIS vs 13.9% OTS)
  - Specific adverse events not published in abstract
- Total hospital cost
  - Not statistically significant ($16,192 vs $16,240)
- Discharge disposition
  - Significantly lower percentage of patients in the ConforMIS group were discharge to acute care facilities (ConforMIS 2.4% vs 13.9% OTS)

Presented by Martin at ICJR Pan-Pacific Meeting 2014

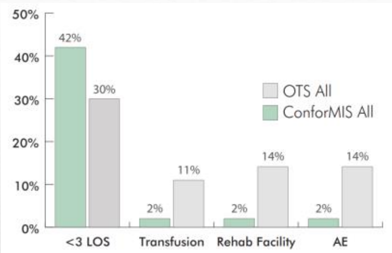


Figure 1: Comparison of key outcomes between OTS and ConforMIS TKAs for all hospitalizations

Presented by Martin at ICJR Pan-Pacific Meeting 2014

Conclusions

- Significantly lower transfusion rates
  - Likely related to eliminating the need for intra-medullary guides
  - General estimated associated cost of $2200 per blood transfusion
- Significantly lower reported adverse event rates
  - Specific adverse events not defined in abstract
  - Costs associated with these specific adverse events not know
- Fewer patients discharged to acute care facilities with ConforMIS
  - Authors reasons for this not revealed
  - Criteria for discharge to acute care facility unknown
  - Estimated $16,000 per discharge to acute care facility
- No statistical difference in overall hospital costs between the two groups

Presented by Martin at ICJR Pan-Pacific Meeting 2014

PSI vs. OTS TKR vs. Custom TKR

- Is the difference in the cutting blocks vs. the conventional cutting systems when an OTS type knee is still being used??

OR

- Is it the combination of PSI and a custom patient specific TKR?

In Conclusion

- There is NO clear data that PSI demonstrates consistent improvement in function, ROM, alignment, or patient reported outcomes in the current literature.
- The literature is limited and short term at this time.
- The cost justification is lacking with few exceptions.
- Should the Healthcare System be paying the bill?

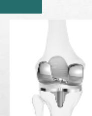
THANK YOU

In Vivo Kinematics for Subjects Implanted With Either a Traditional or a Customized, Individually Made TKA

Kurtz, WB; Zeller, IM; Hamel, WH; Young, MA; Anderle MR; Komistek, RD

Presented at the proceedings of ICJR Pan-Pacific 2014, Abstract #O21A2

- 20 patients by single surgeon
  - 11 ConforMIS CR TKA
  - 9 Off-the-shelf (OTS) CR TKA (Zimmer NexGen)
- Mobile fluoroscopic system used to analyze knee motion
  - Deep knee bend
  - Chair rise
  - Fluorscopic 2D images were converted into 3D representation of kinematics
- Comparison of kinematics
  - ROM
  - Posterior femoral rollback
  - Axial rotation



Presented at ICJR Pan-Pacific Meeting 2014

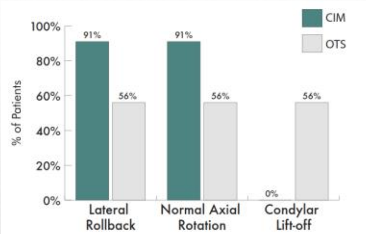


Figure 1: Comparison of Deep Knee Bend kinematics between the CIM and OTS TKA arms.

Presented by Kurtz at ICJR Pan-Pacific Meeting 2014

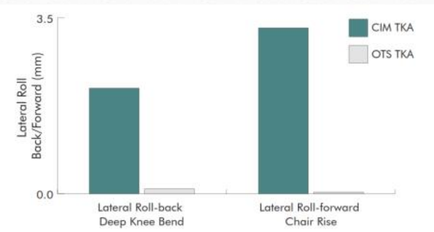


Figure 2: Comparison of average anterior/posterior translation for the CIM and OTS TKAs during Deep Knee Bend and Chair Rise.

Presented by Kurtz at ICJR Pan-Pacific Meeting 2014

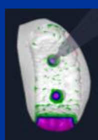
Conclusions

- Authors conclude ConforMIS TKA patients experienced a more normal kinematic pattern of the knee compared to an OTS TKA
- OTS TKA experienced greater variability in kinematic patterns
- No patient satisfaction or outcome scores reported
- Do differences in kinematic patterns equate to improved patient satisfaction, function, or longevity of the implant?

Presented by Kurtz at ICJR Pan-Pacific Meeting 2014

Robotics in UKA: Latest Advances in Technique and Cost Efficiency

Jess H. Lonner, MD
Rothman Institute
Associate Professor, Department of Orthopaedic Surgery
Thomas Jefferson University
Philadelphia, PA



Jefferson. University Hospitals

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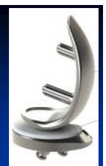
Disclosure



- Royalties
  - Zimmer, Blue Belt Technologies
- Consultant
  - Zimmer, Blue Belt Technologies
- Speaker's bureau
  - Zimmer, Blue Belt Technologies
- Publishers: Saunders, Lippincott Williams Wilkins
  - Shareholder: Blue Belt Technologies, CD Diagnostics

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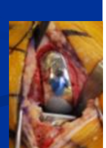
Growing Use of UKA in US 1998-2005

- UKA utilization increased 32.5% (vs TKA: 9.4%)
  - Expanding use of early intervention strategies
  - Improved surgeon education
  - Better diagnosis
  - Demographics- younger, employed, restless



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Riddle DL, Jiranek WA, McGlynn FJ. J Arthroplasty 2008

Advantages of UKA vs TKA

- Tissue sparing
- Safer (Lower M &M)
- Rapid recovery
- More normal feel
- Greater functionability
- Less expensive
- Growing emphasis on outpatient surgery

Durability???

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UKA:

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

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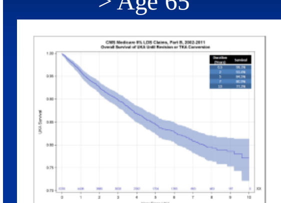
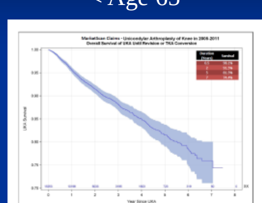
…But

> Age 65



10-yr survivorship 77%

< Age 65



7-yr survivorship 74%

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Ong, Lonner etal AAHKS 2014

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What Impacts the Results of UKA?

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

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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

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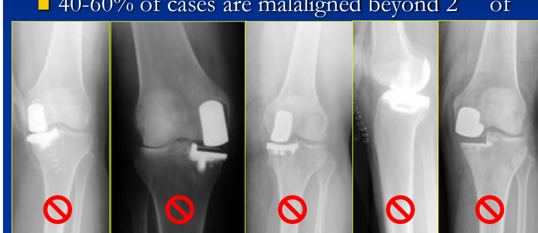
Outliers in Alignment in UKA with Conventional Methods

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



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

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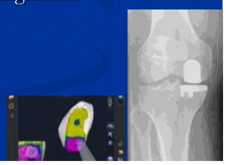
Rationale of Robotics for UKA

- 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



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Story of Robotics in UKA

- Study in patterns that define technological progress and innovation, in general
  - Declining capital and maintenance costs
  - Smaller space requirements
  - Broadening access
  - Increased utilization

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Expanding Role for Robotics in UKA

- 15% of UKA's in US (2013)

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www.OrthopedicNetworkNews.com. 2013

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Semi-autonomous Robotics in UKA

- Mako (Mako Stryker, Ft. Lauderdale, FL)
  - Initial FDA approval 2005; revised 2008
  - Image-based (CT scan)

- Navio PFS (Blue Belt Technologies, Plymouth, MN)
  - Initial FDA approval 2012
  - Image-free

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1st Generation Semi-Autonomous Robotic Arm for UKA: Mako*

- FDA clearance 2005
- Haptic constraint
- Efficient
- Safe
- Image-based (preop CT scan)
- Closed system (metal backed, FB UKA)

*Mako Stryker, Ft. Lauderdale, FL

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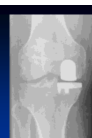
Alignment – UKA Conventional vs. Mako Robotic



- 2.6x more variability with manual techniques ($p<0.05$)
- Average error:
  - Manual: 2.7°
  - Robot: 0.2° ($p<0.0001$)

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(Lonner, John, Conditt CORR 2010)

Mako Results vs Conventional UKA

- RCT, 100 patients
- Conventional Oxford UKA vs Robotic Mako
- Postop CT to assess coronal, sagittal, rot'l alignment
- Significantly less error in tibial slope, femoral v/v, tibial rotation ($p<0.01$)

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Blyth MJ et al. AAOS 2013

Downsides of 1st Generation Robotic System in US

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

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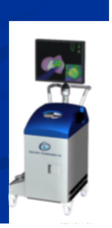
2nd Generation Robotic System: Navio PFS

- FDA clearance: 2012
- Image-free (No CT scan)
- Intraop registration/mapping/planning
- Intraop gap balancing
- Semi-autonomous
- Burr Speed/Exposure control



Navio Technique: Surface Mapping

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Dynamic Intraop Gap Balancing

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Selection of Implant Size/Position and Virtual Gap Balance

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Virtual Tracking of Femur on Tibia

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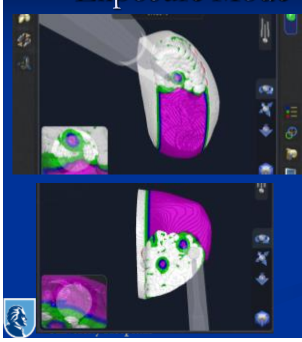
Technique: Exposure Mode



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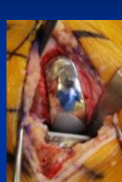
Prepared Surface



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Data???

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Key Studies

- Accuracy of bone preparation
  - Pre-clinical (cadaveric specimens)
- Comparison of intraoperative plan for limb alignment with postop limb alignment
  - Clinical (navigated measures)
- Accuracy of tibial component alignment
  - Radiographic
- Safety
- Radiation avoidance

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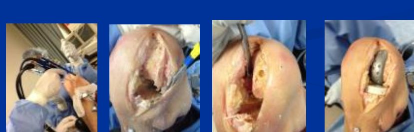
Study 1: Pre-Clinical Accuracy

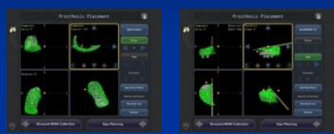
- 25 cadaveric specimens
  - Medial UKA (Tornier HLS Uni Evolution)
- 3 surgeons



Jefferson University Hospitals | Lonner, Smith, Picard, Hamlin - Clin Orthop 2014 | ROTHMAN

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

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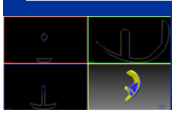
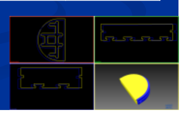
Alignment: Vs. Other Semi-Autonomous (CT-based) Robots and Manual

RMS Error	NavioPFS	Mako Rio	Acrobot	Manual
Flex/Ext (°)	1.6	2.1	2.1	4.1
Varus/Valgus (°)	2.3	2.1	1.7	6.0
Int/Ext (°)	1.7	3.0	3.1	6.3
Prox/Dist (mm)	1.3	1.0	1.0	2.8
Ant/Post (mm)	1.3	1.6	1.8	2.4
Med/Lat (mm)	0.9	1.0	0.6	1.6



Dunbar et al J Arthrop 2012
Cobb J JBJS Br 2005
Jenny J Arthrop 2002
Lonner et al CORR 2014



Study 2: Planned versus Achieved Limb Alignment

- 65 cases
- 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

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Study 3: Safety of Hand-Held Robot

- Initial 1000 cases
- No soft tissue complications

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Study 4: Learning Curve

- Mean of 8 procedures (range 5-11) to reach a steady state surgical time.
- Mean steady state surgical time was 50 minutes (range 37-55 minutes)

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

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Study 5: Avoidance of Radiation from preop CT Scans (Mako protocol)

- 236 scans 2011-2013
- 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

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Economics of Robotic Technologies

- Assumptions:
  - Avg. Medicare payment per case: $12,500

Lien Item	1st Generation	2nd Generation
System List Price	$1,200,000	$450,000
Svc Costs (List Price)	$100,000	$45,000
CT scan	$400-$800	$0
Implant/Disposable Costs	negotiated	negotiated
Break even on ROI	240 cases	60 cases

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Costs of Care (Partial Knees)

Cohort	Mean	Min	Max
Hospital (Inpatient) N=50	$16,495	$12,784	$28,644
Hospital (Outpatient) N=50	$13,295	$7,249	$24,758
ASC N=50	$9,969	$3,406	$15,321

Uhr A, Davis D, Lonner J. 2015

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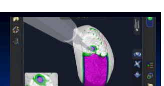
Conclusion:



- Precise preoperative/intraop planning
  - Surface mapping
  - Gap balancing
- Accurate bone preparation, implant alignment, component positioning
- Enhanced early outcomes
- Impact on late results?
- Cost analysis

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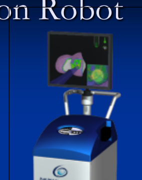
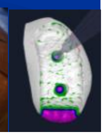
Conclusion: 2nd Generation Robot



- Semi-autonomous system
- Image-free
- Cost favorable
- ASC-feasible
- Work flow intuitive
- Implant-specific vs open platform
- Expanding applications



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New Approaches: Robotics in THA

Adam M Freedhand, MD
Assistant Professor

The University of Texas Health Science Center at Houston

Disclosures

- Stryker
  - Educational consultant
- OrthoSensor
  - Stockholder

What are we improving?

i.e. Why robotics?

Goals of THA

Pain relief
Restoration of Function
Durable results

- Implants
- Materials
- Approaches

Areas of Improvement

- Component / Mechanical failures
- Product recalls
- *Surgical Complications*

THA Issues

Lawsuits

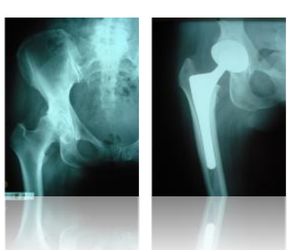
- Component Malposition
  - Leg length discrepancies
  - Instability/Dislocation

Upadhyay, JOA 2007

Critical Factors

Biomechanics/Kinematics

- Implant Sizing
- Implant Positioning
- Fit
- Alignment

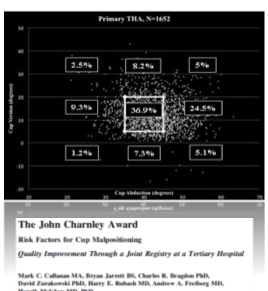


Component Malposition

- Early
  - LLD/Dislocation
    - 4%
- Late
  - Impingement/Wear
    - Loosening

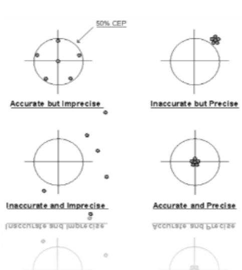
Component Malposition

Acetabulum



Conventional Instruments

Little Guidance



- Manual instruments inconsistent
- Outcomes depend on alignment
  - Acetabulum / Femur

How Can We Improve?

Low and High Tech

- Surgical planning - template
- Intra-operative X-ray
- Alignment tools
- CAS
- Robotics

Robotics

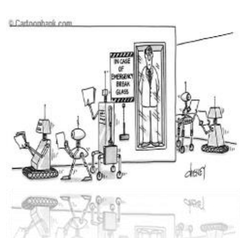
What's available

- Think Surgical
  - Since 1992
  - Femur
  - Open platform
- Mako
  - Since 2006
  - Acetabulum
  - Closed platform

Robotics

Advantages

- Advanced surgical planning
- Precise robotic machining of bone
- Improved component placement
- Know result before leaving the OR



Mako / Think Surgical

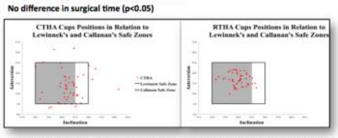
- Pre-operative CT scans
- 3D virtual surgery
- Intra-operative execution of plan
- Optimize implant position
  - Improve outcomes?

Accuracy and Precision

Robot vs Manual Instruments

Methodology:
- Matched groups of 50 robotic THA's and 50 manual THA's by a single surgeon using a posterior approach were analyzed radiographically for cup positioning

Key Results:
- **100% of robotic cups were placed within the Lewinnek "Safe Zone" for anteversion and inclination compared to 80% of manual cases**
- **92% of robotic cups were placed within the Callanan "Safe Zone" for anteversion and inclination compared to 62% of manual cases**
- **No difference in surgical time ($p<0.05$)**



Comparison of Robotic-assisted and Conventional Acetabular Cup Placement in THA: A Matched-pair Controlled Study. Domb BG, El Bitar YF, Sadik BS, Stake CE, Botser IB, *Clin Orthop Relat Res.* 2014 Jan;472(1):329-36.

Clin Orthop Relat Res (2010) 468:1072–1081
DOI 10.1007/s11999-009-1158-2

CLINICAL RESEARCH

A Comparison between Robotic-assisted and Manual Implantation of Cementless Total Hip Arthroplasty

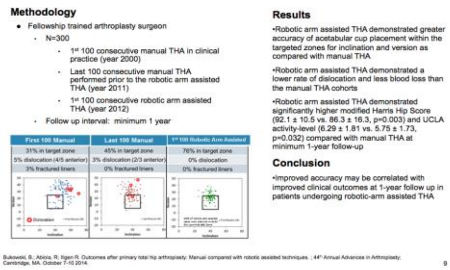
Nobuo Nakamura MD, Nobuhiko Sugano MD, Takashi Nishii MD, Akihiro Kakimoto MD, Hidenobu Miki MD

146 hips: 75 robot, 71 manual

- Leg lengths more accurate
- Slightly better JOA Clinical scores
- Less stress shielding in the Robot Cohort

Patient Outcomes

Higher Harris Hip Scores, Lower Dislocation Rate



Methodology

- Fellowship trained arthroplasty surgeon
  - N=300
    - 1st 100 consecutive manual THA in clinical practice (year 2000)
    - Last 100 consecutive manual THA performed prior to the robotic arm assisted THA (year 2011)
    - 1st 100 consecutive robotic arm assisted THA (year 2012)
  - Follow up interval: minimum 1 year

First 100 Manual	Last 100 Manual	1st 100 Robotic Arm Assisted
31% in target zone	45% in target zone	76% in target zone
5% dislocation (4/5 anterior)	3% dislocation (2/3 anterior)	0% dislocation
3% fractured liners	0% fractured liners	0% fractured liners

Results

•Robotic arm assisted THA demonstrated greater accuracy of acetabular cup placement within the targeted zones for inclination and version as compared with manual THA

•Robotic arm assisted THA demonstrated a lower rate of dislocation and less blood loss than the manual THA cohorts

•Robotic arm assisted THA demonstrated significantly higher modified Harris Hip Score (92.1 ± 10.5 vs. 86.3 ± 16.3, p=0.003) and UCLA activity-level (6.29 ± 1.81 vs. 5.75 ± 1.73, p=0.032) compared with manual THA at minimum 1-year follow-up

Conclusion

•Improved accuracy may be correlated with improved clinical outcomes at 1-year follow up in patients undergoing robotic-arm assisted THA

Bukowski, B.; Abiola, R.; Ilgen R. Outcomes after primary total hip arthroplasty: Manual compared with robotic assisted techniques. ; 44th Annual Advances in Arthroplasty; Cambridge, MA. October 7-10 2014.

9

Think Surgical THA

Outcomes

- Less fractures
- Better fit/fill
- Precise placement of the femoral component
  - Size, alignment, depth of seat

Clinical Orthopaedics & Related Research:
September 1998 - Volume 354 - Issue - pp 82-91
Symposium: Computer Assisted Orthopaedic Surgery: Medical Robotics and Image Guided Surgery

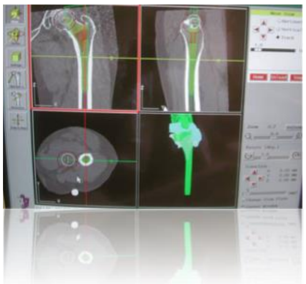
Mako THA

More Cups in the Safe Zone

- Cup inclination/Version
  - <5˙ from plan
- Acetabular COR
  - <2mm from plan

Robotics in THA

Workflow



- 3D surgical plan
- Exposure
- Registration
- Machining of the bone
- Trial / Implantation
- Closure

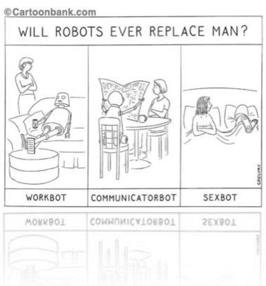
Bone Registration

- Mako
  - Pelvic array
  - Acetabulum and Femur checkpoints
- Robodoc
  - Femoral head armature
  - CAS for acetabulum

Robotic Bone Resection

- Robodoc
  - Surgeon clears workspace
  - Active femur prep
- Mako
  - Passive acetabular prep
  - Visual, tactile and audible feedback

Surgeon's Role

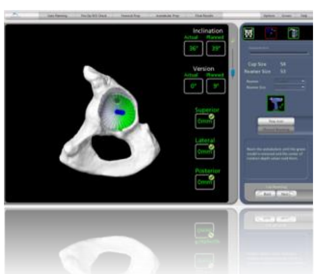


- Patient selection
- Implant selection
- Virtual Surgical Plan
- Expose / Protect / Close tissues
- Execute / Verify surgical Plan

Robotics

Not Experimental

- Robodoc since 1992
  - 60 units worldwide
  - Over 30K cases- Hip/Knee
- Mako since 2006
  - 29K cases- Knee/Hip



Industrial Revolution Analogy

Before:

- Everything Handmade
- Apprenticeship / Artisans
- Variation in Quality and Outcome

After:

- Mostly Machine-made
- Quality Control
- Minimize Human error

Robotic Surgical Revolution

Before

- Surgeon Apprentices
- Apprenticeship / Artisans
- Conventional Instruments
- Variation in Quality and Outcome

The Future is now!

- CAS/Robotics for precision and accuracy
- Quality Control
- Minimize Surgical error