

Preliminary Experience with Conformis Custom TKR

Ted Firestone MD

Joint Replacement Center of Scottsdale, PC

Scottsdale, AZ

The **JOINT REPLACEMENT**
CENTER *of* **SCOTTSDALE**

(480) 237-5727



What is Conformis?

- Custom TKR implant generated from CT scan
- Jigs and Implants made by 3D printing and Direct Laser Sintering
- 5 to 6 week turnaround
- Burlington Mass





iTotal G2 System



WHY DID I EVEN TRY THIS?

- TKR results are good with success at 95% plus
- Average 120 degrees of flexion
- Haven't manipulated a knee in 10 years
- Very low re-op rate
- 98% patients go home and are off walker within 2 weeks

Why try Conformis?

- Despite my results @ 95% satisfaction
- Most of my successful TKR patients don't tell me that their joint replacement feels normal!
- Even the happiest patients often have some "comment"



What were my thoughts?

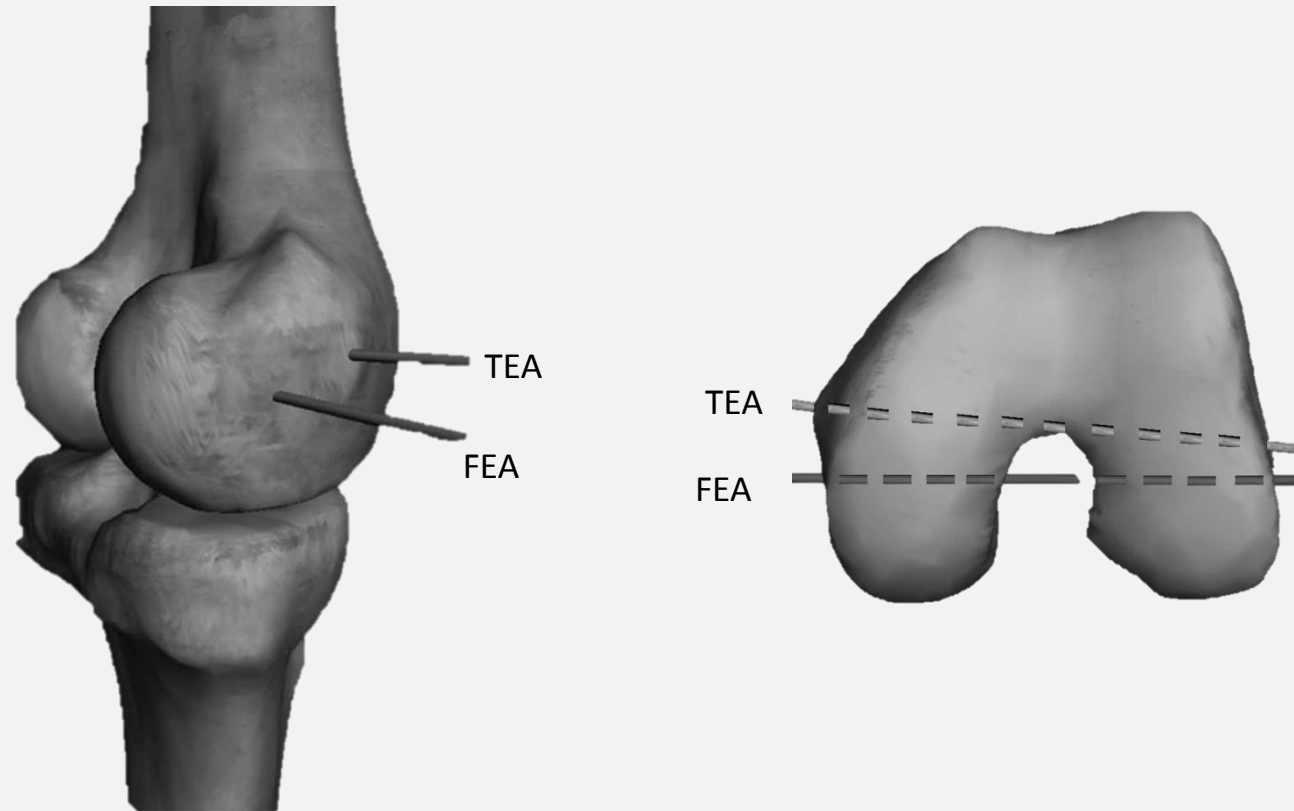
- Avoid drilling canal and intramedullary rod
- Resect a little less bone
- Avoid overhang - impingement
- Avoid undersize and exposed bone which could bleed more and cause more initial swelling

MAYBE I COULD DO BETTER!



RESTORING MORE NATURAL KINEMATICS

- Studies have shown that the natural Flexion-Extension Axis (FEA) and the Transepicondylar Axis (TEA) are not the same and differ an average of 4.6 degrees¹
- iTotal respects each patient's native condylar geometry, allowing the knee to rotate about its natural axis



¹Eckhoff D et al. Difference Between the Epicondylar and Cylindrical Axis of the Knee. Clin Orthop Relat Res. 2007; Aug(461) 238-244.

In Vivo Kinematics for Subjects Implanted With Either a Traditional or Personalized TKA

Komistek, ICJR Pan Pacific 2014

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

INTRODUCTION

Until recently, knee implants were designed using average patient measurements. More recently, using imaging techniques, patient specific posterior cruciate retaining (PCR) total knee arthroplasty (TKA) implants have been individually made based on each patient's anatomy using a pre-operative CT scan. The objective of this study was to use a state-of-the-art mobile fluoroscopy unit to determine the in vivo kinematics for subjects having either a traditional, off-the-shelf (OTS) knee implant or a customized, individually made (CIM) knee implant that replicates each patient's femoral and tibial geometries.

METHODS

In vivo kinematics for 20 subjects, 11 having a CIM TKA (Total, ConforMIS, Inc., Bedford, MA) and 9 having an OTS TKA (NexGen, Zimmer USA, Warsaw, IN), were assessed. A mobile fluoroscopic system was used and each patient was asked to perform a weight-bearing deep knee bend and a chair rise under fluoroscopic observation. Those fluoroscopic 2D images were then converted into a 3D representation of actual kinematics. All the subjects were implanted by a single surgeon and each patient was deemed clinically successful (KSS Score >90) without any laxity or pain. Comparison of kinematics between the two designs focused on range of motion, posterior femoral rollback and axial rotation.

RESULTS

Differences in overall motion and pattern were evident between the two groups. During a deep knee bend, subjects with a CIM TKA experienced 112° of weight-bearing flexion, compared to only 102° for subjects with an OTS TKA. Subjects having a CIM knee implant experienced more posterior femoral rollback of their lateral condyle (2.1 vs. 0.1 mm) and greater axial rotation (4.2 vs. 2.9°) than subjects with OTS TKA type. Also, 44.4% of the subjects with an OTS TKA experienced an anterior slide of their lateral condyle and a reverse axial rotation pattern, compared to only 9.0% of the subjects with a CIM TKA. Additionally, 56% of patients in the OTS TKA group experienced condylar lift-off > 1.0mm compared to 0% of patients in the CIM TKA group (Figure 1). During the chair-rise activity, subjects with an OTS TKA experienced a posterior slide of their lateral condyle opposite the normal knee, while subjects with a CIM TKA experienced a roll forward motion (Figure 2) typical in pattern for a normal knee. The OTS TKA experienced 0.9° of axial rotation, while subjects with a CIM TKA experienced 5.3°. Interestingly, subjects with an OTS TKA experienced high magnitudes of femoral external rotation (opposite the normal knee), whereas the CIM TKA subjects experienced a change from external to internal rotation of the femur (similar to the pattern of a normal knee).

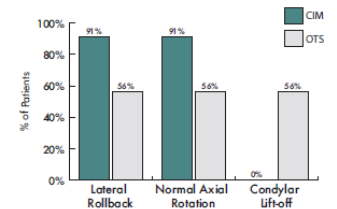


Figure 1: Comparison of Deep Knee Bend kinematics between the CIM and OTS TKA arms.

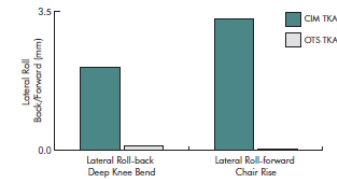


Figure 2: Comparison of average anterior/posterior translation for the CIM and OTS TKAs during Deep Knee Bend and Chair Rise.

DISCUSSION

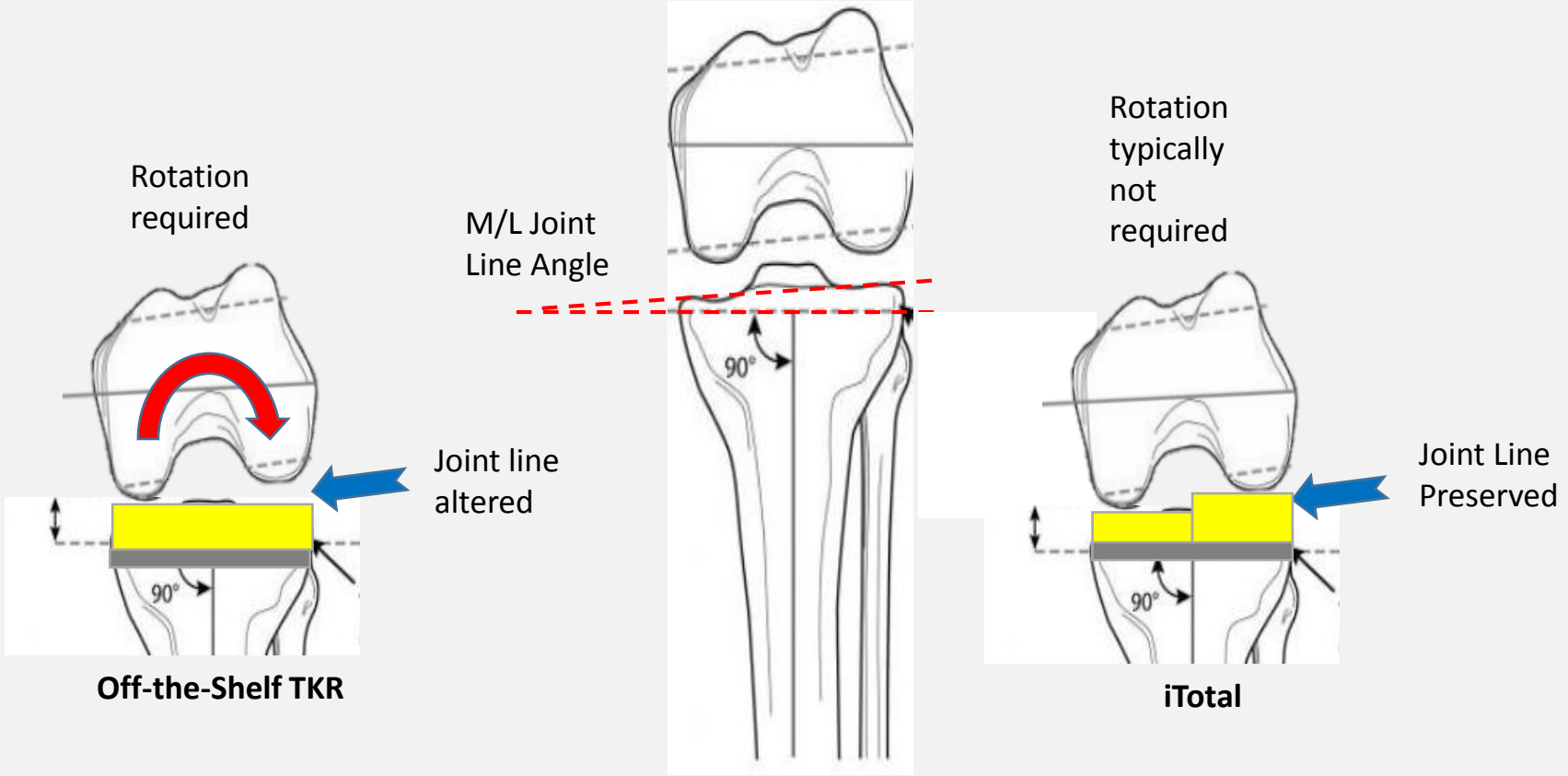
Subjects with a CIM TKA experienced a kinematic pattern similar to a normal knee. Subjects with an OTS TKA experienced greater variability in their kinematic patterns, differing from the normal knee. This is the first study to utilize mobile fluoroscopy to assess deep knee bend, chair-rise and gait for subjects having two distinctly different TKA types.

MK-02958-AA

- More appropriate roll back pattern
- Less condylar lift-off

Femoral Rotation - Restoring the M/L Joint Line

Restores Normal Kinematics



¹Poivache et al. Rotational Landmarks and Sizing of the Distal Femur in Total Knee Arthroplasty. Clin Orthop Relat Res 1996, 331, pp 35-46.

²Martin J, Whiteside L. The Influence of Joint Line Position on Knee Stability After Condylar Knee Arthroplasty. Clin Orthop Relat Res 1990, 259, pp 146-156.

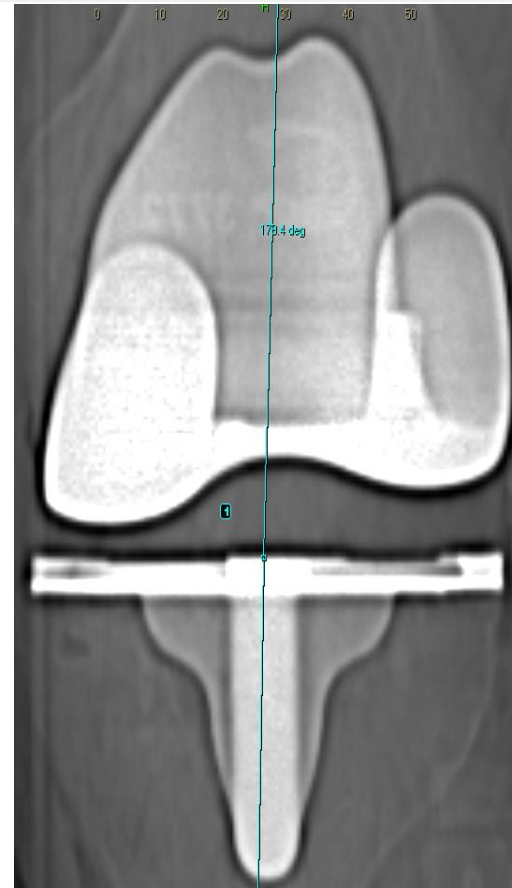
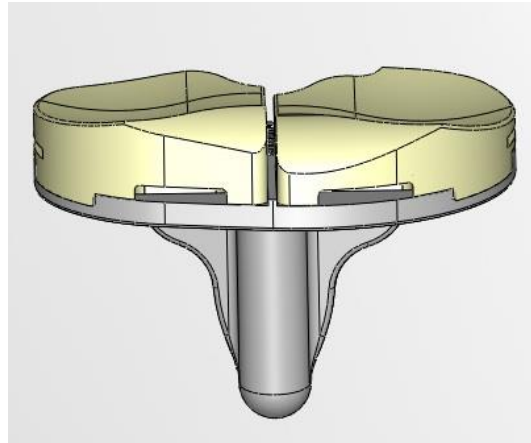
Femur Matched Offset Polys

Separate medial and lateral poly inserts matched to femoral offset

Medial insert more conforming than lateral insert to facilitate rollback

3 lateral thicknesses (medial+offset)

3 medial insert options (6, 7, and 8mm)



MEDIAL AND LATERAL POLY INSERTS

- There have also been situations where at the end of the case...there was a little excess lateral laxity
- Can be a cause of symptomatic instability



MY EXPERIENCE

- JULY, 2014 TO FEB, 2015
- 48 PATIENTS
- 56 KNEES
- 8 Bilaterals
- 23 FEMALES 25 MALES
- AVG AGE - 63 (45 – 89)
- AVG WT - 88kg (55 -130)



EARLY RESULTS – UNILATERAL TKR

40 PATIENTS

LOS – 1.2 DAYS

AVG HGB – 12.0 (9.1 – 14.2)

AMBULATORY WITHOUT WALKER

- 1ST VISIT – 33/40 NO WALKER
- 2ND VISIT – 33/35 NO CANE



EARLY RESULTS – BILATERAL TKR

8 PATIENTS

LOS – 2.2 DAYS (2 D/C TO REHAB)

AVG HGB – 11.3 (9.3 – 13.2)

AMBULATORY WITHOUT WALKER

- 1ST VISIT – 2/8 CANE ONLY
- 2ND VISIT – 6/8 NO CANE



EARLY RESULTS – SATISFACTION

48 PATIENTS (8 BILAT) @AVG 3 MOS

EXTREMELY – 30

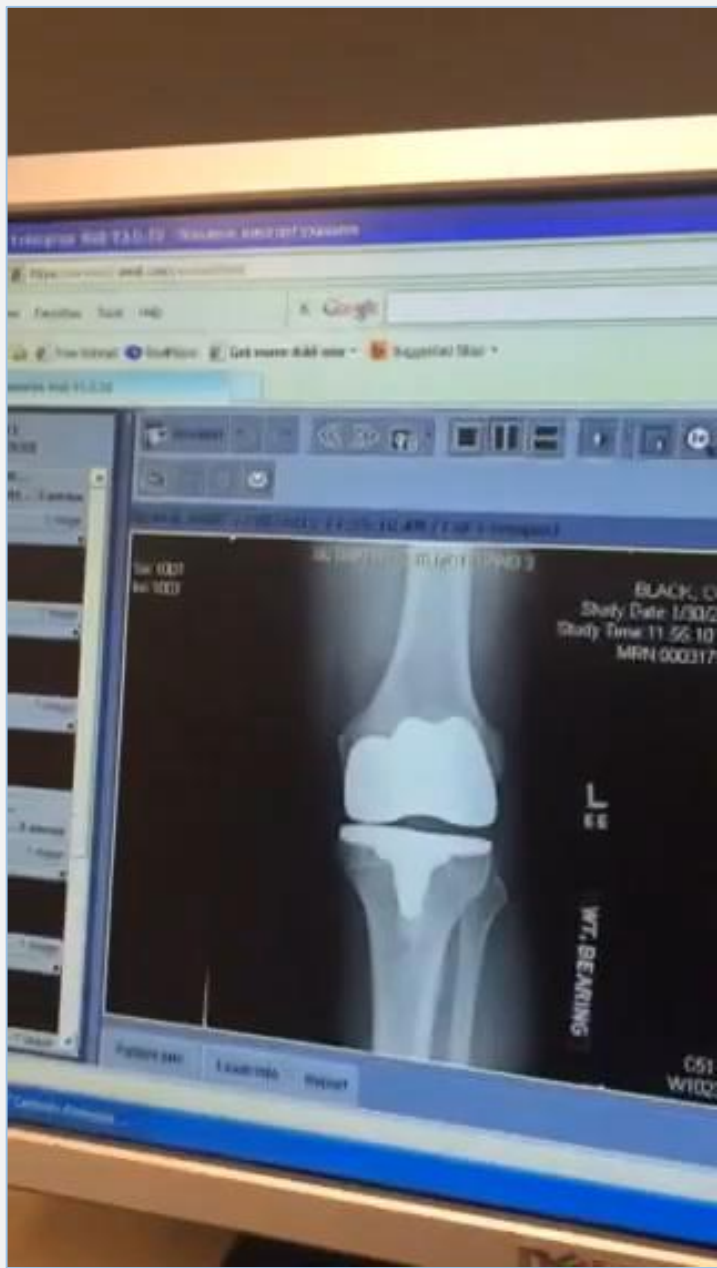
VERY – 12

FAIR – 3

POOR – 3

(2 related to patellar impingement –1 patellar revision)

(1 trauma – revision to stabilized tkr)

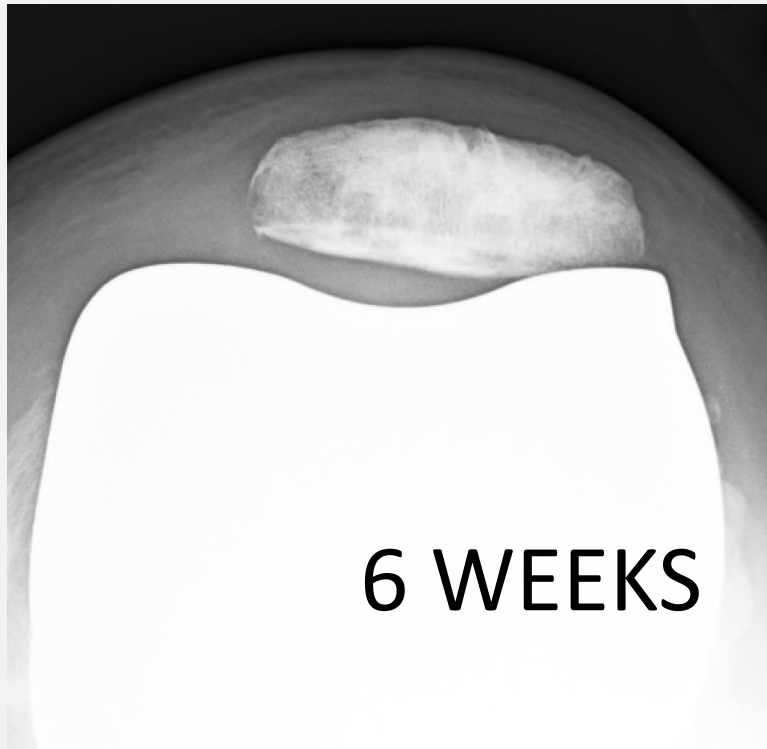


Complications – 2 Re-ops

- 63 yo male
- Bilateral TKR
- D/C post op day 2
- ↑ pain/swelling @ 6 weeks (R knee)
- Aspiration 50 cc blood, no wbc's
- No improvement with therapy
- Reoperation @ 4 mos



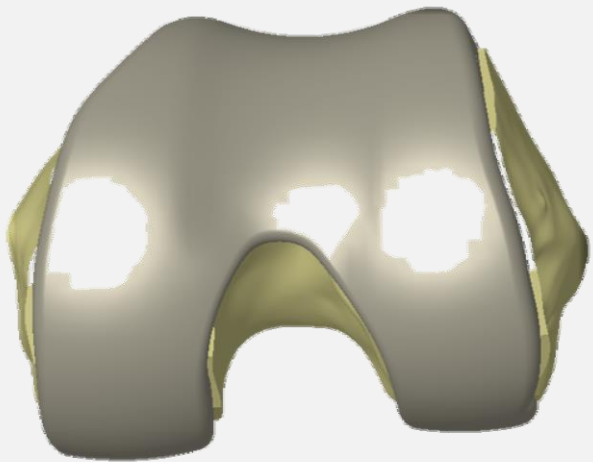
PATELLAR REVISION WITH LYSIS OF ADHESIONS



DRAMATIC IMPROVEMENT AT ONE WEEK –AMBULATORY WITHOUT SUPPORT

My Early Impression - Intraoperative

- Very Impressed with fit and accuracy of cutting blocks
- Component sizing is very accurate



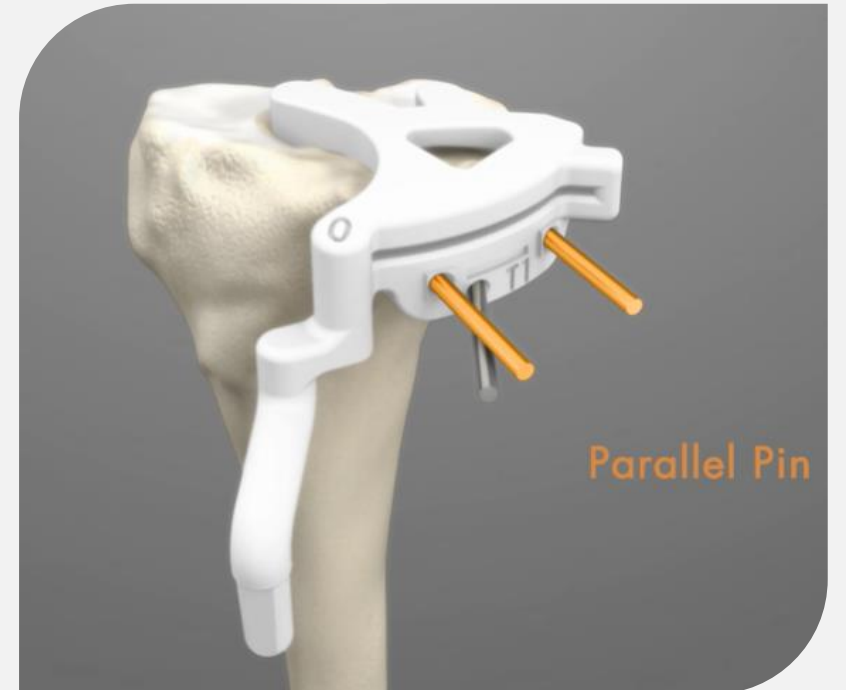
My Early Impression – Clinically

- Excellent mid flexion stability by exam
- Patients still c/o pain in similar pattern to standard TKR but less c/o clicking (noise)
- Patients definitely aware of improved stability from pre-op



MY RECOMMENDATION

- Cadaver lab
 - Familiarize yourself with cutting guides
 - Especially tibial jig – there is some play
 - Very important to use the alignment rod
- REMEMBER TKR IS A SOFT TISSUE OPERATION



Careful Patient Selection

- Less than 10 degrees of deformity
- Determine patients soft tissue status
- Degree of laxity
- Does the deformity fully correct

- *If lax*
- *Minimize bone resection*
- *Prep and trial for thinnest insert*



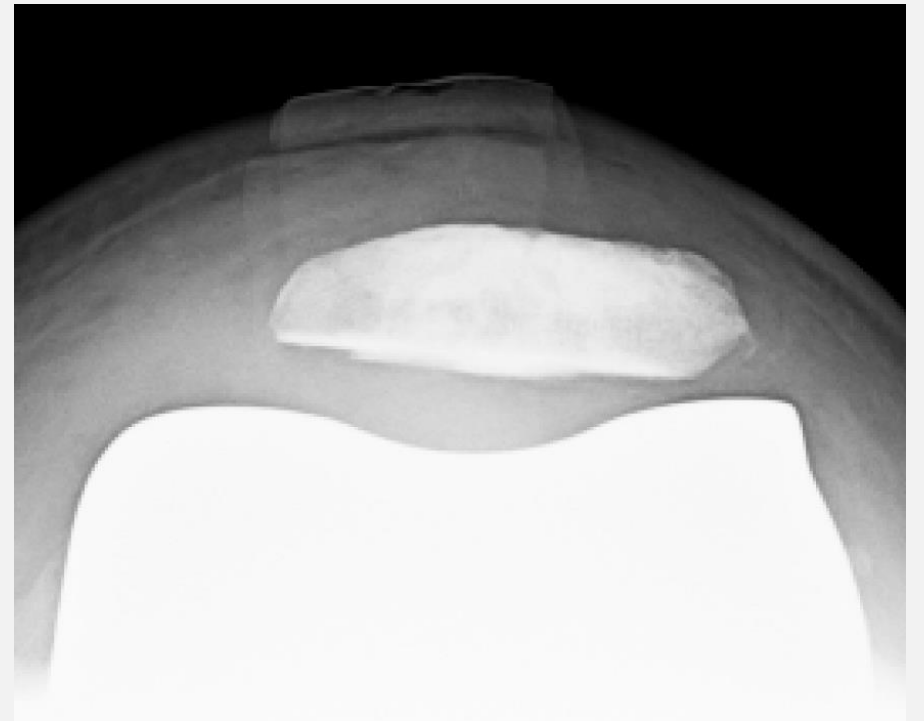
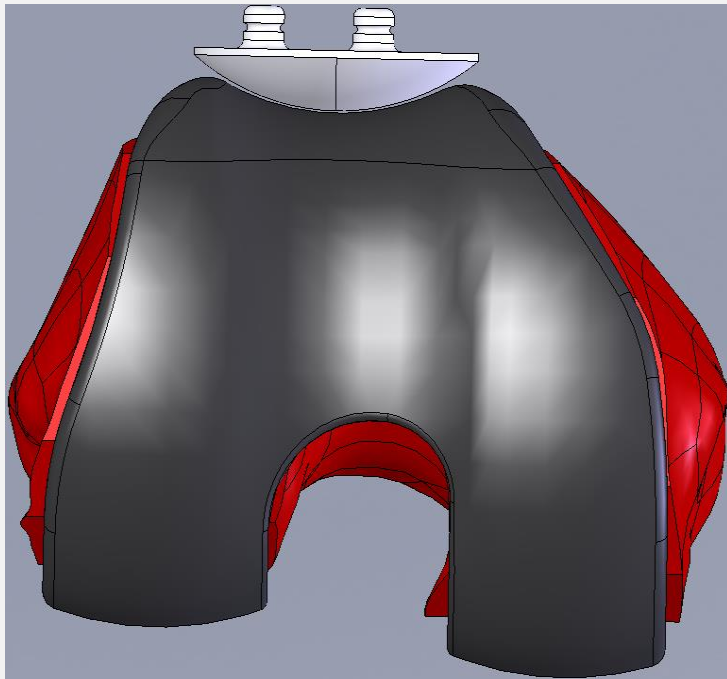
My advice - Intraoperative

- Not easy going to surgery with only one of everything!
- Limited thicknesses and no peg!
- Prepare for the thinnest poly combo
- Be very familiar with your scrub tech given the fact there is only one set of each poly insert
- Dropping a poly = bad day!
- XE poly is my choice (upcharge)



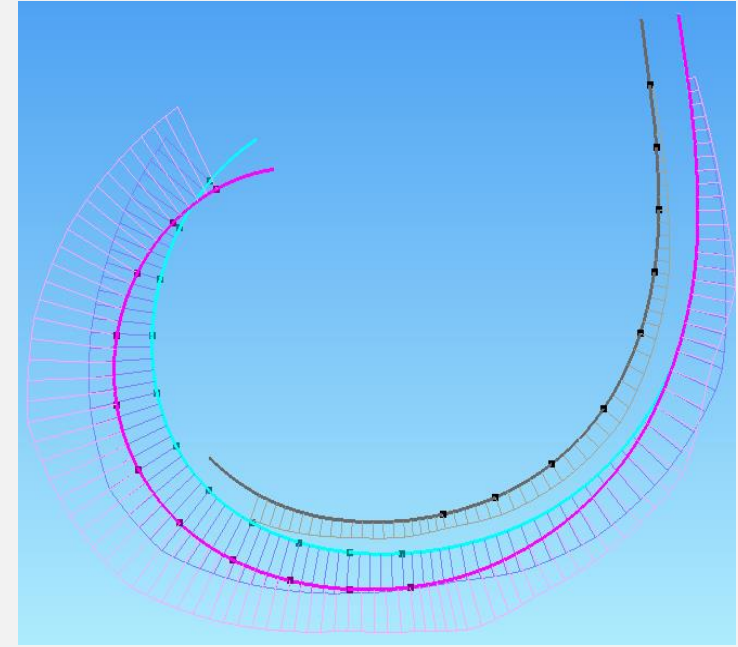
RECOMMENDATIONS

- ASSESS PATELLAR TRACKING AND IMPINGEMENT
- MAXIMIZE POLY THICKNESS OF PATELLAR COMPONENT



MY CONCLUSION TO DATE

- FIRST GENERATION OF CUSTOM TKR
- 3D PRINTING TECHNOLOGY IS IMPROVING
- RESTORING PATIENTS KNEE ANATOMY AND INDIVIDUAL “j CURVE” MAY TRANSLATE TO IMPROVED RESULTS
- TIME WILL TELL





THANK YOU