

Conformis iUni & iDuo

Raj K. Sinha, MD, PhD
S.T.A.R. Orthopaedics, Inc
La Quinta, CA



Disclosures

- ConforMIS—Consultant
- Mako Surgical—Consultant, Research Support
- Zimmer Holdings—Design Surgeon, Consultant, Research Support
- Biomet, Inc—Consultant
- Corin USA-IDE surgeon



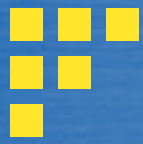
Why Conformis?

- What's wrong with a total knee?
- Do you believe in Unis?



What's wrong with a TKA?

- Kinematics are nowhere near a normal knee
 - Komistek et al, numerous pubs
 - Banks et al, numerous pubs
- Patient satisfaction is lower than we think
 - Bourne et al, CORR, Jan 2010
 - Noble et al, CORR, Nov 2006
- Patient activity levels are lower than we think
 - Noble et al, CORR, Feb 2005



Do you believe in Unis?

- If not, why not?



The Paradox of Unis...

- Uni patients are the happiest... and some of the unhappiest
- Why the disparity?
 - Technical challenge of unis
 - Poor patient selection
 - Bone resection doesn't make sense...impingement, joint line alteration, malrotation/edge loading---Not really half a total knee



Why Conformis?

- Things that patients want:
 - Minimally disruptive
 - Short hospital stay
 - Rapid recovery
 - Less pain
 - Reproducibility & accuracy
 - Customizability (excellent fit)



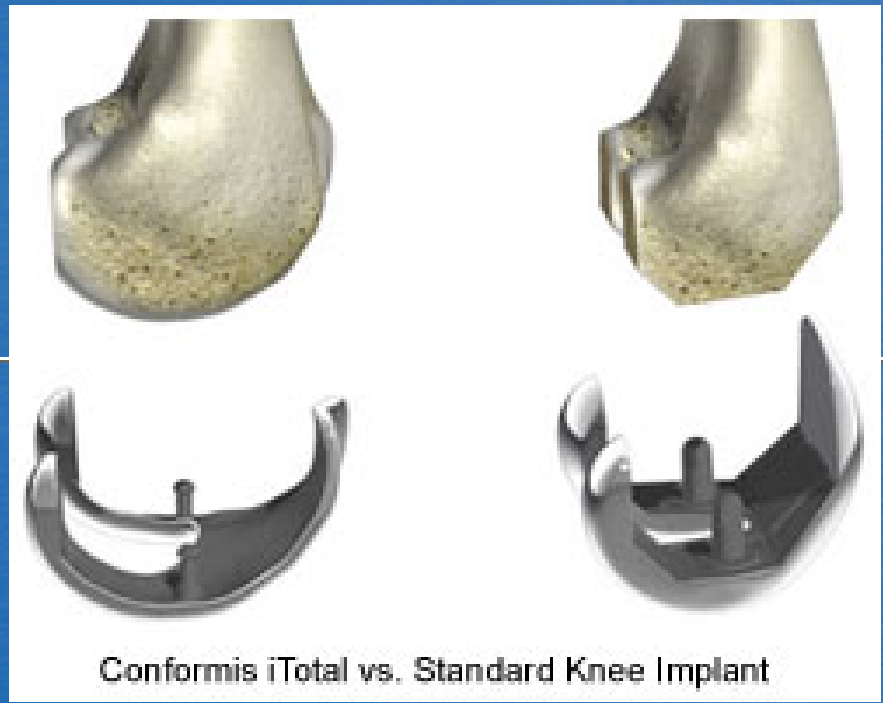
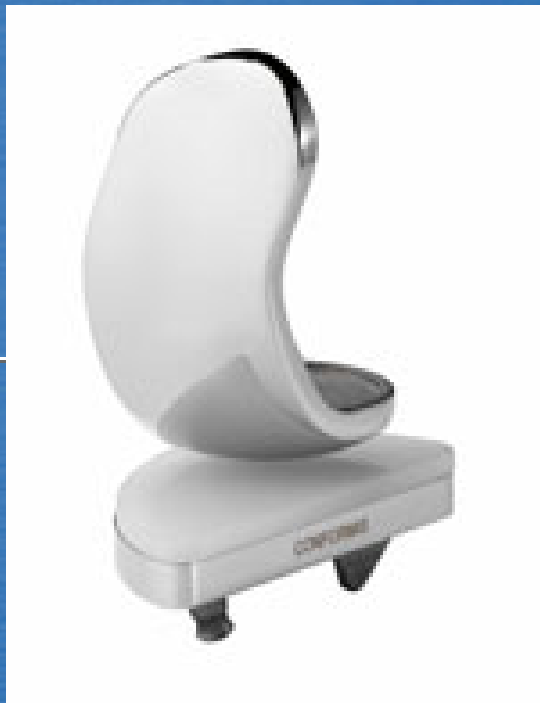
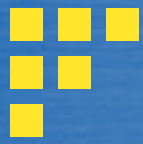
Indications

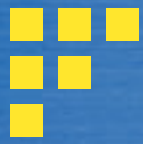
- Low Grade Osteoarthritis in one or two compartments
- No inflammatory joint disease
- Mild To Moderate Deformity
- Intact Ligaments
- Age \geq 55 yrs. (?)



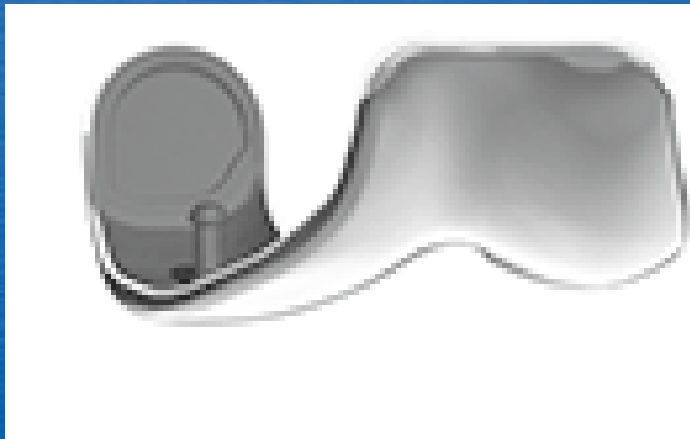
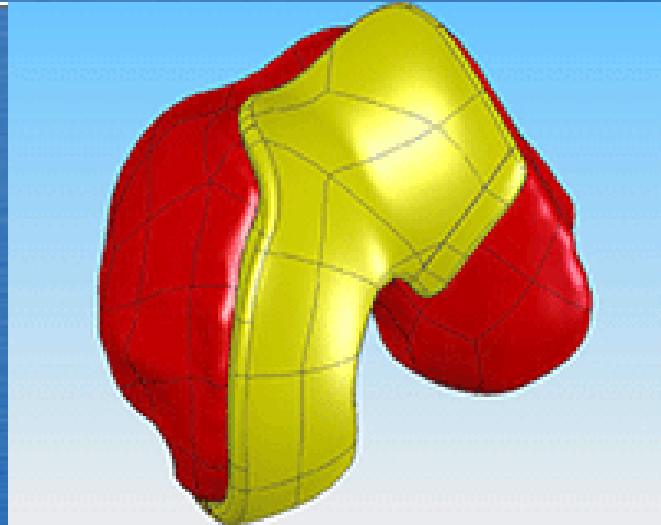
Contraindications

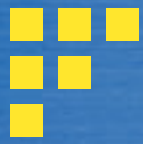
- Tricompartmental disease
- Poor range of motion
- Greater than 15 degree angular deformity
- Inflammatory arthritis
- Age?





Concept





iFit animation



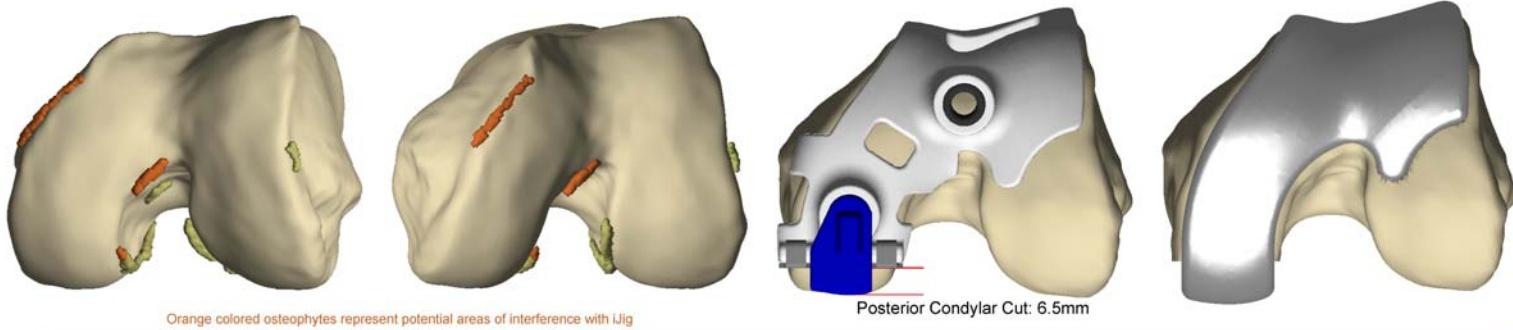
Pre-Operative Planning Images Provided for Review

Serial Number: 0004866

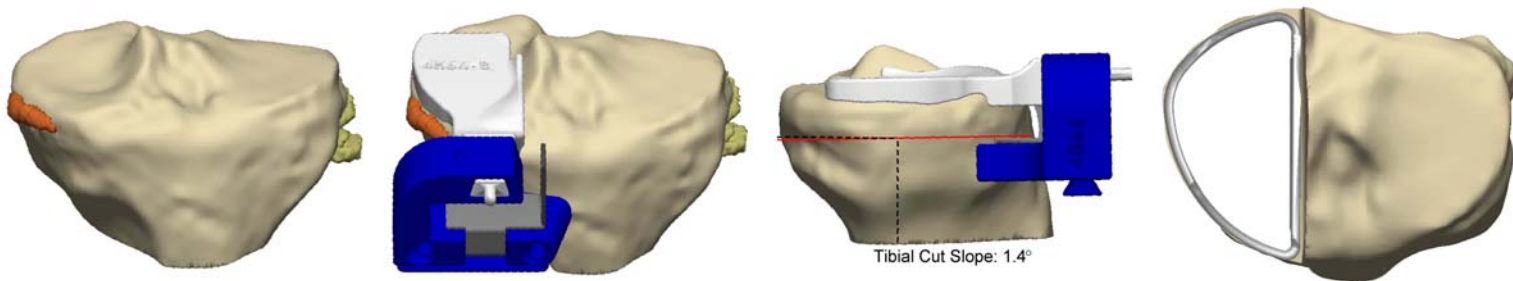
iView™ Patient-Specific Planning Images



Femoral Images

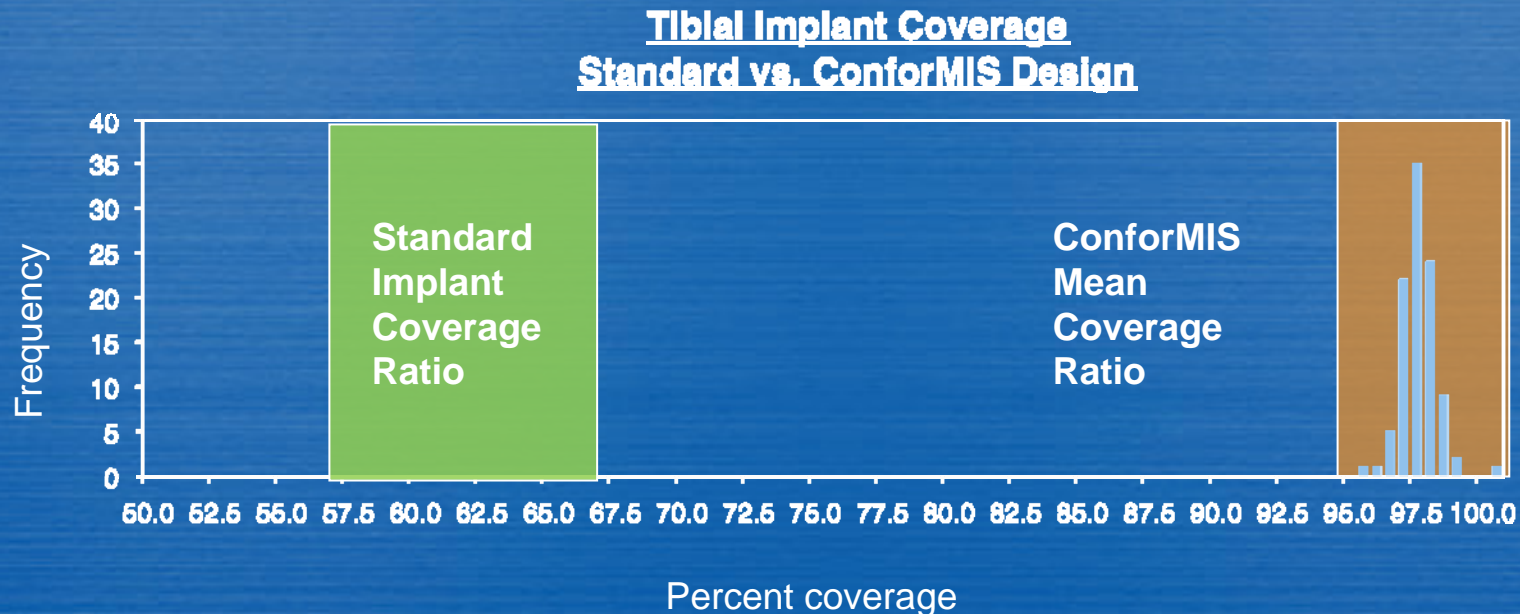


Tibial Images



Anatomic Fit

- Standard implants cover between 57%-67% of the cortical rim¹
- ConforMIS tibias from 100 patients show an average tibial profile coverage ratio of 98%²



¹ Statistical design of unicompartamental tibial implants and comparison with current devices. C. Fitzpatrick et. al. *The Knee*, 14 (2007) 138-144

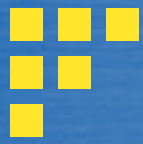
² ConforMIS technical document number: TD-02507



What does Patient-specific PKR offer?



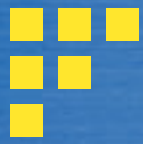
- Small number of instruments
- No intra-operative implant sizing
- Fewer bone cuts, fewer trials
- Patient-specific placement built into iJigs



Case Examples

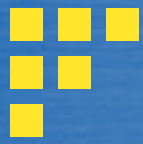


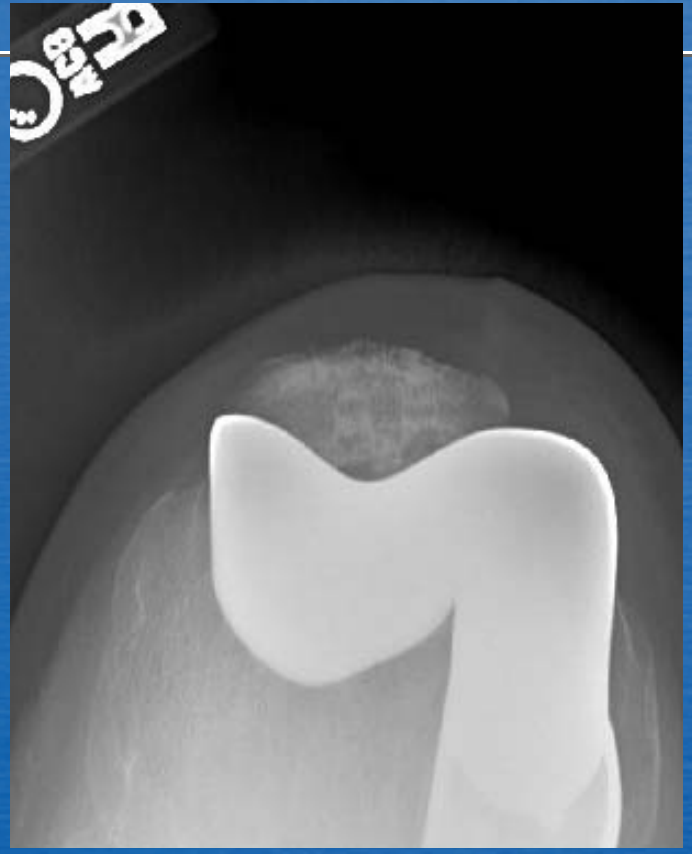
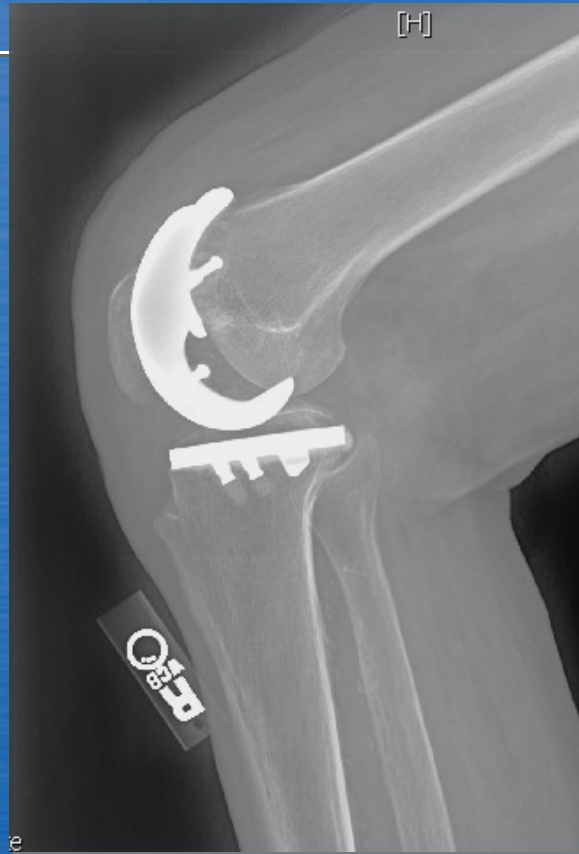
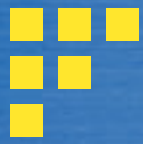


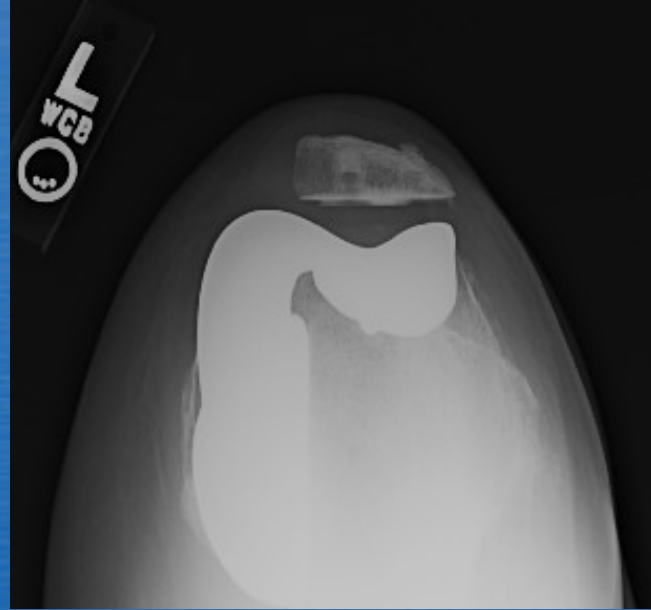
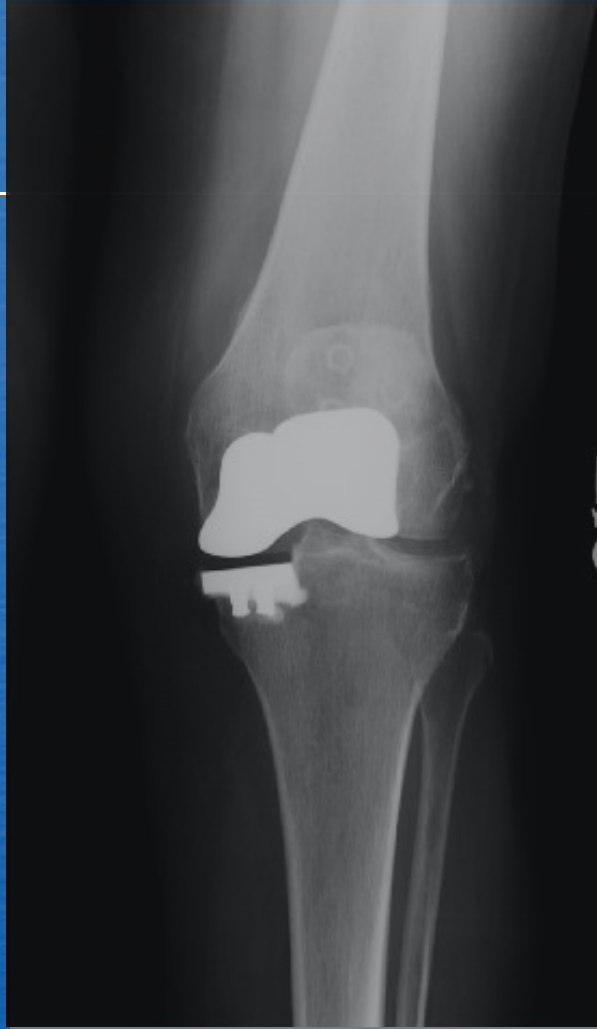
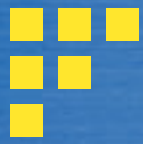


Case Example











Early clinical results

- Number of cases
 - iUni-11
 - iDuo-7
- Age range
 - 53-82
- iUni medial 10 vs lateral 1



Early clinical results

- Ambulation
 - All walking day of surgery
 - All off aids by 4 week follow-up
- ROM
 - All greater than 95 degree flexion by 4 week followup
- Work/Play
 - 4-6 weeks
- All Pts satisfied/would do again except 1 (iDuo)



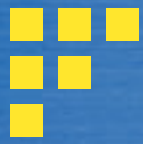
Future issues

- OR time
- Reimbursement
- Flexion contractures
- iTotal

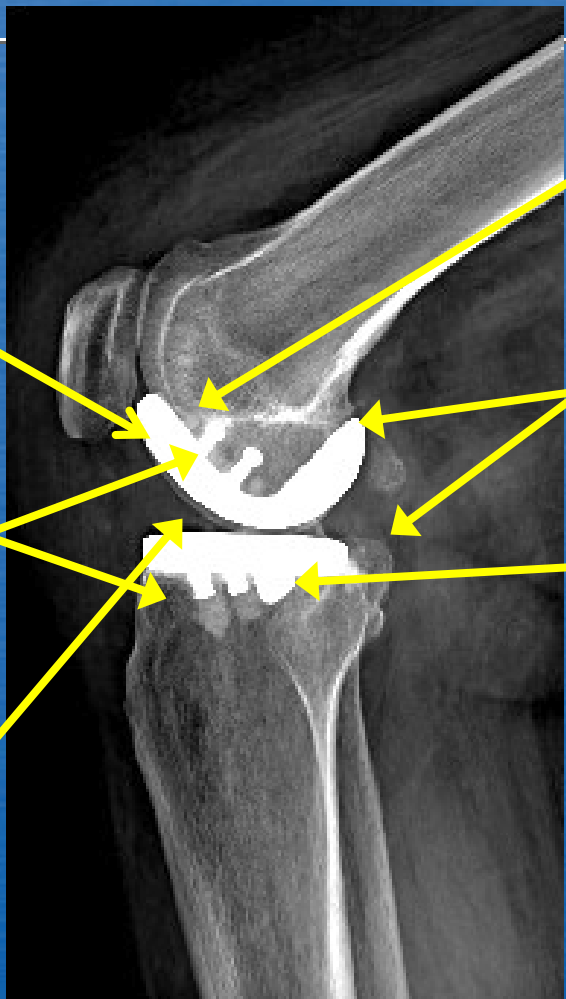


Uniqueness

- ConforMIS offers the only true patient specific implant
- Signature/Visionare/Otismed/TruMatch
 - Off the shelf standard implants
 - Amount of bone resection is the same
 - Anatomic landmarks used are the same
 - Really, all that is new is that some of the metal cutting jigs have been replaced with plastic ones



Uniqueness



Shape of articular surface

Shape of bone side surface

Orientation of pegs

Amt of bone resection

Poly insert shape

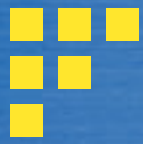
Position of keel

--Restores joint line every time
--Requires ligament balancing

Thank You!

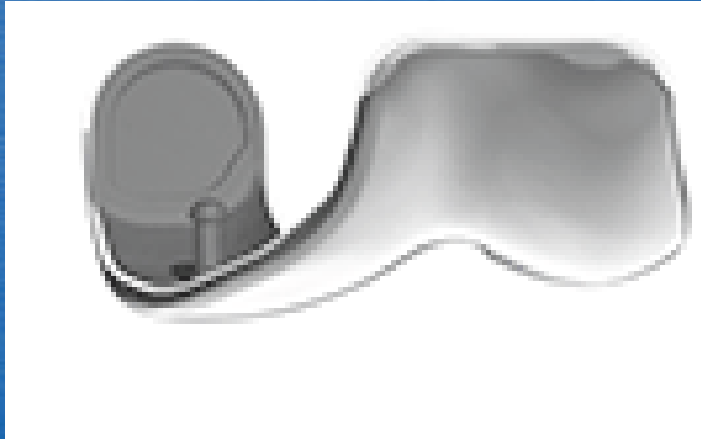
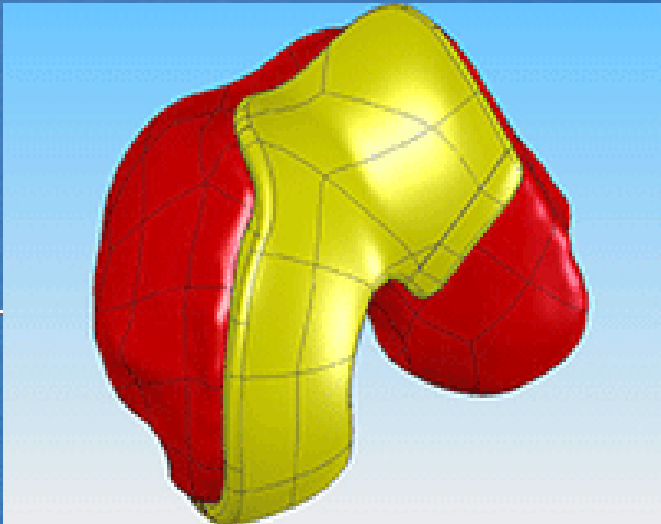
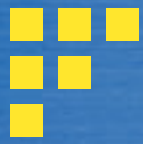






Technique- iUni animation







Operative Tips

- Incision length—don't skimp
- Full ligament release
- Sharp osteotomes and curettes
- Use 1/2 inch curved osteotome for tibial and posterior femoral condyle cartilage
- Notch osteophyte removal
- Femoral iJig tends to start off too posterior

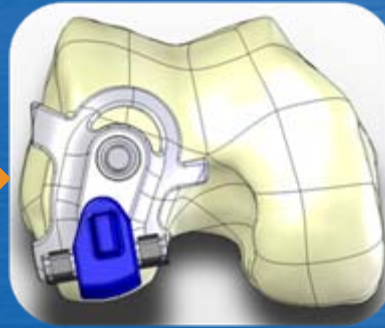
ConforMIS Process



PATIENT IMAGING STUDY



3D IMAGE PROCESSING



IMPLANT & JIG DESIGN & MANUFACTURE



DELIVERY FOR SURGERY

A screenshot of the ConforMIS Implant Request Form, showing patient information, surgeon information, and a checklist of items to be included in the request.

IMPLANT REQUEST FORM SUBMITTED

6 WEEK PROCESS