Patient Specific Instrumentation in TKA

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Disclosure

Institutional/Educational Support

- Smith & Nephew, Depuy Synthes, Stryker, Microport, Zimmer-Biomet

Consulting agreements

- Smith & Nephew, Zimmer-Biomet

Royalties

- Journey™ UKA (Smith & Nephew)

Disclosure

Grant Support

- Canadian Orthopaedic Research Legacy Grant

Canadian Orthopaedic Foundation

Mitigating Potential Bias

Non-industry funded study

- Patient specific blocks donated in-kind by Smith & Nephew

Disclosure

I do not routinely use patient specific instrumentation for my total knee arthroplasty patients

Objectives

Review the current evidence and discuss the role for patient specific instrumentation in total knee arthroplasty

Goals of Knee Arthroplasty

Restoration of mechanical alignment

- Neutral aligned lower extremity (3^0-7^0 valgus)

Preservation of joint line

Ligament balancing

Patellofemoral tracking

Full range of motion

Lotke, PA, Ecker, ML: Influence of positioning of prosthesis in total knee replacement. *J Bone Joint Surg Am* 1977;59:77–9.

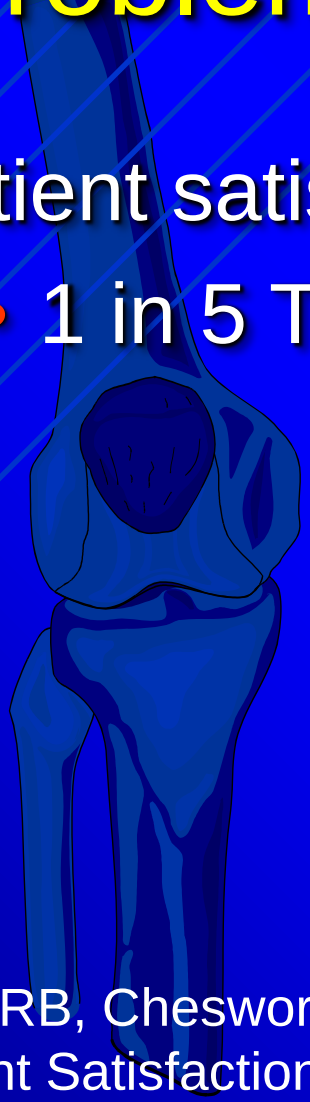
Goals of Knee Arthroplasty

- Patient satisfaction and function
- Long-term survivorship
- Avoidance of complications
- Minimize risks of future surgery
- Cost-effective

Problem

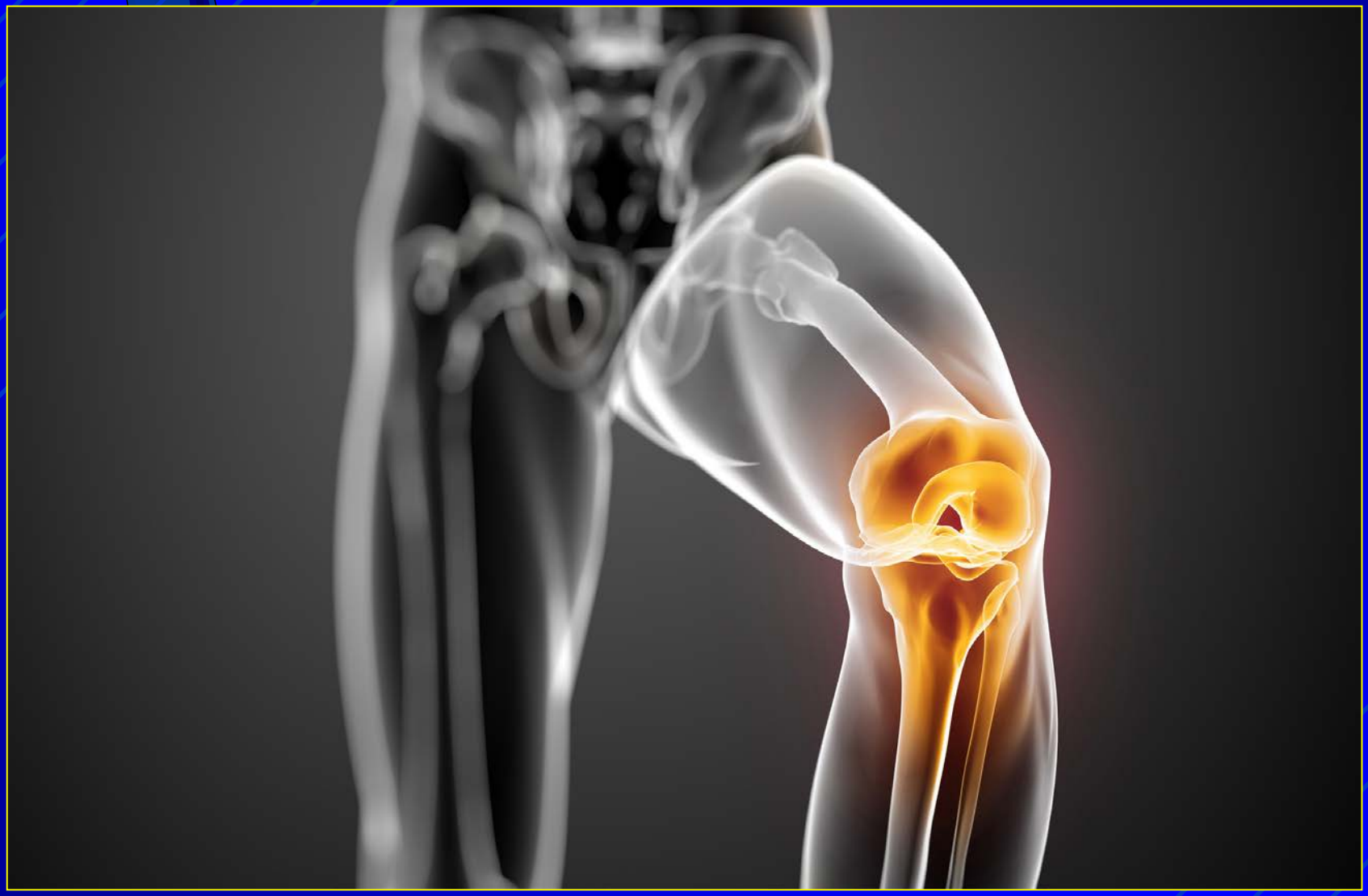
Patient satisfaction and function

- 1 in 5 TKAs is not satisfied



Bourne, RB, Chesworth, BM, Davis, AM, Mahomed, NN, Charron, KDJ, Met, D: Patient Satisfaction after Total Knee Arthroplasty Who is Satisfied and Who is Not ? 2010;57–63.

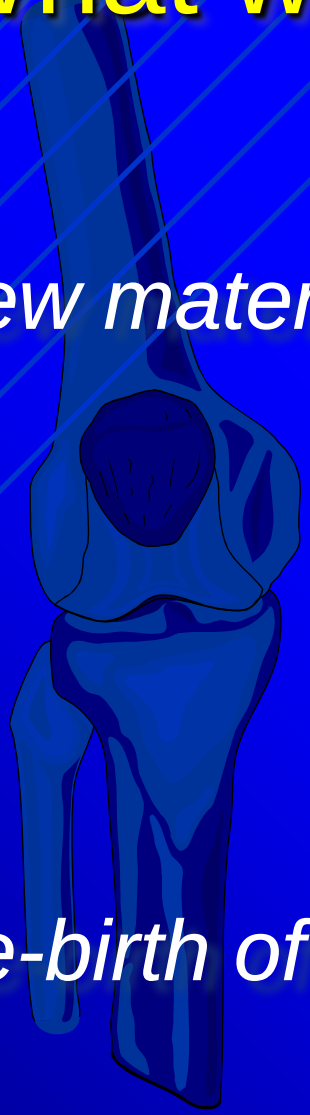
How can we improve?



How can we improve?

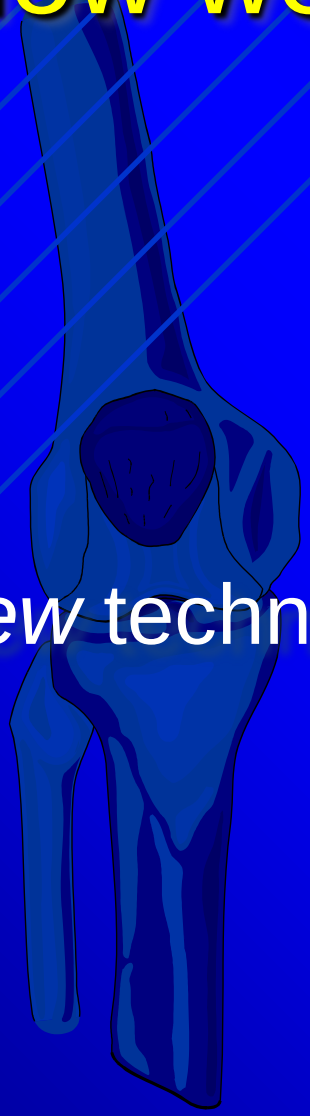
- What we are putting in
- How we are doing it

What we are putting in



- *New materials*
  - *Different plastics*
  - *Different metals*
  - *Different biomechanics*
- *Re-birth of old things* → *UKA*

How we are putting it in



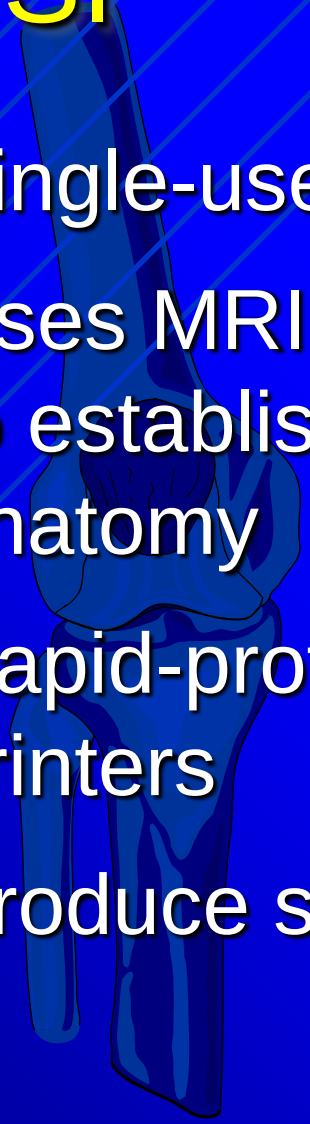
- *New* techniques

Computer Assisted Surgery (Navigation)

Robotic Surgery

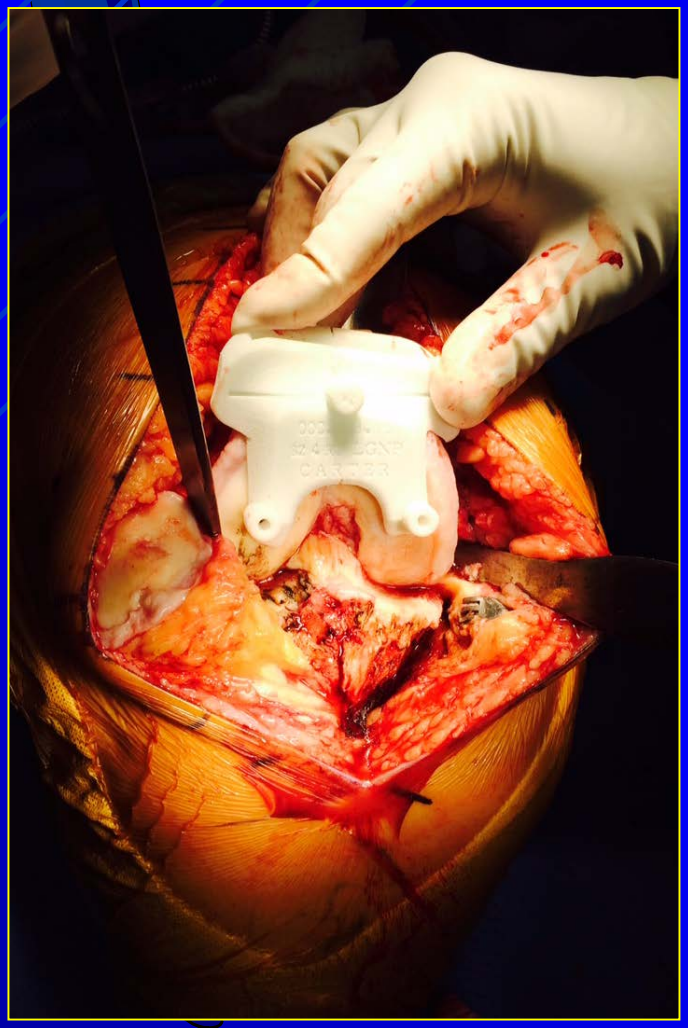
Patient Specific Instrumentation (PSI)

PSI

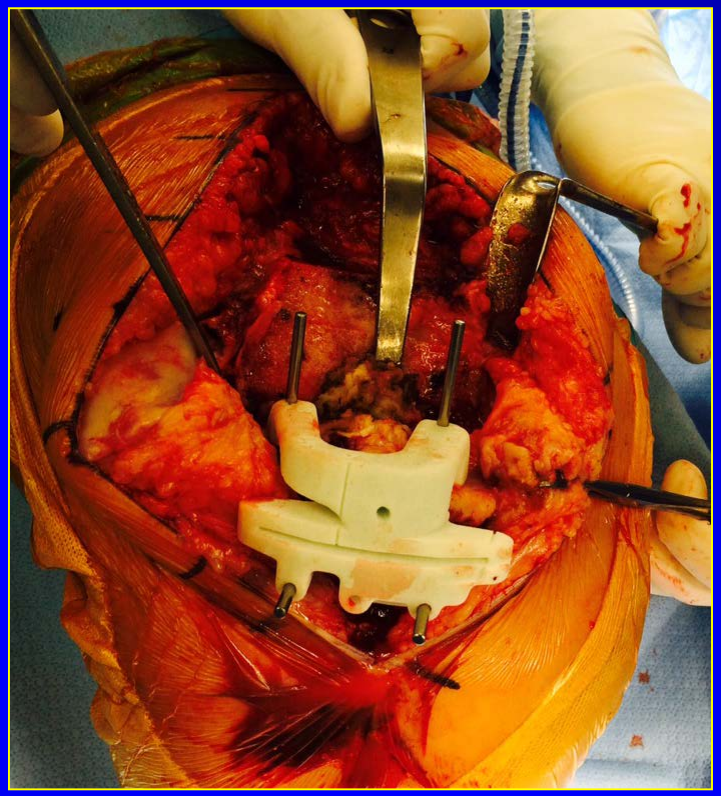


- Single-use patient-specific instrumentation
- Uses MRI or CT (+/- standing radiographs) to establish the 3D contour of knee anatomy
- Rapid-prototyping technique and 3D printers
- Produce sterile guides to perform TKA

PSI



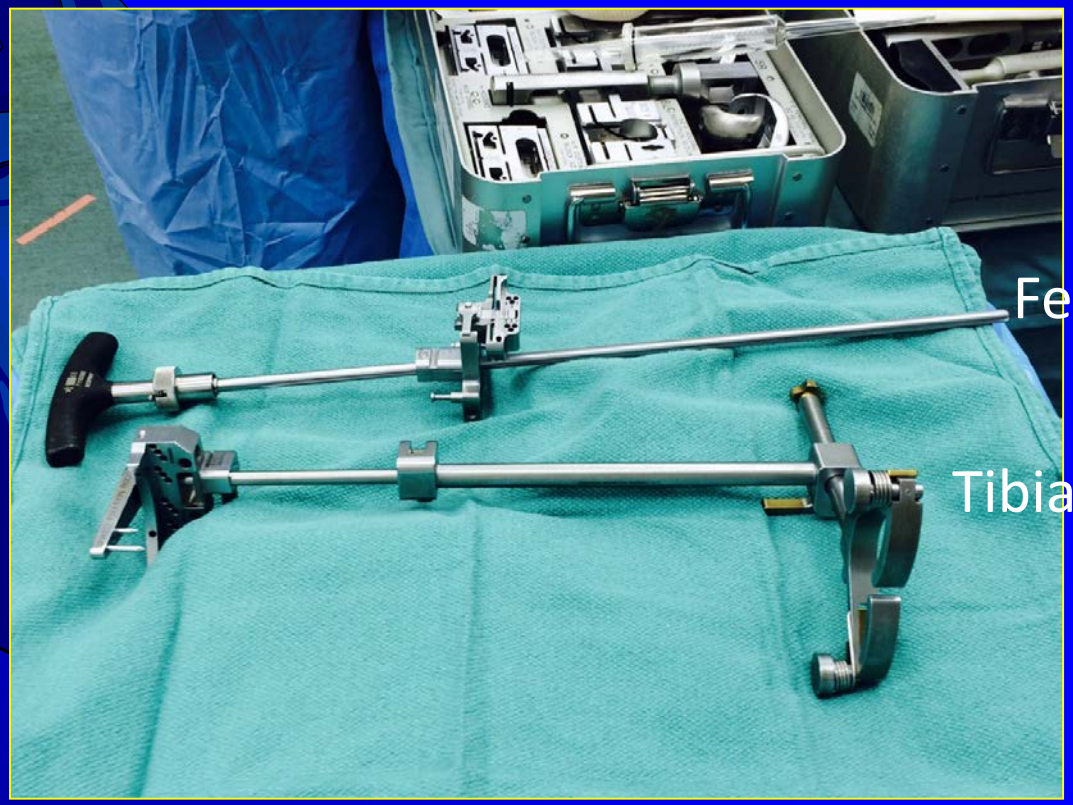
Femoral



Tibial

Rationale

- Conventional instrumentation involves simple tools with inherent inaccuracies



Conventional Instrumentation

Limitations

- Numerous jigs and fixtures
- Risk of infection from repeated-use
- Risk of bleeding, fat embolism, or fracture with the insertion of intramedullary alignment guides

PSI

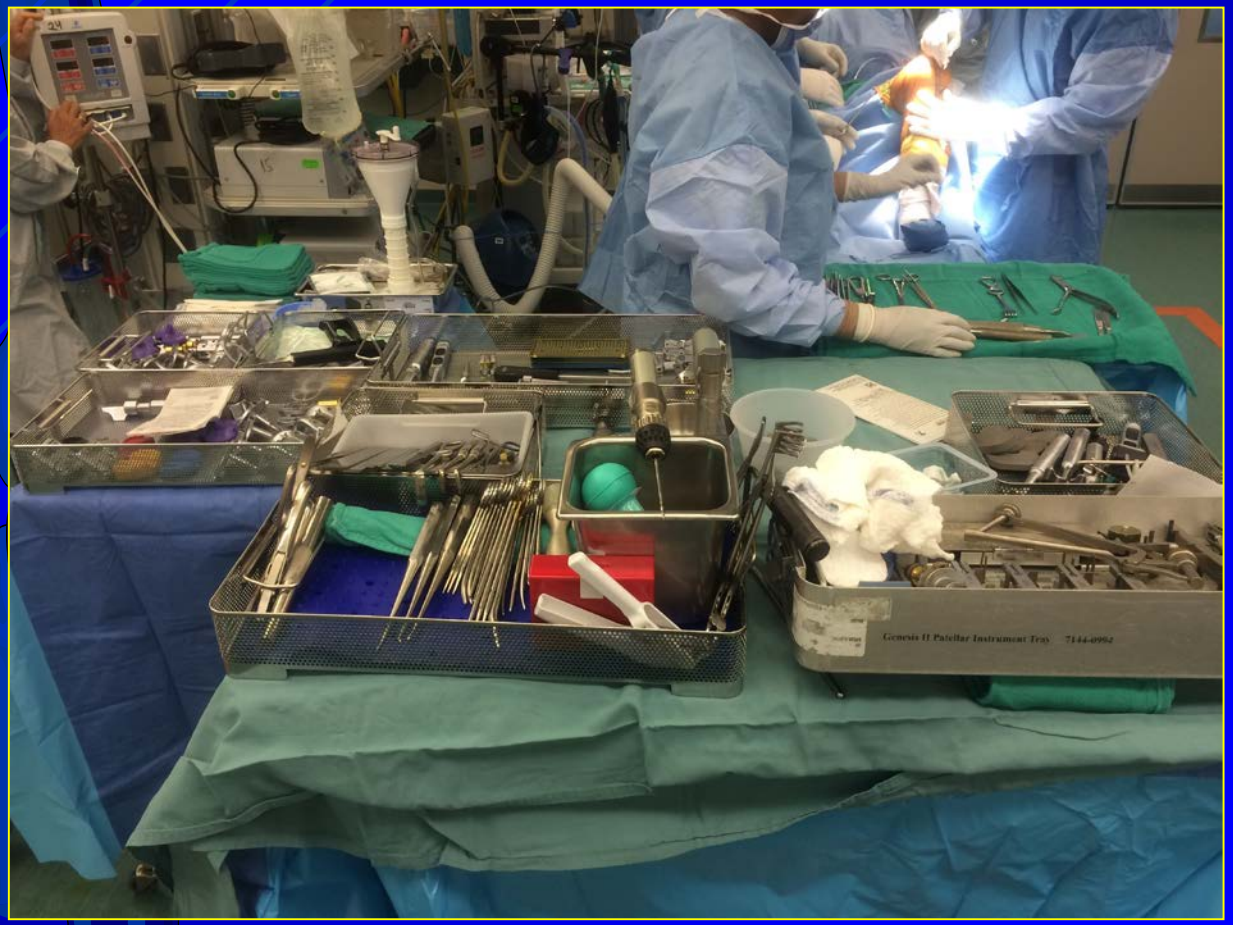
Purported Advantages

- Reduced operative time
- Reduced inventory
- Cost savings

Rationale

Conventional instrumentation

Rationale



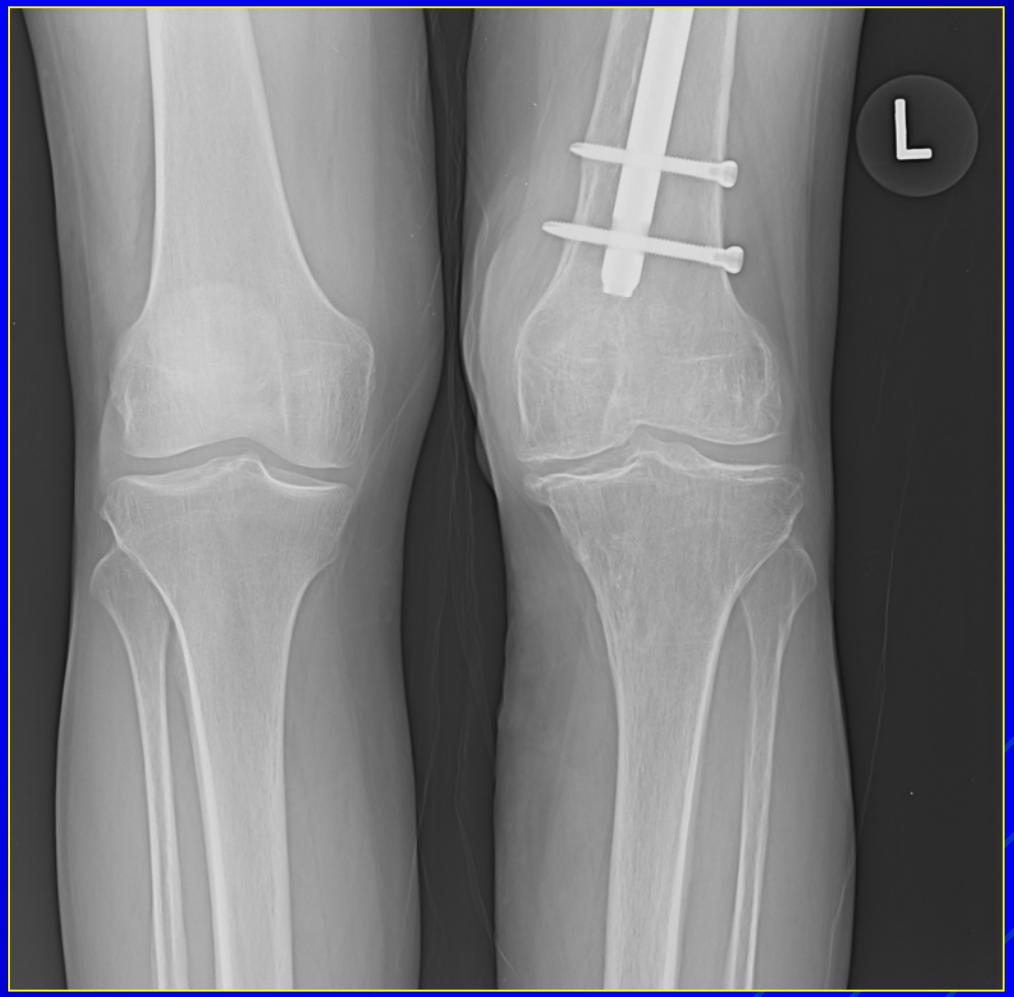
Patient-specific instrumentation

Rationale

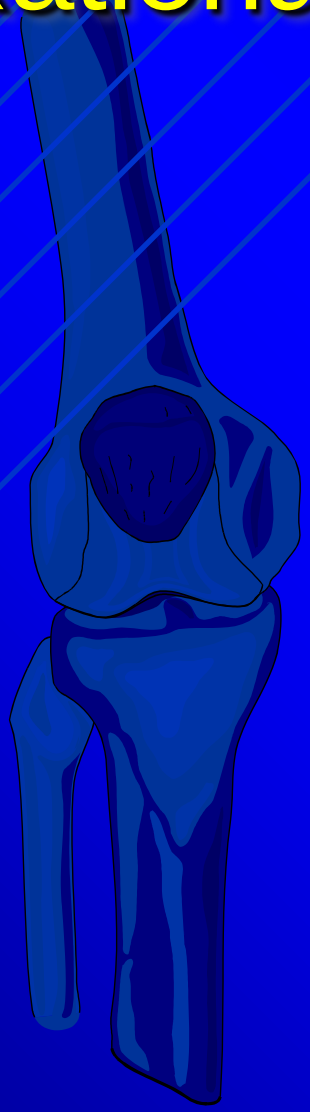
Some cases preclude conventional (IM) instrumentation

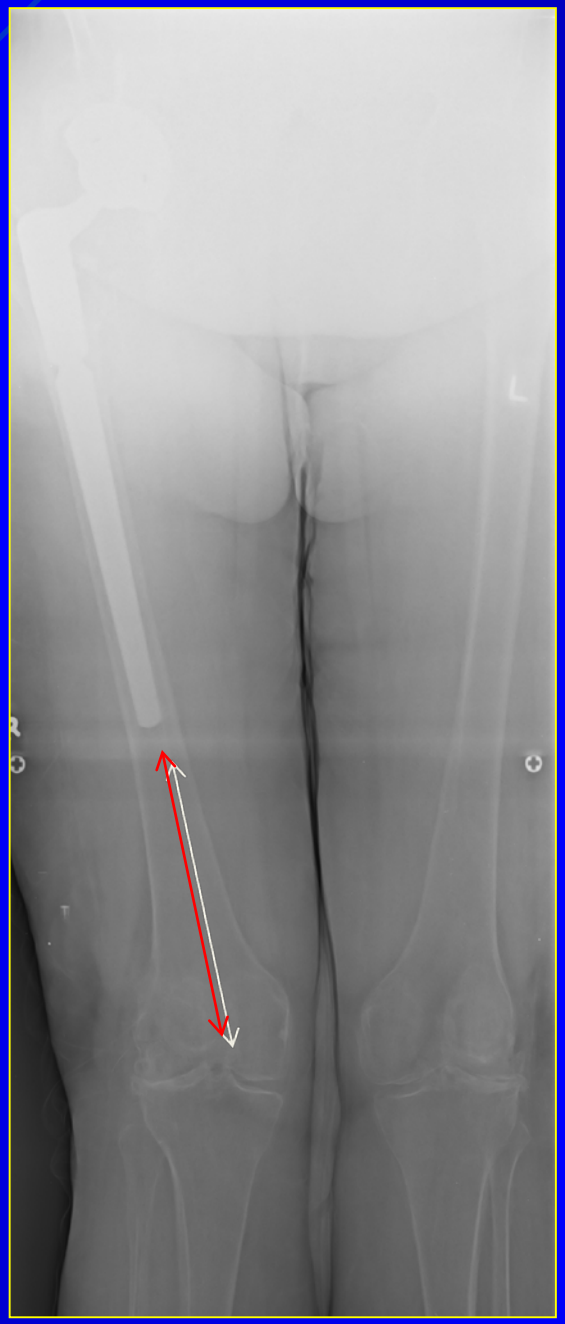
Rationale

Some cases preclude conventional (IM) instrumentation



Rationale

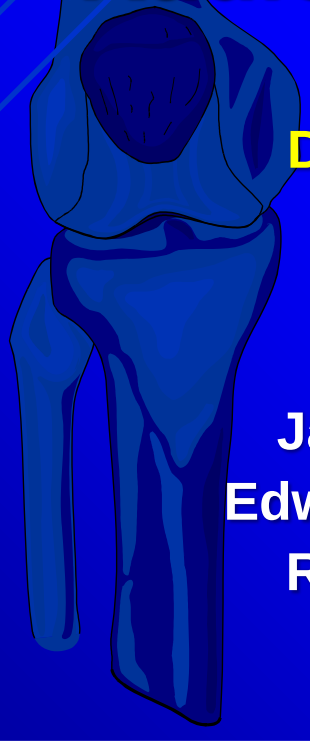




Rationale

- Used routinely, PSI guides might
  - Improve alignment
  - Increase efficiency
    - Decrease instruments
    - Reduce surgical steps
  - Reduce operation time
  - Improve longevity
  - Improve kinematics

Evaluation of Conventional and Patient-Specific Instrumentation in Total Knee Arthroplasty using Radiostereometric Analysis



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Background

- In practice, PSI success has been mixed
- Cost-effectiveness of PSI has been questioned

Lombardi AV, and Frye BM. *Curr Rev Musculoskelet Med* 2012;5(4):309-14.
Ng VY, DeClaire JH, Berend KR, et al. *Clin Orthop Relat Res* 2012;470(1):99-107.
Barrack RL, Ruh EL, Williams BM, et al. *J Bone Joint Surg Br* 2012;94(11):95-9.
Nam D, Park A, Stambough JB,et al. *Clin Orthop Relat Res* 2016;474(1):40-6.

Objective

- Evaluate PSI technology compared to conventional instrumentation for TKA
  - Resource utilization
  - Surgical waste
  - Patient outcomes
  - Economics
  - Alignment
  - Implant migration and kinematics (RSA)

Objective

- Evaluate PSI technology compared to conventional instrumentation for TKA
  - In context of Canadian healthcare system

Methods: PRCT

- 50 patients:
  - 25 PSI
  - 25 Conventional
- Powered for implant migration using RSA
- Western University Health REB approval
- Clinicaltrials.gov (NCTO2230215)

Methods: PRCT

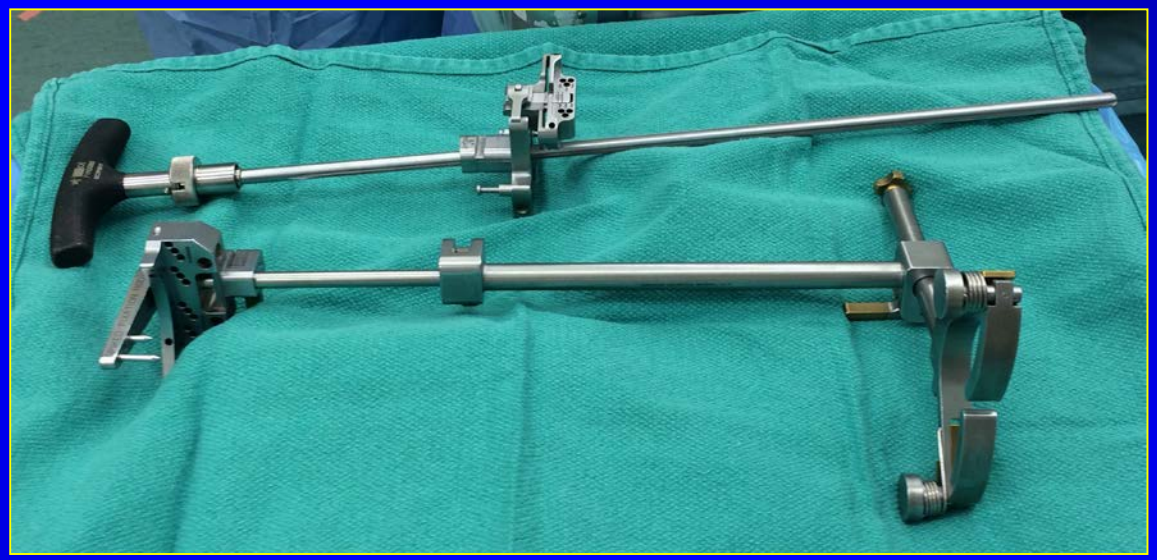
- Legion™ PS implant
  - Smith & Nephew, Memphis, TN
- Cemented fixation
- Resurfaced patella
- Marker beads inserted in femur and tibia

Methods: PSI vs Conventional

- PSI
  - MRI; 3-foot hip-ankle x-rays
  - Approval of OR plan
  - Visionaire™ cutting guides

Methods: PSI vs Conventional

- Conventional
  - IM femur
  - EM tibia

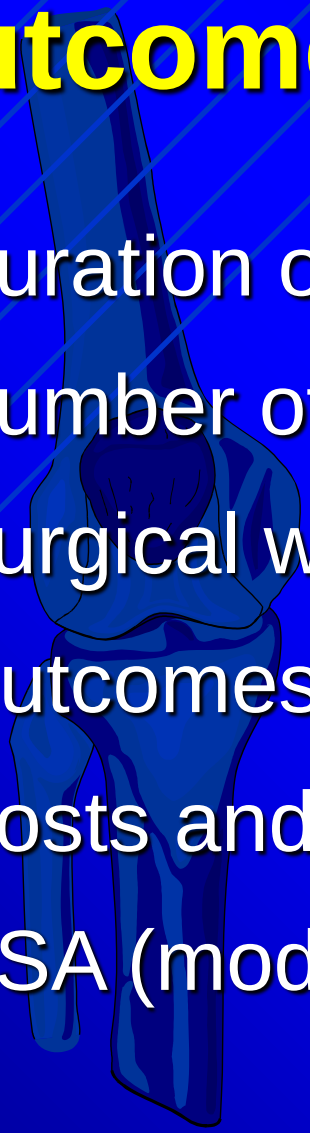


Follow-up

- Standard of care visits
- Baseline – implant position
- 6 weeks
- 3 months
- 6 months
- 1 year
- 2 years

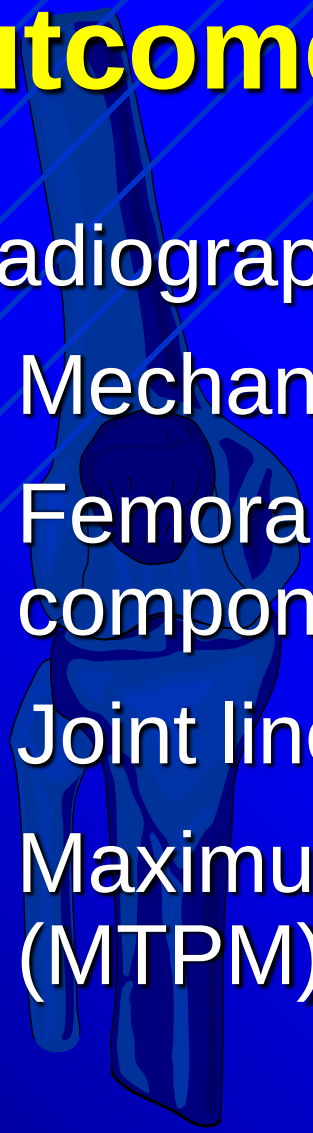
Outcomes

- Duration of OR
- Number of procedure-specific trays
- Surgical waste audit
- Outcomes (WOMAC, SF-12, EQ5D, UCLA)
- Costs and healthcare resource use
- RSA (model-based software)

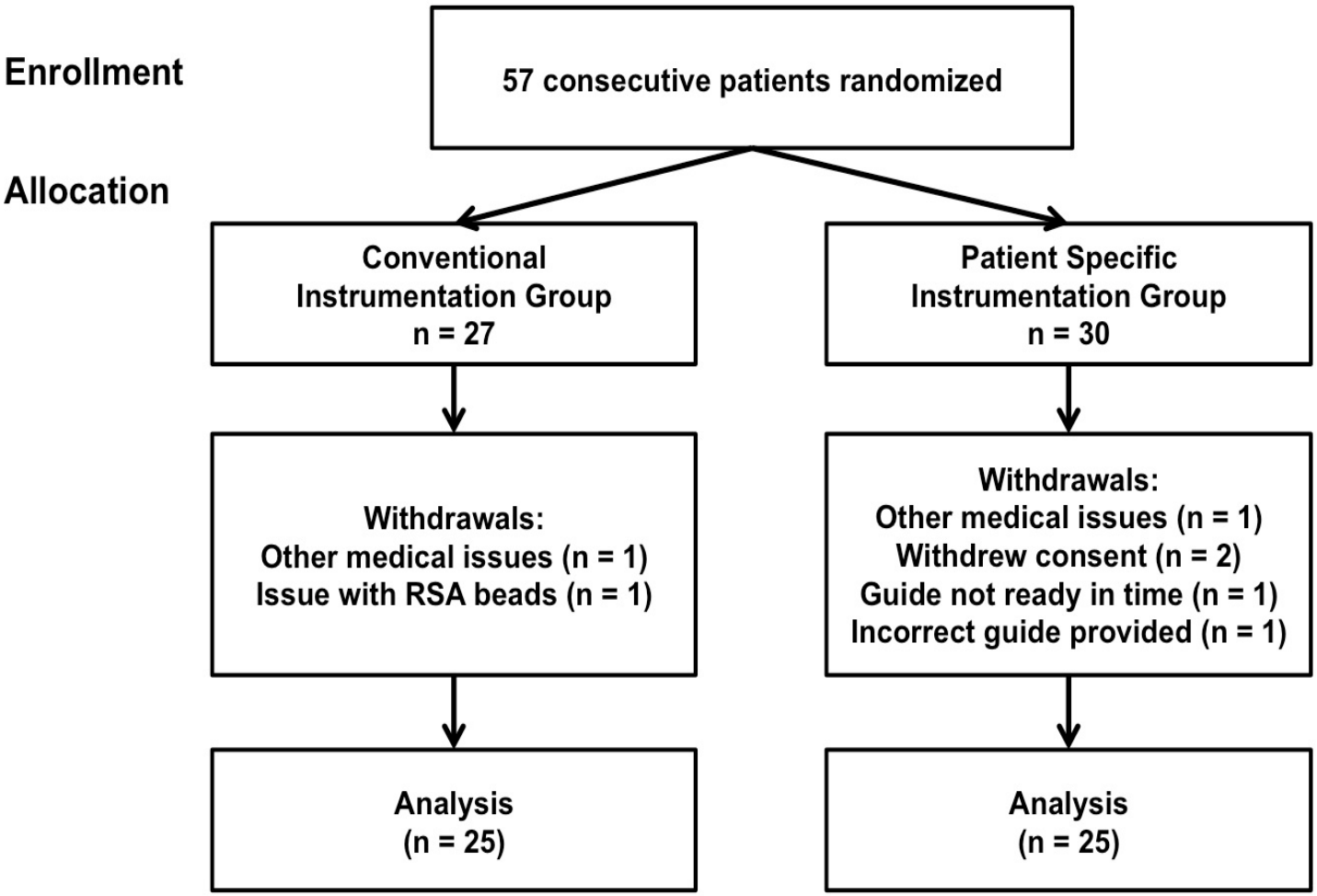


Outcomes

- Radiographic and RSA data
  - Mechanical axis
  - Femoral and tibial component alignment
  - Joint line elevation
  - Maximum total point motion (MTPM)



Results: Exclusions



Results: Demographics

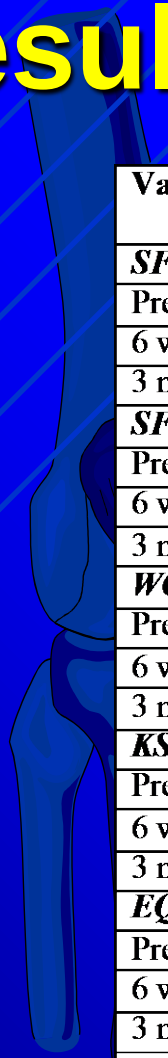
Variable	Patient Specific	Conventional	p Value
Age (years)	69 ± 8	69 ± 8	0.87
Male : Female	12 M : 13 F	7 M : 18 F	0.24
Height (cm)	170 ± 11	165 ± 10	0.08
Weight (kg)	88 ± 18	84 ± 16	0.11
BMI (kg/m^2)	30 ± 5	31 ± 6	0.74

Similar between cohorts

Results: Resources and Waste

Variable	Patient Specific Instrumentation n = 25	Conventional Instrumentation n = 25	p Value
Intraoperative Resource Utilization			
Total OR time (min)	112.5 ± 20.2	101.7 ± 14.7	0.04
Procedure time (min)	80.0 ± 11.4	73.9 ± 8.4	0.04
Tourniquet time (min)	76.2 ± 15.7	73.6 ± 8.3	0.16
Blood loss (ml)	133.0 ± 196.2	117.0 ± 83.8	0.58
Trays opened (number)	4.8 ± 0.7	8.1 ± 0.9	< 0.0001
Deviation from plan	7 of 25 cases	3 of 25 cases	0.50
Surgical Waste			
Total waste (kg)	10.1 ± 1.5	10.6 ± 1.7	0.24
Cardboard/paper (kg)	0.4 ± 0.1	0.4 ± 0.1	0.63
Biohazardous (kg)	1.6 ± 0.5	1.7 ± 0.5	0.74
Blue Recyclables (kg)	0.3 ± 0.1	1.4 ± 0.5	< 0.0001
Landfill (kg)	7.8 ± 1.0	7.3 ± 1.2	0.16

Results: Patient Outcomes



Variable	Patient Specific Instrumentation	Conventional Instrumentation	p Value
SF-12 Mental Score			
Pre-operative	59.2 ± 6.6	51.7 ± 11.1	0.03
6 weeks	52.5 ± 8.8	53.7 ± 10.8	0.70
3 months	56.3 ± 7.2	50.0 ± 10.1	0.10
SF-12 Physical Score			
Pre-operative	32.4 ± 7.9	34.0 ± 10.8	0.77
6 weeks	32.7 ± 8.1	35.5 ± 8.8	0.29
3 months	37.7 ± 8.8	42.1 ± 9.1	0.13
WOMAC Total Score			
Pre-operative	51.9 ± 12.3	53.3 ± 17.6	0.95
6 weeks	62.1 ± 16.0	76.2 ± 13.4	0.005
3 months	71.9 ± 11.8	74.5 ± 14.4	0.54
KSS Flexion Score			
Pre-operative	108.5 ± 13.4	105.5 ± 17.8	0.58
6 weeks	95.6 ± 13.8	111.4 ± 12.3	0.004
3 months	111.0 ± 10.6	115.5 ± 11.0	0.23
EQ5D			
Pre-operative	76.5 ± 12.5	76.5 ± 15.5	0.99
6 weeks	78.9 ± 14.8	80.7 ± 12.3	0.57
3 months	77.7 ± 19.3	78.1 ± 14.8	0.79
UCLA Activity Score			
Pre-operative	4.6 ± 1.6	4.6 ± 1.6	0.96
6 weeks	3.5 ± 1.2	4.0 ± 1.4	0.20
3 months	4.6 ± 1.6	4.7 ± 1.3	0.75

Results: Complications

- PSI
  - 1 infection
  - 3 manipulations
- Conventional
  - None

Results: Procedure Costs

	Patient Specific Instrumentation	Conventional Instrumentation
Procedure and inpatient stay	$8,290.29 ± 1,502.59	$6,502.91 ± 1,437.76
Postoperative resource use		
Ministry of Health	$3,046.75 ± 8,429.12	$608.54 ± 394.47
Societal	$8,356.38 ± 13,365.05	$5,154.84 ± 6,920.98
Total Cost per Case		
Ministry of Health	$11,361.17 ± 8,692.48	$7,111.45 ± 1,567.46
Societal	$16,670.80 ± 13,463.19	$11,657.75 ± 6,800.54

Results: Procedure Costs

	Mean Difference (95% CI), p-value
Procedure and inpatient stay	1,787.38 (951.10 to 2,623.67), p < 0.01
Postoperative resource use	
Ministry of Health	2,438.21 (1,124.01 to 6,000.43), p = 0.17
Societal	3,201.55 (2,879.16 to 9,282.26), p = 0.29
Total Cost per Case	
Ministry of Health	4,249.72 (534.43 to 7,964.99), p = 0.03
Societal	5,013.05 (1,079.73 to 11,105.83), p = 0.10

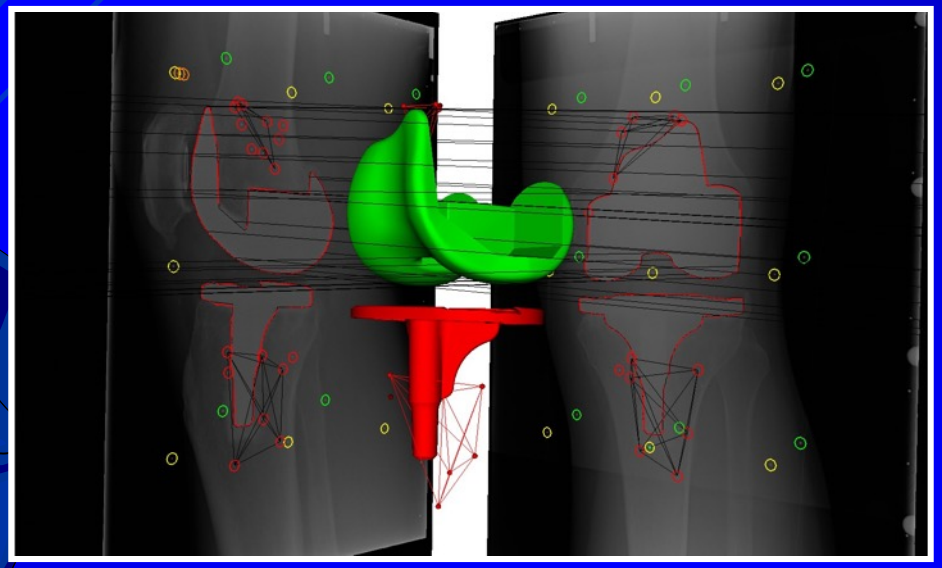
Greater avg. cost per procedure for PSI: $1,787.38

If revision for infection excluded: $1,765.92

Results: Alignment

- No difference
  - Hip knee angle
  - Tibial slope

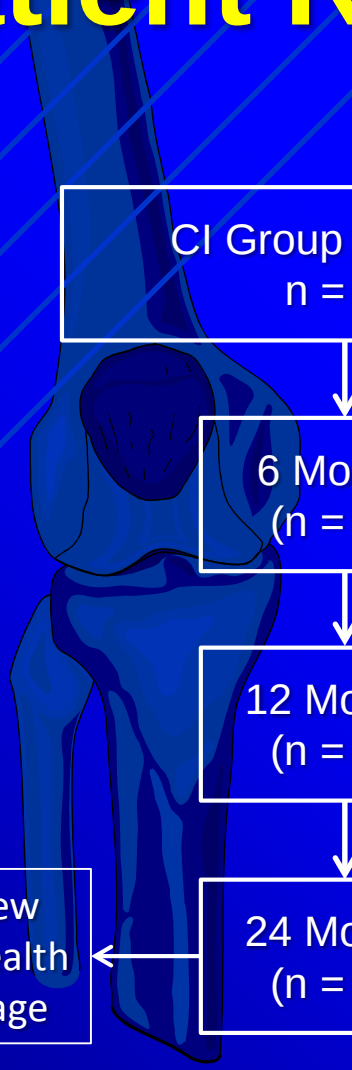
Radiostereometric analysis



- Beads in femur, tibia
- Supine RSA exams
- Model based RSA

- 2 wks (baseline), 6 wks, 3 mos, 6 mos, 12 mos, 24 mos

Patient RSA exams



CI Group Baseline
n = 25

6 Months
(n = 20)

12 Months
(n = 21)

24 Months
(n = 22)

1 Withdrew
1 Poor health
1 Bad image

PSI Group Baseline
n = 25

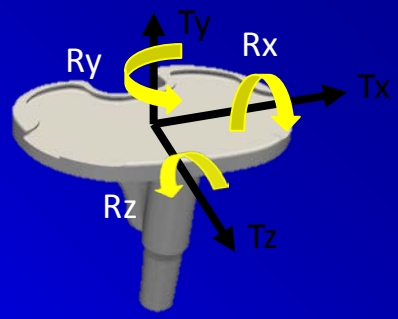
6 Months
(n = 22)

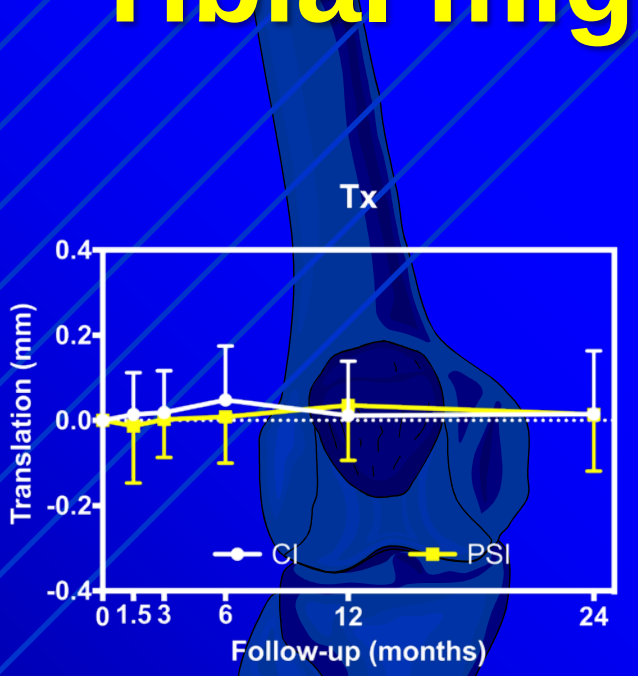
12 Months
(n = 24)

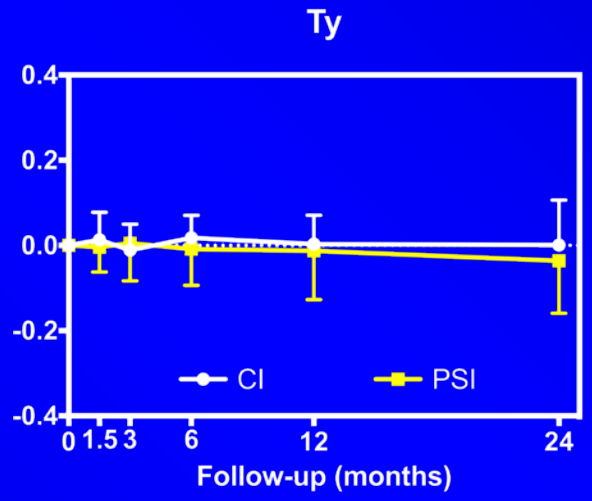
24 Months
(n = 20)

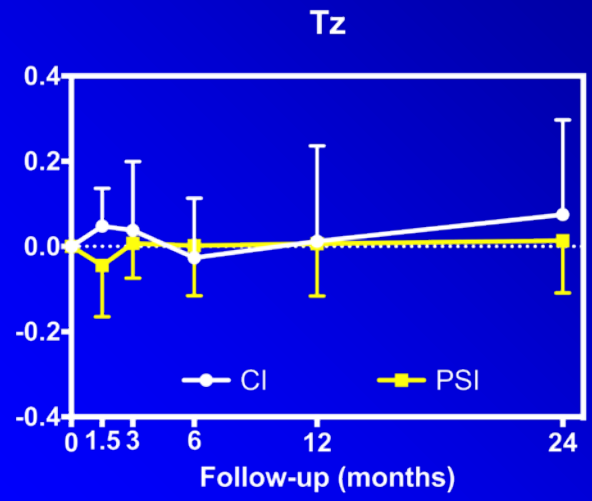
3 Unreachable
1 Poor health
1 Bad image

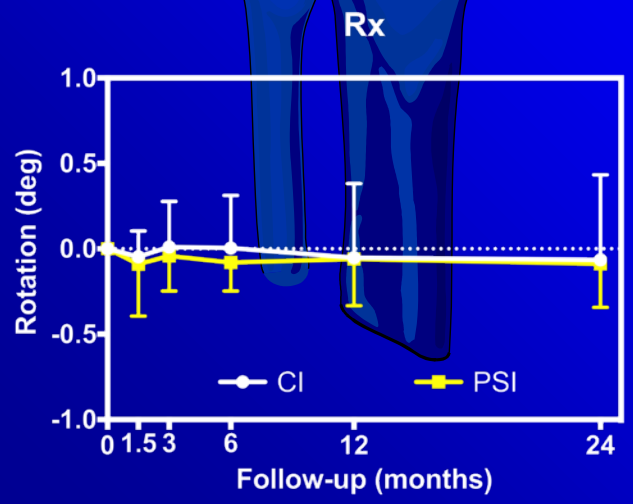
Tibial migration

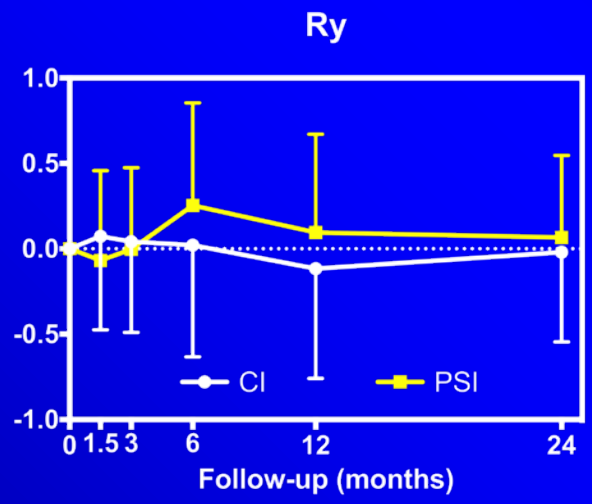


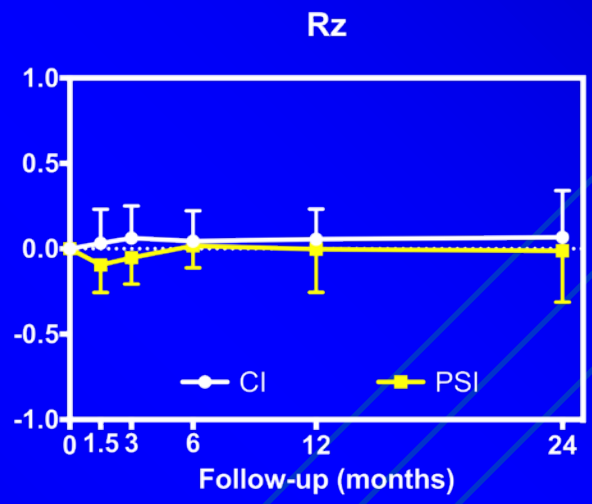






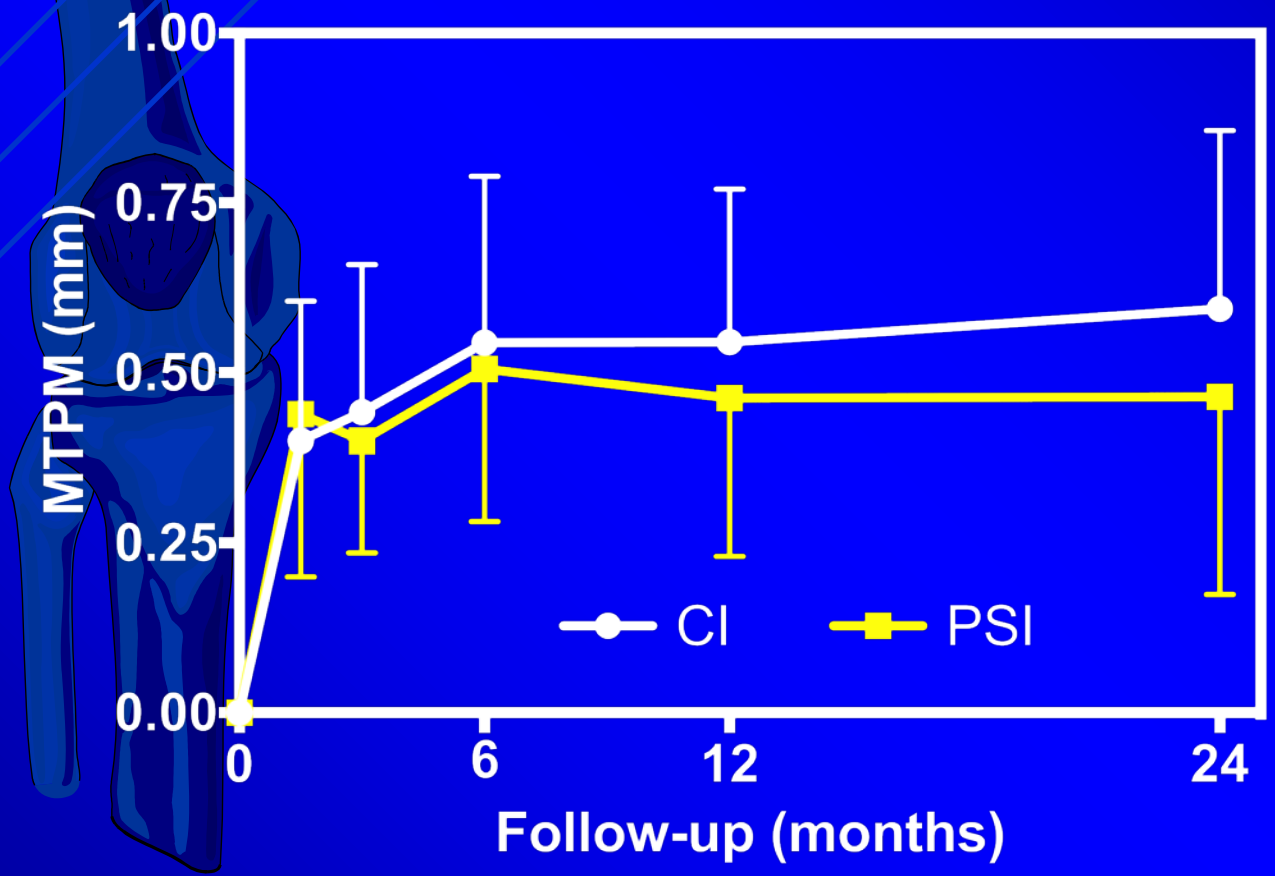






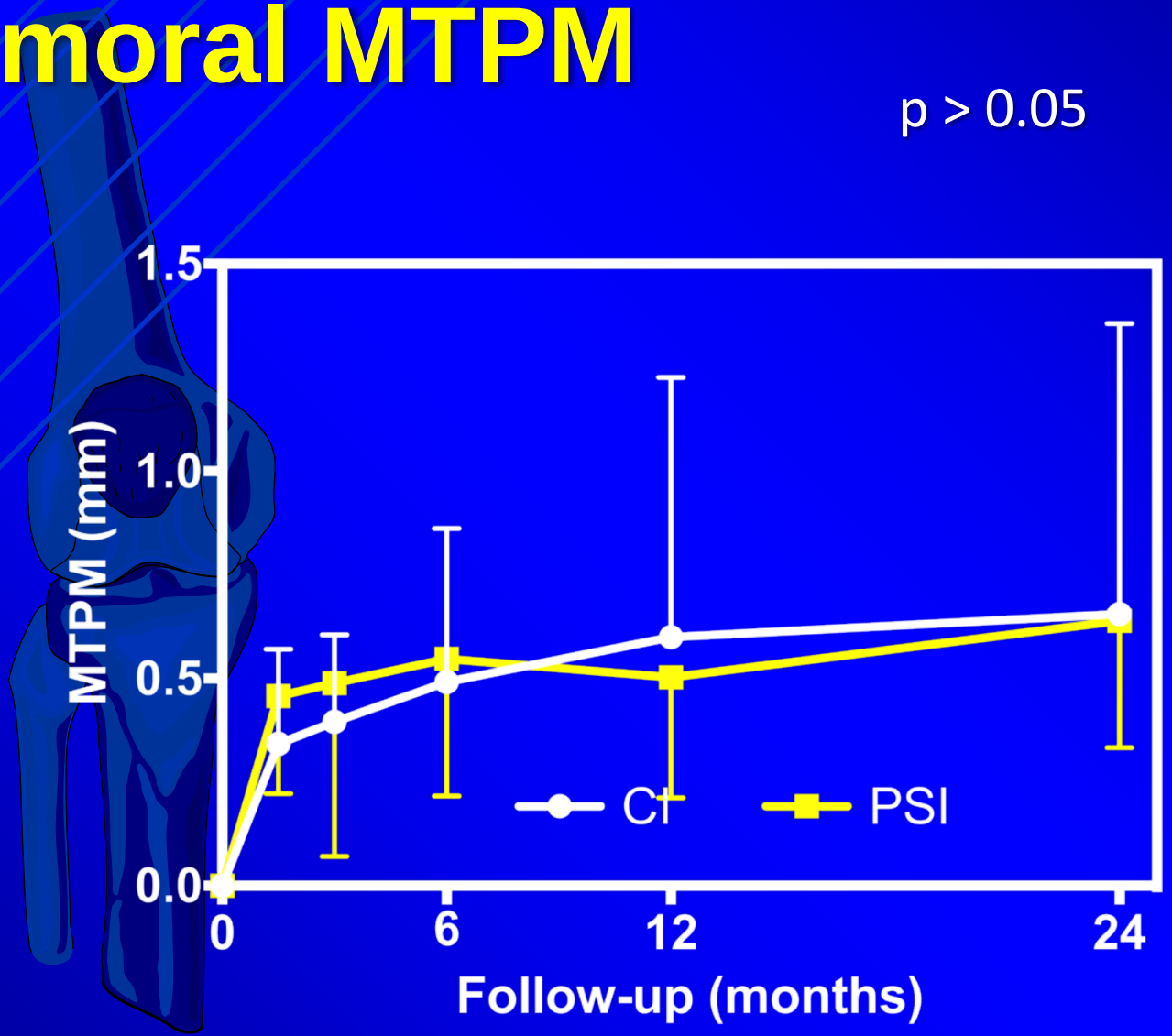
Tibial MTPM

p = 0.77



Femoral MTPM

$p > 0.05$

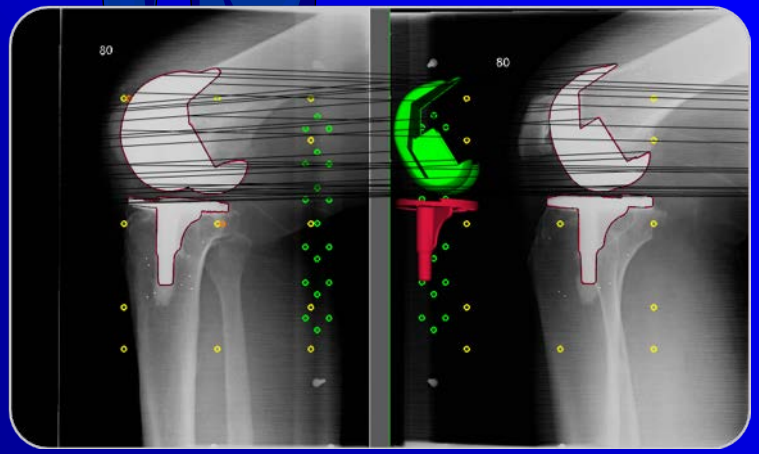


Predicted loosening

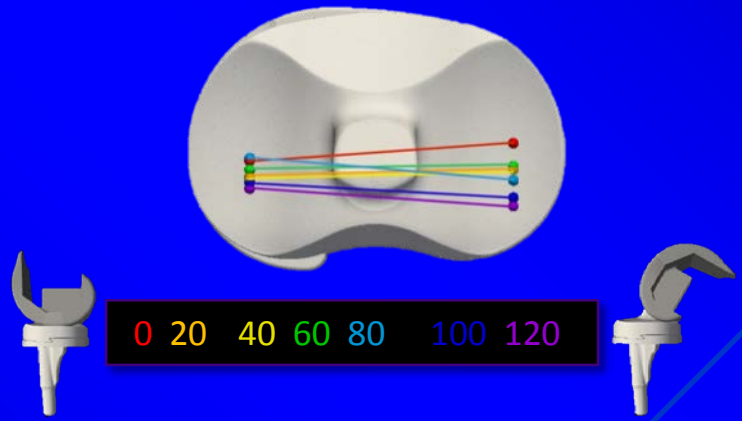
Published Threshold	Patient Specific	Conventional
[1]MTPM at 6 months <0.5 mm	0.51 mm (None > 1.6 mm)	0.54 mm (None > 1.6 mm)
[2]MTPM at 12 months <0.5 mm	0.46 mm (None > 1.6 mm)	0.55 mm (None > 1.6 mm)
[3]MTPM from 12-24 months <0.2 mm	-0.01 mm (5 > 0.2 mm)	0.06 mm (3 > 0. 2mm)
[4]Rx at 24 months <0.8 deg	-0.09 deg (None > 0.8 deg)	-0.06 deg (3 > 0.8 deg)

[1]Pijls et al. (2018) *Acta Orthop*.
[2]Pijls et al. (2012) *Acta Orthop*.
[3]Ryd et al. (1995) *JBJS Br.*
[4]Gudnason et al. (2017) *Acta Orthop.*

Contact kinematics



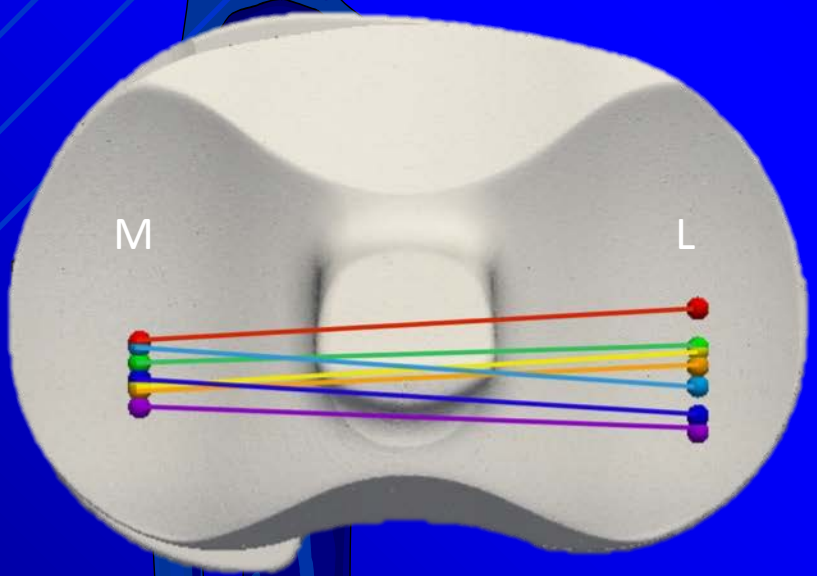
Quasi-static RSA takes exams at 0, 20, 40, 60, 80, 100, and 120 degrees of flexion

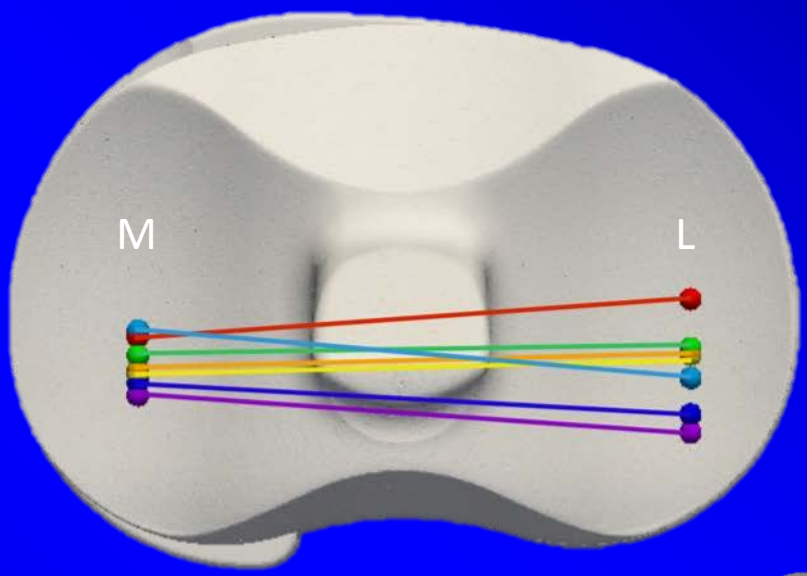


Contact kinematics

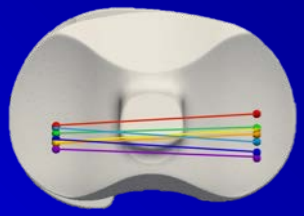
Conventional Instrumentation

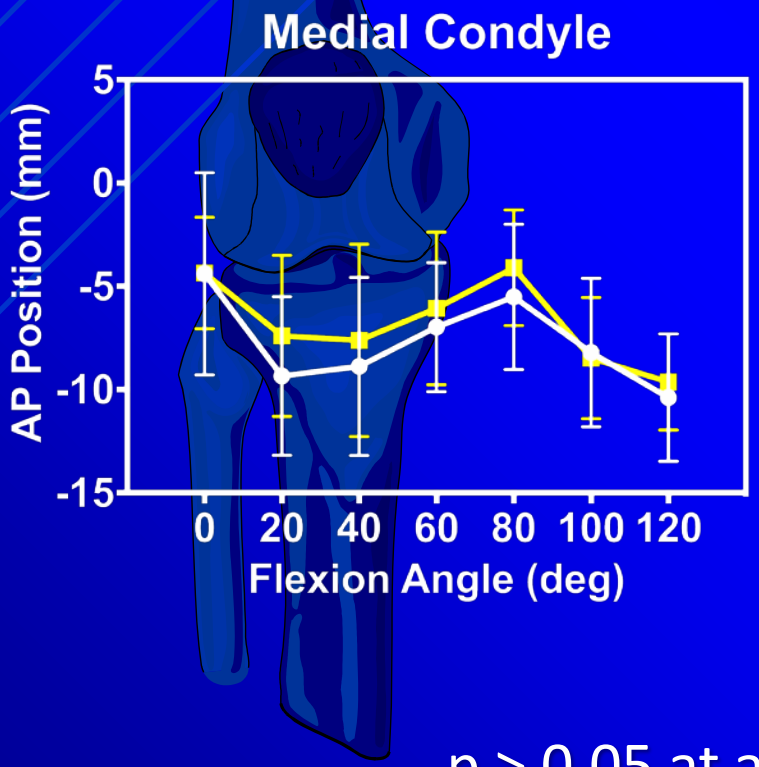
Patient Specific Instrumentation

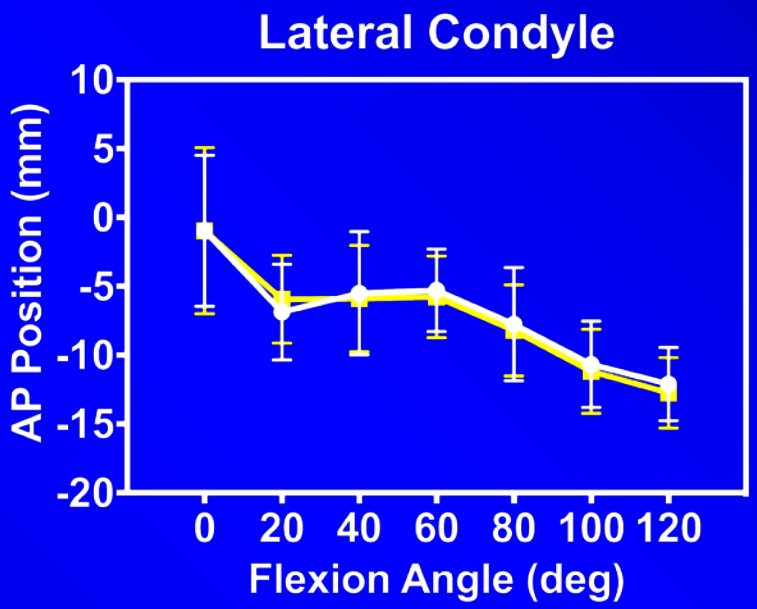




Contact location

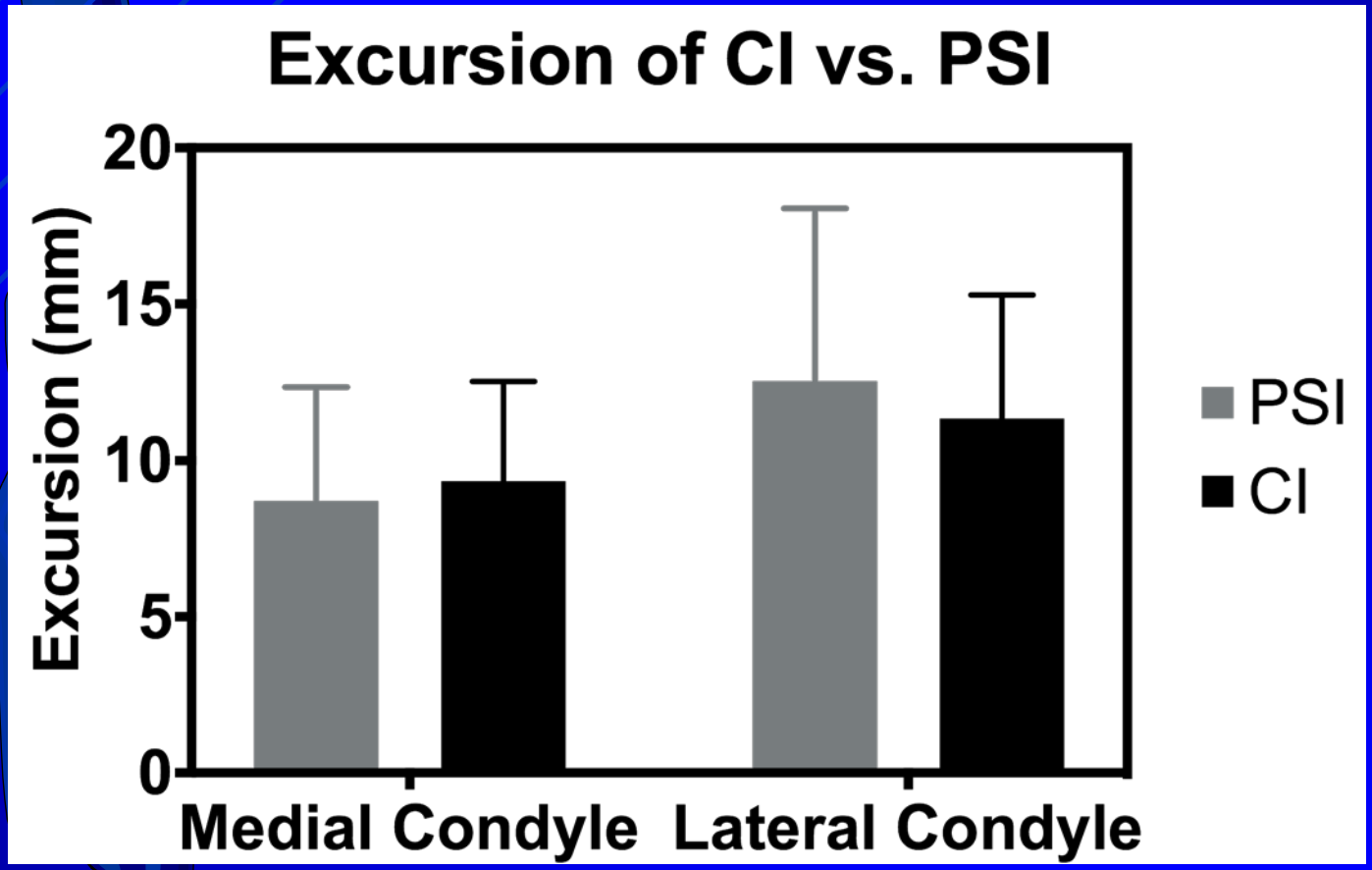






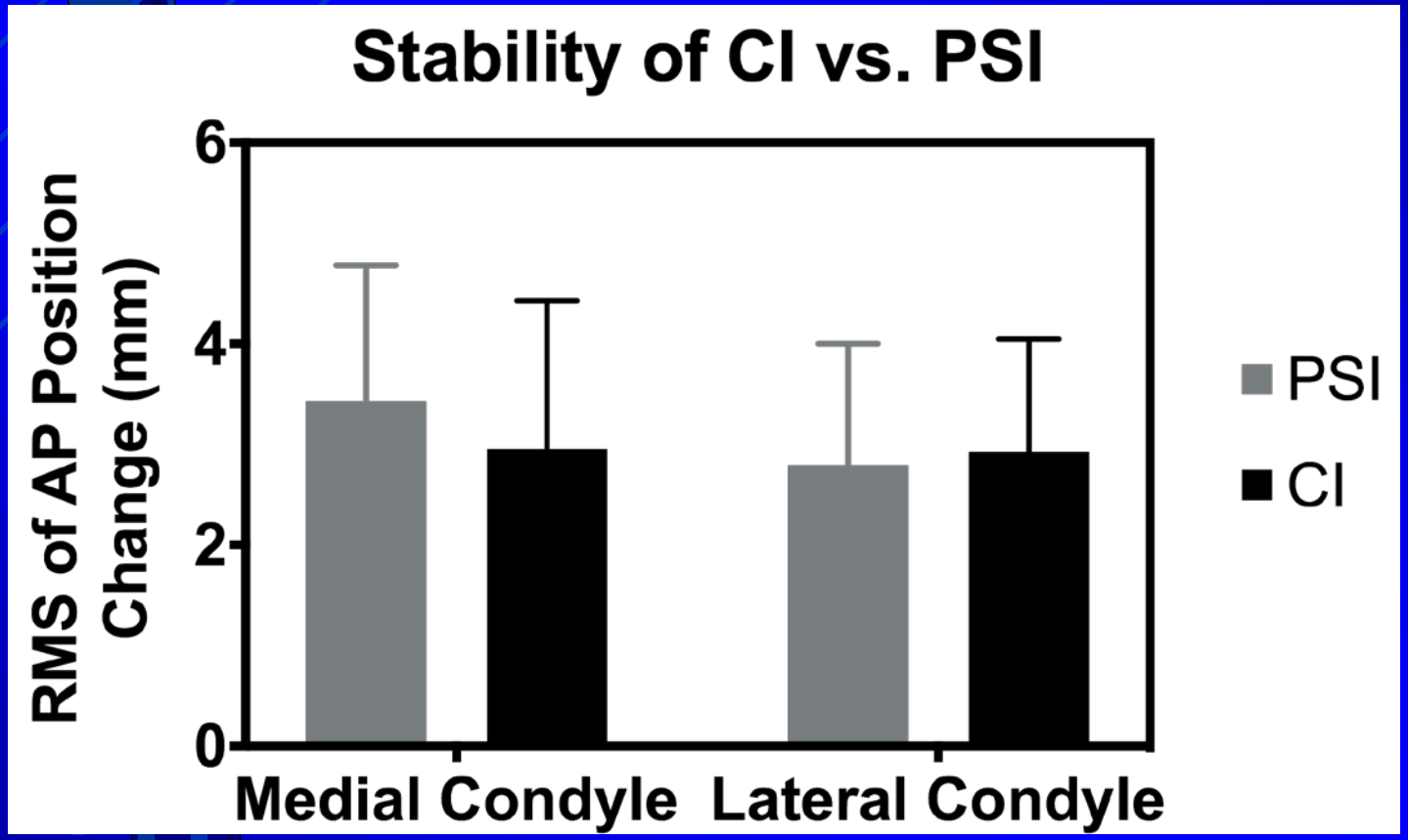
$p > 0.05$ at all flexion angles

Magnitude of excursion



$p > 0.05$

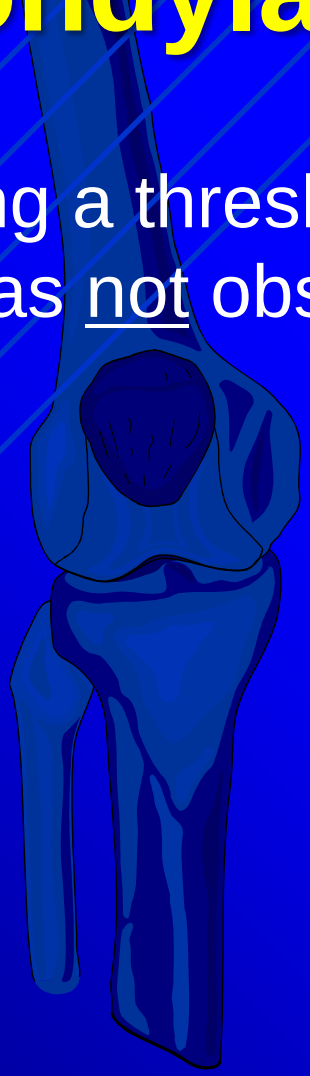
Stability



$p > 0.05$

Condylar lift-off

Using a threshold of 1 mm, condylar separation was not observed in either group



Discussion

Efficacy of Patient-Specific Instruments in Total Knee Arthroplasty

A Systematic Review and Meta-Analysis

Emmanuel Thienpont, MD, MBA, PhD, Pierre-Emmanuel Schwab, MD, and Peter Fennema, DSc

Investigation performed at the University Hospital Saint Luc, Brussels, Belgium, and AMR Advanced Medical Research, Männedorf, Switzerland

J Bone Joint Surg Am. 2017;99:521-30

- 44 studies
  - 2,866 PSI
  - 2,956 standard instrumentation

Discussion

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- Risk of mechanical axis malalignment
  - Significantly lower for PSI

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- Risk of femoral coronal-plane malalignment
  - Significantly lower for PSI

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- Risk of tibial sagittal-plane and coronal-plane malalignment
  - Higher for PSI

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- Minor reductions in total operative time and blood loss were noted for PSI

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- PSI improves accuracy of femoral component alignment and mechanical alignment

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- But at the cost of increased risk of outliers for the tibial component alignment

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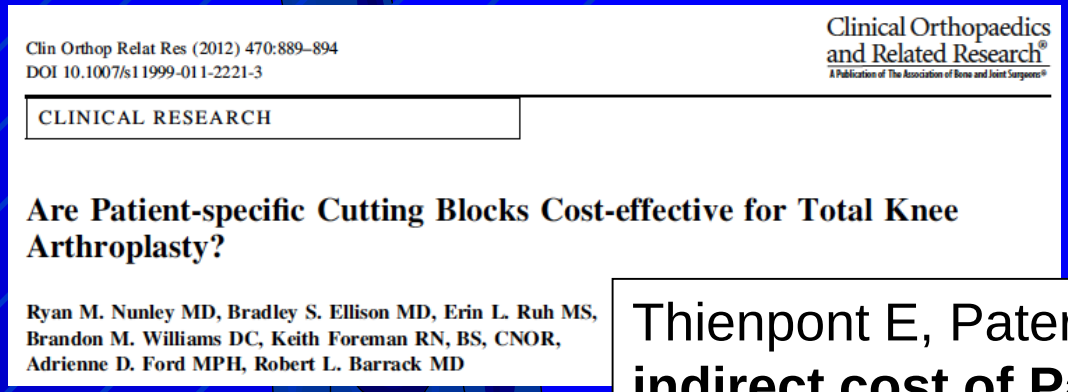
- Not a substantial justification for routine use of the technology

Discussion



Clin Orthop Relat Res (2012) 470:889–894
DOI 10.1007/s11999-011-2221-3

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

CLINICAL RESEARCH

Are Patient-specific Cutting Blocks Cost-effective for Total Knee Arthroplasty?

Ryan M. Nunley MD, Bradley S. Ellison MD, Erin L. Ruh MS, Brandon M. Williams DC, Keith Foreman RN, BS, CNOR, Adrienne D. Ford MPH, Robert L. Barrack MD

Thienpont E, Paternostre F, Van Wymeersch C. **The indirect cost of Patient-Specific Instruments**. *Acta Orthop Belg.* 2015;81(3):462-70.

- Additional costs of several thousand U.S. dollars for using PSI technology
- Total cost of €1,142 for PSI beyond conventional instrumentation

Discussion

Can J Surg, Vol. 56, No. 2, April 2013

Surgical waste audit of 5 total knee arthroplasties

Nathan M. Stall, BSc, MD*
Yoan K. Kagoma, BASc, MD*
Jennifer N. Bondy, MSc, MD*
Douglas Naudie, BSc, MD†

From the *Schulich School of Medicine and Dentistry, Western University, and the †Department of Orthopaedic Surgery, London Health Sciences Centre, London, Ont.

- Routine operation produces more waste than family of 4 produces in one week

Discussion

Early migration of tibial components is associated with late revision

A systematic review and meta-analysis of 21,000 knee arthroplasties

Bart G Pijls[1], Edward R Valstar[1,2], Klaas-Auke Nouta[1], Josepha WM Plevier[3], Marta Fiocco[4], Saskia Middeldorp[5,6], and Rob GHH Nelissen[1]

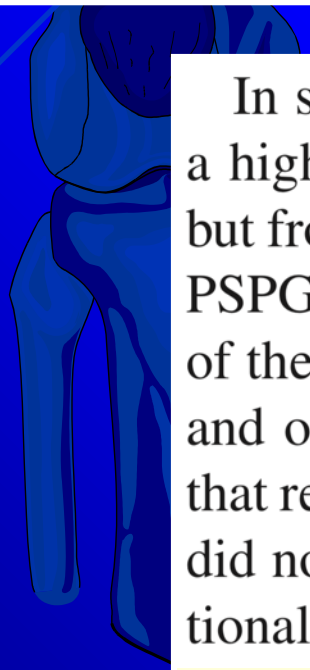
- Acceptable early implant migration
- Not considered at risk of revision

OPEN ACCESS

Acta Orthopaedica 2018; 89 (x): x–x

A 2-year RSA study of the Vanguard CR total knee system: A randomized controlled trial comparing patient-specific positioning guides with conventional technique

Frank-David ØHRN [1,2], Justin VAN LEEUWEN [3,5], Masako TSUKANAKA [4], and Stephan M RÖHRL [4,5]



In summary we found that the cemented Vanguard CR had a higher initial mean migration than expected at 12 months, but from 12–24 months the conventional group stabilized. The PSPG group also had continuous migration at this point. None of the implants in our study rotated more than recommended, and only 2 implants had a total peripheral subsidence above that recommended, 1 in each group. Although the PSPG group did not have a statistically different MTPM from the conventional group, we think that the findings of the migration pattern of this technique are of some concern and call for longer follow-up.

Limitations

- Powered for an RSA analysis of implant migration
  - Only 50 patients included
- Only one type of guide was examined
  - Visionaire™ (Smith & Nephew, Memphis, TN)
  - Unable to blind surgeon to technique
- PSI not used routinely at our institution
  - Learning curve for this technique

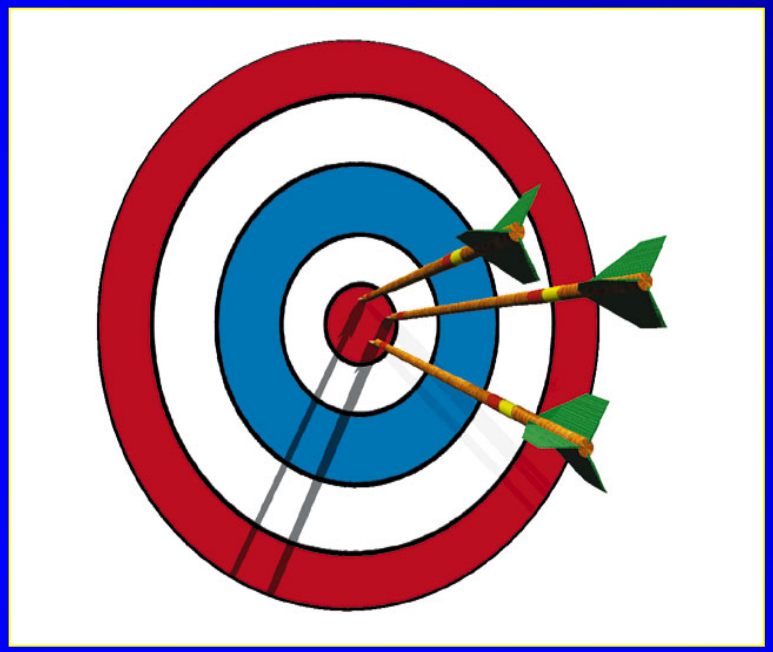
Strengths

- Few studies have been devoted to cost
  - First in the context of Canadian healthcare system
- RSA evaluation
  - Clinically relevant association between early migration of TKAs and late revision for loosening

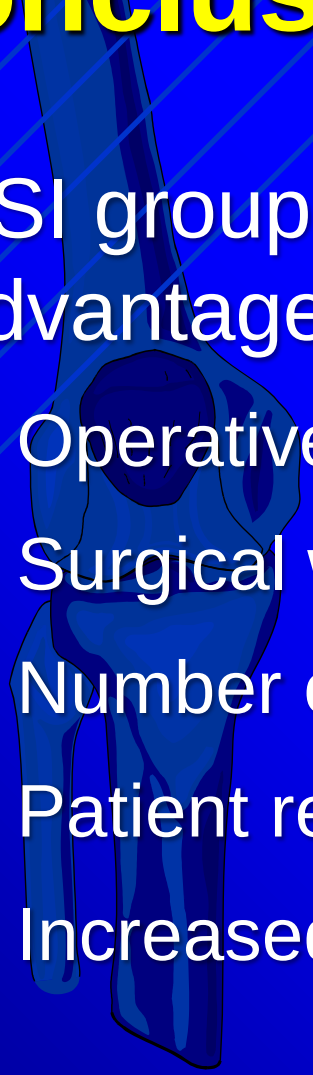
Conclusion

Ideal instrumentation

- Accurate and precise
- Time efficient
- Does not require preop imaging
- Proven benefit
- Minimum cost
- Widely available



Conclusion



- PSI group provided minimal or no advantage over conventional jigs:
  - Operative time
  - Surgical waste
  - Number of adverse events
  - Patient reported outcomes
  - Increased cost

Conclusion

- With RSA, PSI
  - Had acceptable migration patterns
  - None considered at risk of revision

Conclusion

- With RSA, PSI
  - Had acceptable migration patterns
  - None considered at risk of revision
  - Did not reduce the predicted risk of aseptic loosening
  - Did not provide any substantial advantage over CI with respect to contact kinematics

Conclusion

- Literature does not demonstrate a significant clinical or radiological benefit of PSI over other techniques in TKA
- Cost of PSI is a significant barrier for publicly funded healthcare systems
- PSI is not justified for routine use, but can be safely employed in selected cases

Thank You

Email: Douglas.Naudie@lhsc.on.ca

London Health Sciences Centre

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