KineMatch®
Patient-Matched
Patello-Femoral Replacement

Vineet K. Sarin, Ph.D.
President

June 2020

Outline

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- Clinical Relevance
- Indications
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- Why Patient-Matched?
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- Frequently Asked Questions (FAQ)
- Conclusions

Introduction

KineMatch®

Patellofemoral Replacement System

https://www.kinamed.com/products/orthopedic-products/kinematch-pfr

Introduction

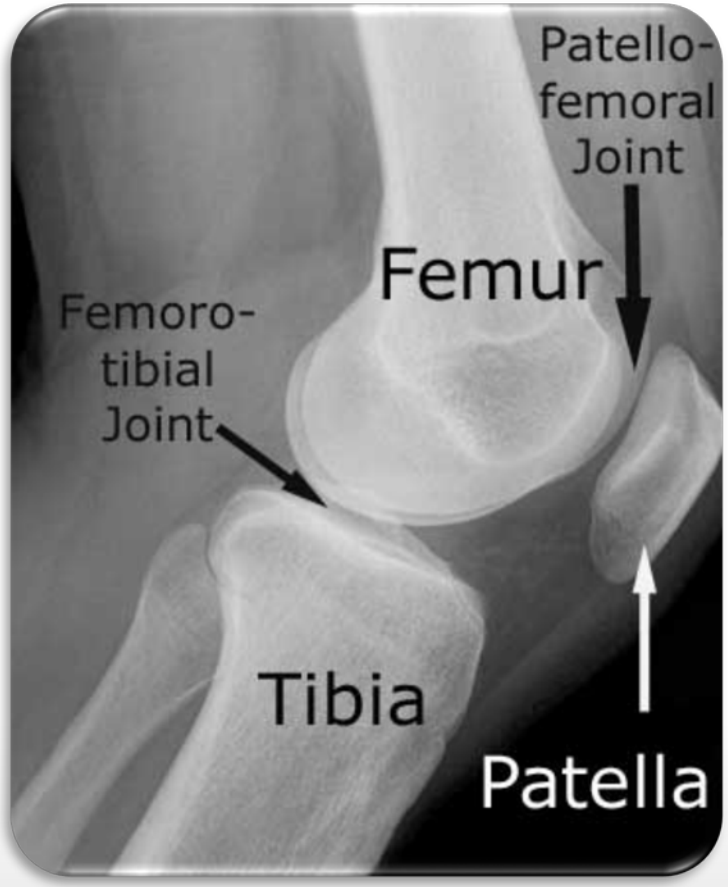
Basic Terminology

- PFR: Patello-Femoral Replacement
- PFA: Patello-Femoral Arthroplasty
- PFJ: Patello-Femoral Joint

- Chondromalacia: Softening of the articular cartilage of the PFJ (not an indication for PFA)

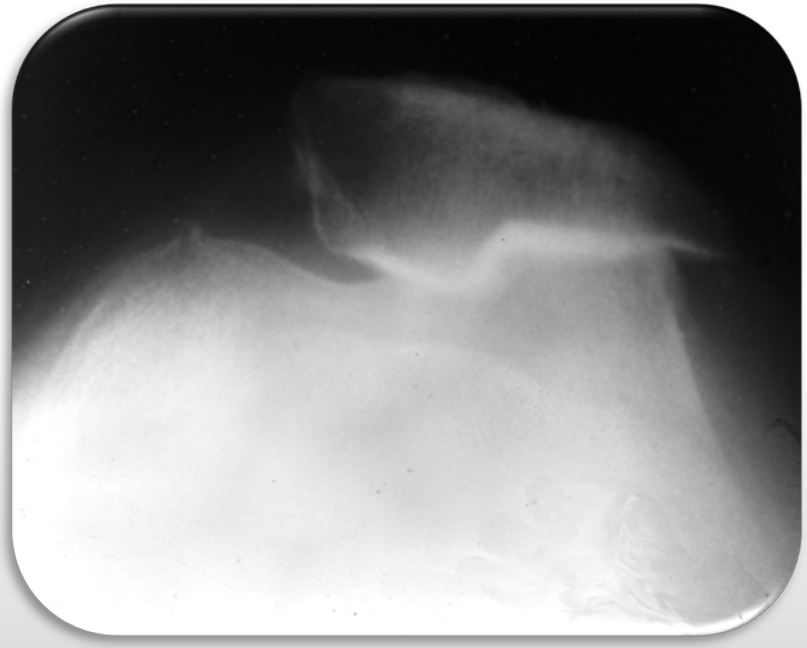
- Trochlea: Groove in the femur where patella articulates

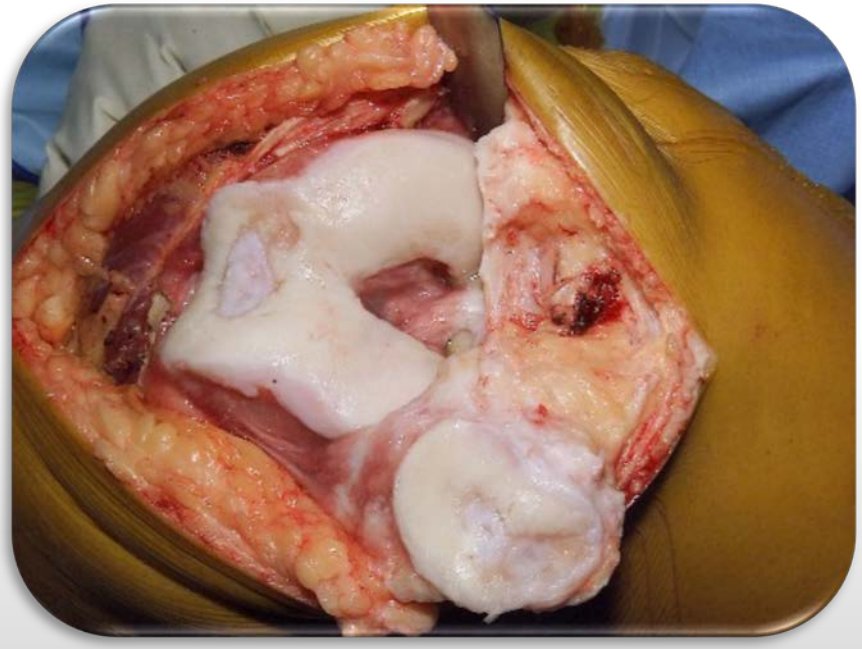
- Q-Angle: Angle between quadriceps tendon and patellar tendon force vectors (causes the patella to be pulled laterally).



Clinical Relevance

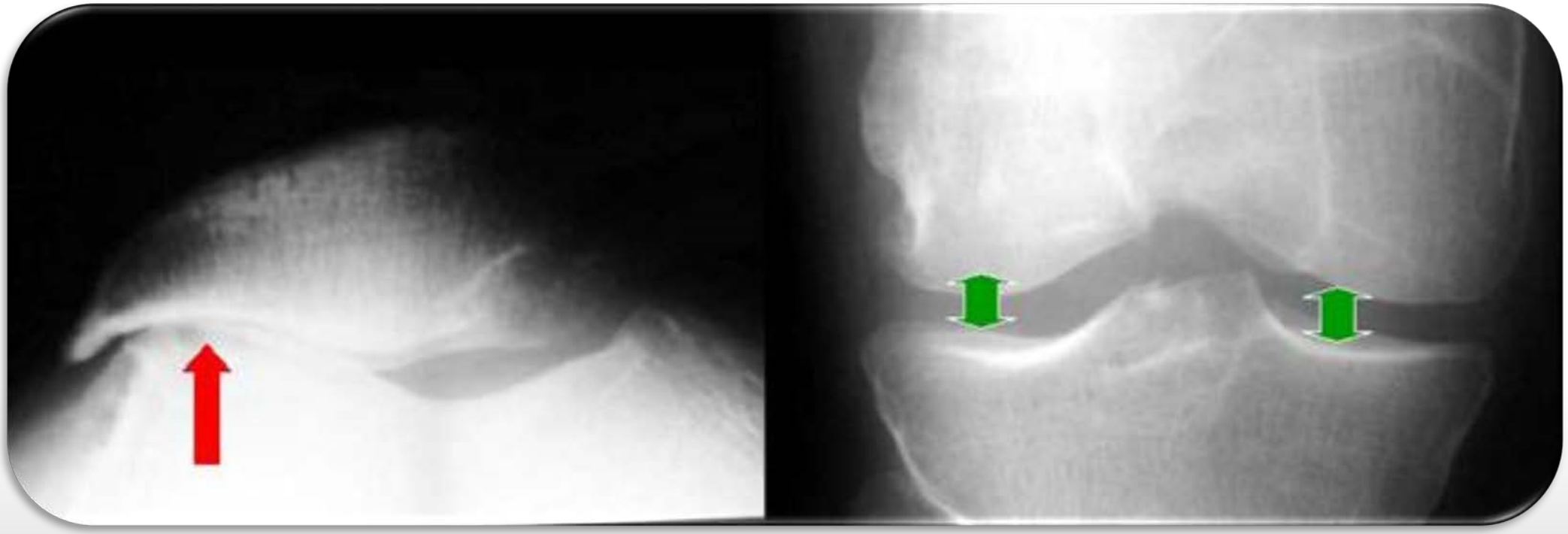
- **Isolated Patellofemoral (PF) Disease affects 11% to 24% of people with painful knee arthritis**
- **Patients tend to be younger**





Clinical Relevance

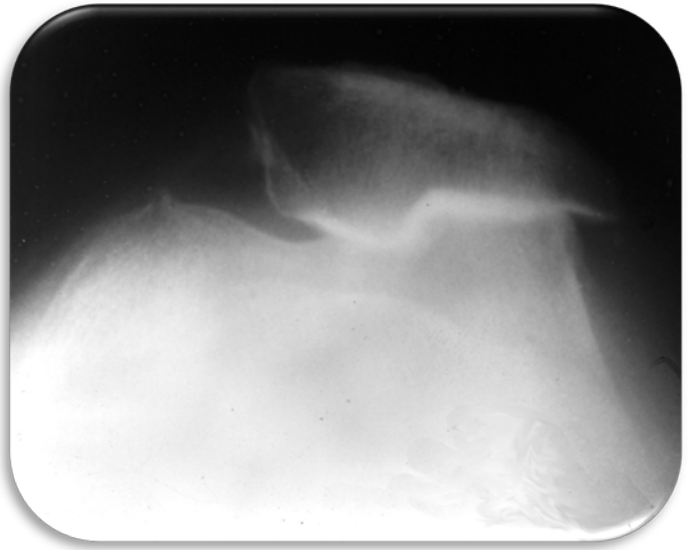
Isolated PF Arthritis

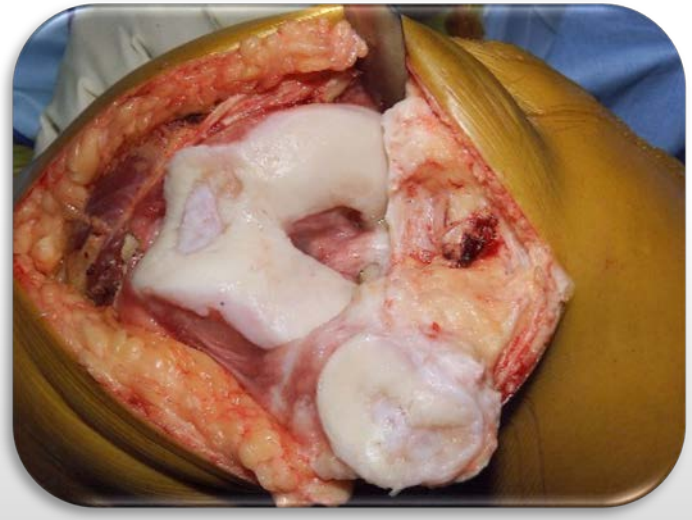


Clinical Relevance

End-Stage Isolated Patello-Femoral Disease

- Arthritis confined to the patello-femoral articulation, with normal femoro-tibial articulations
- Secondary to trauma or progressive chondromalacia
- Causes debilitating pain when climbing stairs, etc
- Women comprise ~2/3 of PFA patients





Clinical Relevance

Indications

- Degenerative or posttraumatic osteoarthritis limited to the patellofemoral joint, so that medial and lateral Ahlbäck scores are less than or equal to 1 point
- Severe symptoms affecting daily activity referable to patellofemoral joint degeneration unresponsive to lengthy non-operative treatment and conservative procedures
- Patellofemoral malalignment/dysplasia induced degeneration with or without instability.

Grelsamer 2006, Leadbetter et al 2006, Lonner 2007

Clinical Relevance

Contraindications

- The lack of non-operative care
- Pain referred from outside the patellofemoral compartment or even outside the knee
- Medial and lateral tibiofemoral Ahlbäck scores greater than 1 point
- Systemic inflammatory arthropathy
- Patellofemoral instability or malalignment that is uncorrectable at the time of arthroplasty

Grelsamer 2006, Leadbetter et al 2006, Lonner 2007

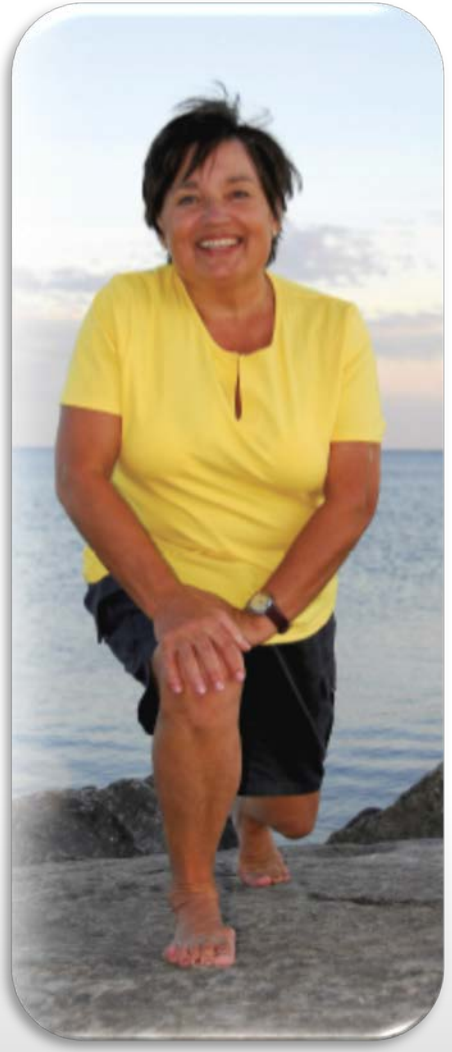
The Market

US market size ~$85 million

- Conservatively, 3-5% of all knee arthroplasty patients are well-indicated for PFR
- An estimated 15,000 procedures performed in the US annually

Kinamed has the best solution for PFR!

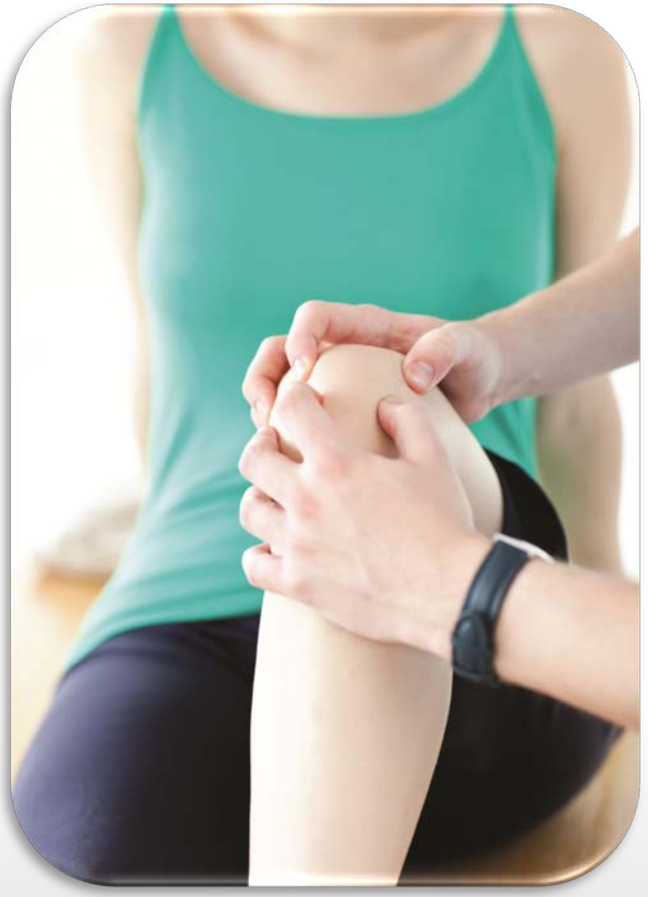
- Clinical results published in JBJS are far superior to any other published clinical results
- Our technology and device is the only proprietary, patented custom device solution with long-term follow-up



The Market

The KineMatch PFR (including patella) is a premium solution in the US, relative to TKA implants

- Surgeon and patient satisfaction is consistently very high. We often receive patient phone calls thanking us for solving their knee problem.
- High percentage of follow-on bilateral cases.
- Our users consistently get insurance re-imbursement for our device.
- Typical patient is younger and has private insurance or is a Workman's Comp patient.



The Market

Four types of surgeons:

1. Surgeons already using PFR
2. Surgeons who do UKA
3. Surgeons who go right to TKR
4. Sports medicine surgeons who don’t or rarely do joints

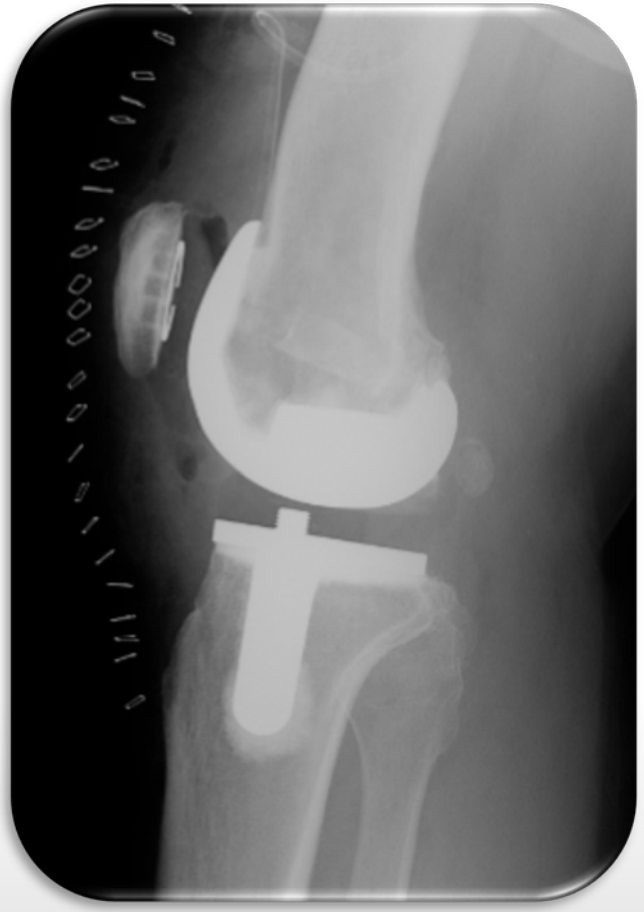
Your approach to each may be different

Competition

Who is our (surgical) competition ?

- Soft tissue and bony re-alignment procedures (early stage arthritis)
- Off-the-shelf PFR devices (highly variable results)
- Total Knee Replacement (can be effective, but often considered “over-treatment”)

(Patellectomy: poor results, rarely performed nowadays)



Competition

Companies & PFR Product Brand Names

- Stryker Avon
- Arthrosurface Wave
- ZimmerBiomet PFJ
- Smith & Nephew Journey
- DePuy LCS

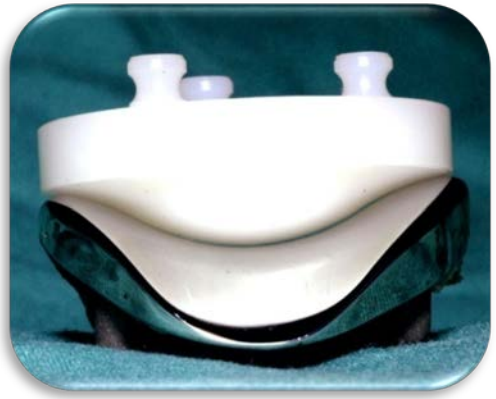
SNN Journey

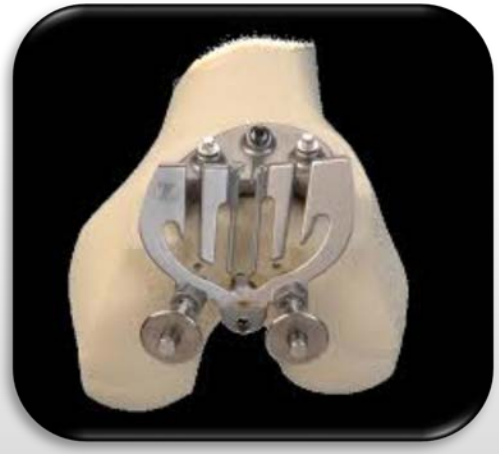
ArthroSurface

Competition

- **“Off The Shelf” Patellofemoral Implants have fit and tracking issues**





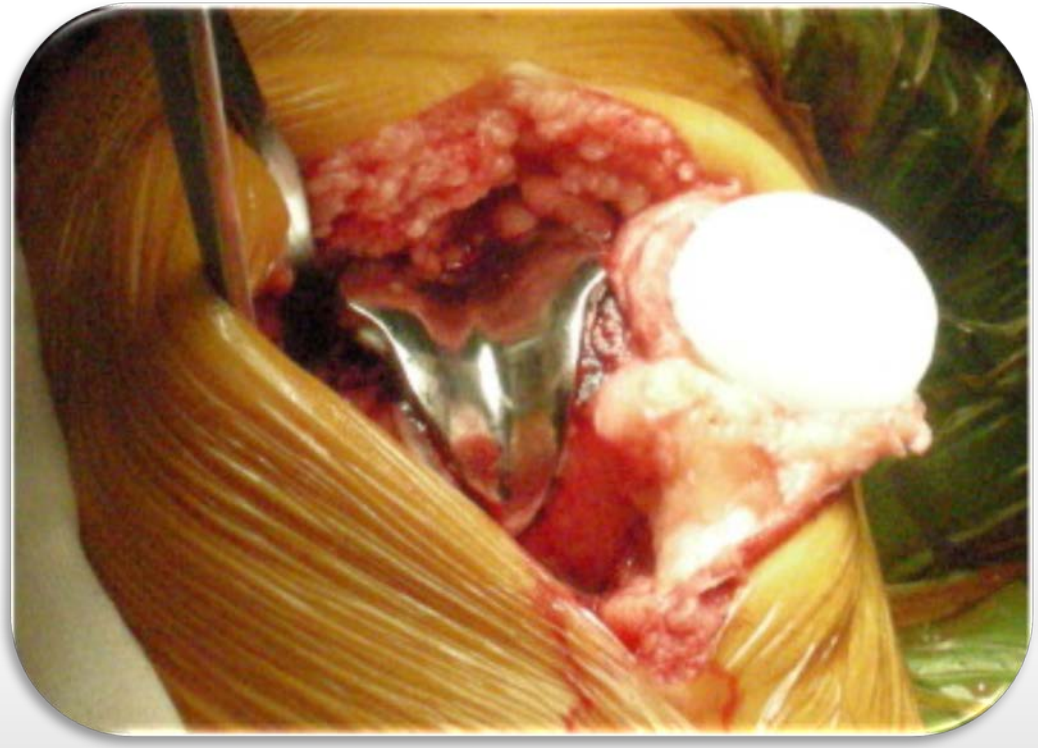



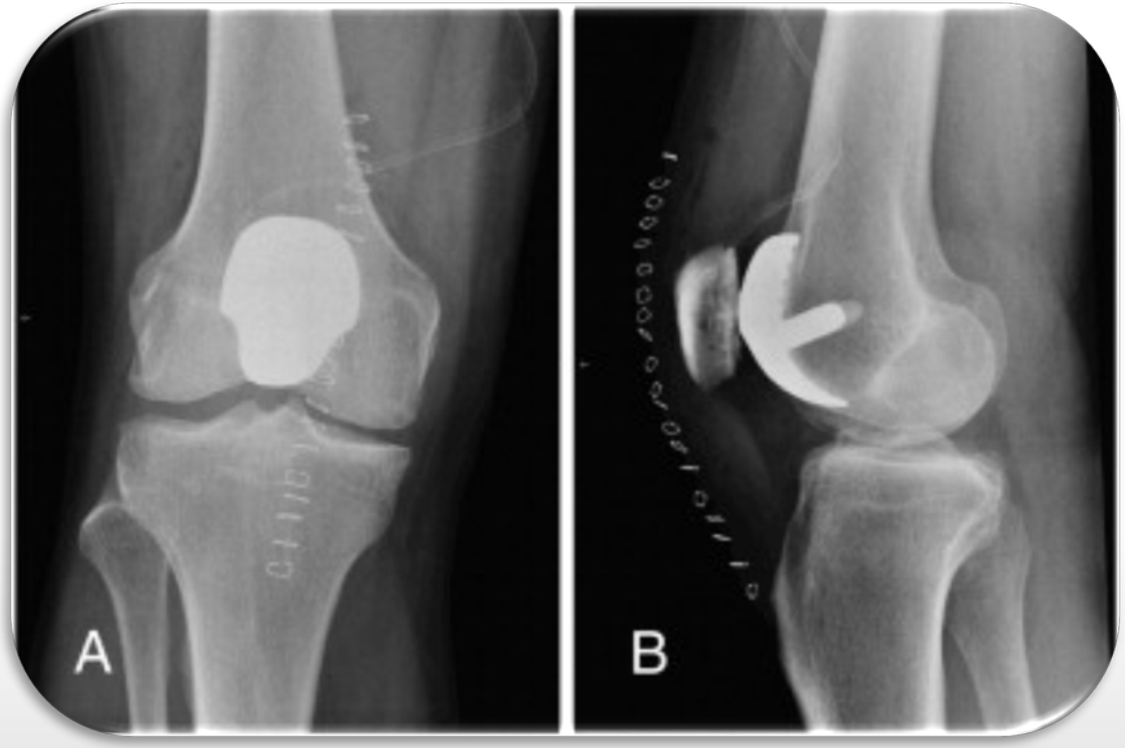
Historical Perspective

- McKeever 1955 (vitallium, only patella)

Historical Perspective

- Blazina 1979





Historical Perspective

- 1980s, 1990s, 2000s, 2010s

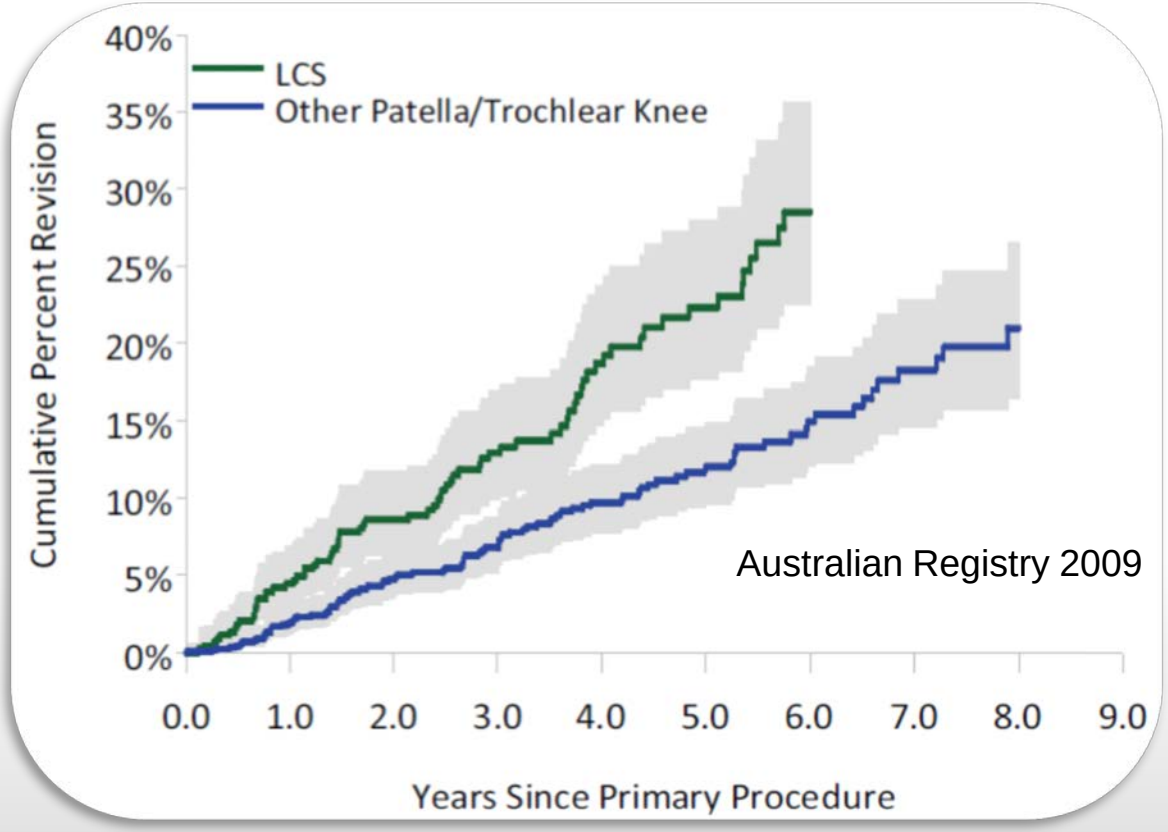
Historical Perspective

Variable Results

Publication	Cases	Years of Follow-Up	Implant (Manufacturer)	Results
Ackroyd et al[1]	306	2 – 5	Avon (Stryker)	87% not revised and complication-free
Arciero & Toomey[2]	25	3 – 9	Blazina II (Richards) & CFS (Wright)	72% good or excellent; 12% revised
Argenson et al[3]	66	2 – 10	Autocentric (Medinov)	85% not revised
Argenson et al[4]	66	12 – 20	Autocentric (DePuy)	56% not revised
Blazina et al[5]	57	1 – 3.5	Blazina I & II (Richards)	78% “much improved”
Cartier et al[6]	72	2 – 12	Blazina II & III (Richards)	85% good or excellent; 8% mechanical complications
De Winter et al[7]	26	1 – 20	Blazina II (Richards)	61% good or excellent; 19% re-operation rate
Kooijman et al[8]	45	15 – 21	Blazina II (Richards)	62% not revised
Krajca-Radcliffe & Coker[9]	16	2 – 18	Bechtol I & II (Richards)	88% good or excellent; 19% re-operation rate
Lubinus[10]	14	0.5 – 2	Lubinus (Link)	“All improved”
Merchant[11]	15	2.2 – 5.5	LCS (DePuy)	93% good or excellent on ADL scale
Smith et al[14]	45	0.5 – 7.5	Lubinus (Link)	64% good or excellent; 19% revised
Tauro et al[15]	62	5 – 10	Lubinus (Link)	45% “satisfactory”; 28% revised
Van Jonbergen et al	185	2 – 30.6	Richards II (Smith & Nephew)	85% survivorship at 10 years, 69% at 20 years
Charalambous et al	51	0.4 – 5	LCS (DePuy)	63% survivorship at 3 years

Historical Perspective

Clinical Results (Off-the-Shelf)



Historical Perspective

Variable Clinical Results

Have Led To….

Skepticism about PF Replacement

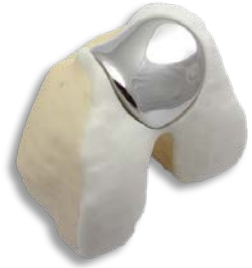
Historical Perspective

Consensus View on Keys to Success:

- Patient Selection
- Prosthesis Design

Why Patient-Matched?

Why Patient-Matched?

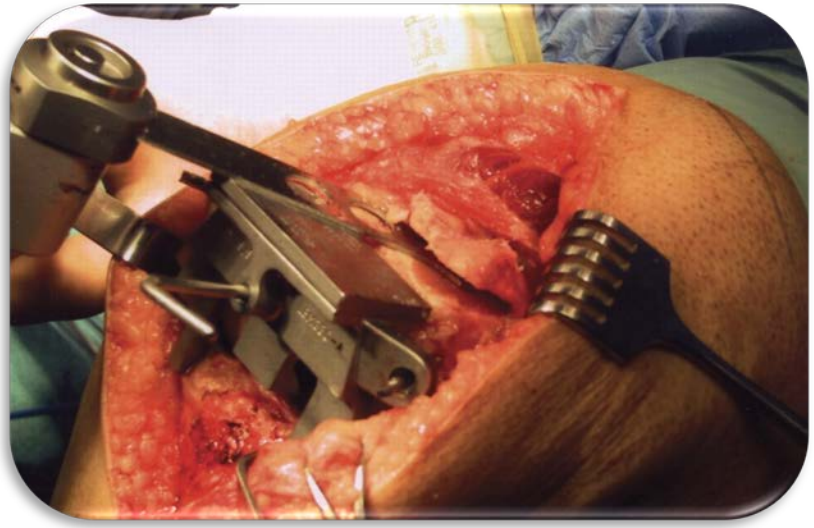


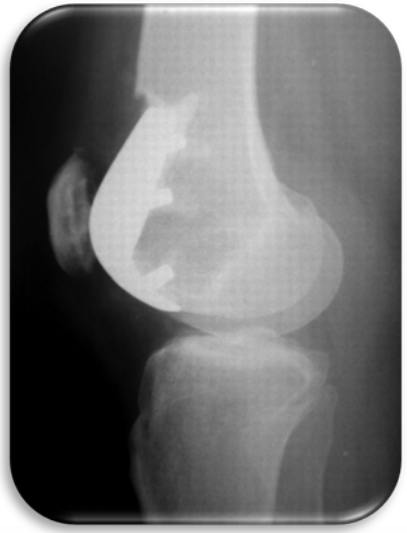
- Off-the-shelf prostheses have fixed shape and finite number of sizes
- Suboptimal fit and alignment can lead to poor clinical outcomes

Lonner 2004, Lonner 2007, Gupta 2010

Why Patient-Matched?

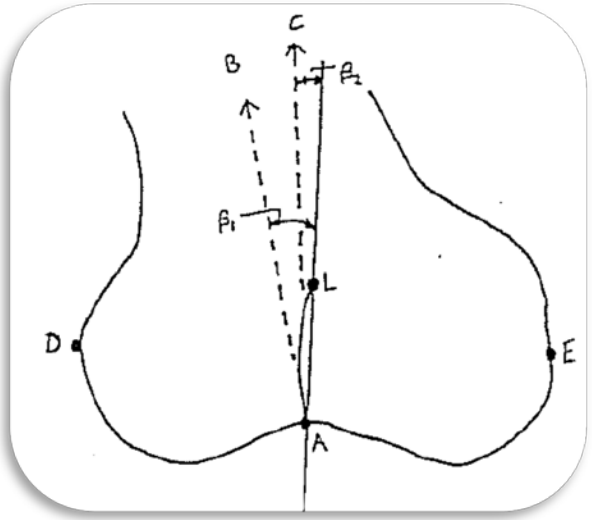
- "Off-the-Shelf" = Make the bone fit the implant





Why Patient-Matched?

- Human trochlea is highly variable
  - PF groove orientation varies by 11° to 16°
  - Failure of femoral components to accommodate this variability may explain PF complications in TKA
- Trochlea is the “fingerprint of the knee”



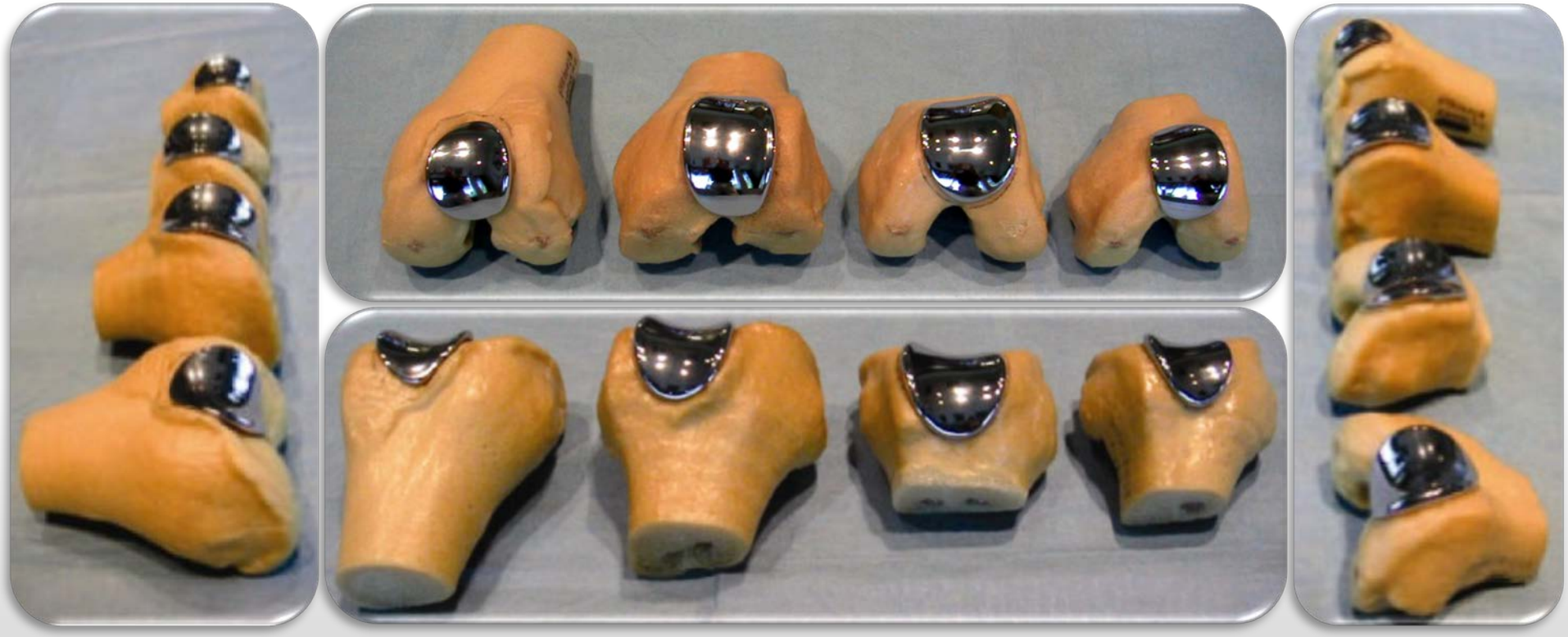
Feinstein et al 1996

Why Patient-Matched?

- **Trochlea is highly variable → one shape does not fit all**

Why Patient-Matched?

- One shape does not fit all
  - ~~"Off the Shelf" = Make the bone fit the implant~~
  - Make the implant fit the bone (Customization)



Why Patient-Matched?

- Customized trochlear prosthesis
  - Bony side matched to trochlear anatomy
  - Inlayed into trochlear cartilage
  - Articular side customized for PF mechanics

Introduction

Design Rationale

KINAMED®
INCORPORATED

RECENT ADVANCES IN HIP AND KNEE ARTHROPLASTY

Edited by **Samo K. Fokter**

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Patient-Specific Patellofemoral Arthroplasty

Domenick J. Sisto[1], Ronald P. Grelsamer[2] and Vineet K. Sarin[3]
[1]*Los Angeles Orthopaedic Institute, Sherman Oaks, California*
[2]*Mount Sinai Medical Center, New York, New York*
[3]*Kinamed Incorporated, Camarillo, California*
USA

INTECHWEB.ORG

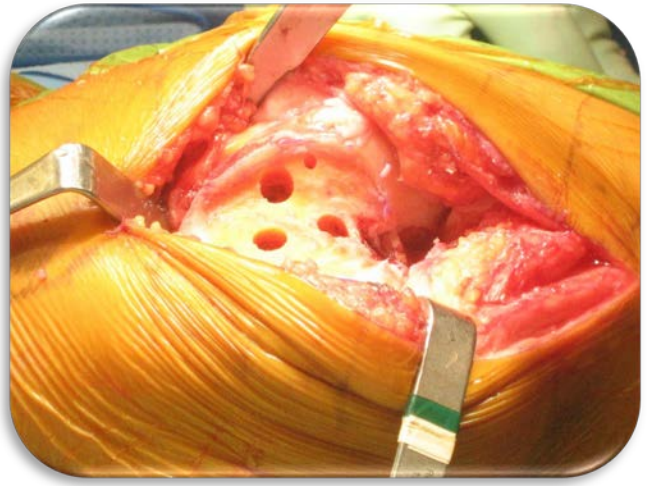
Design Rationale

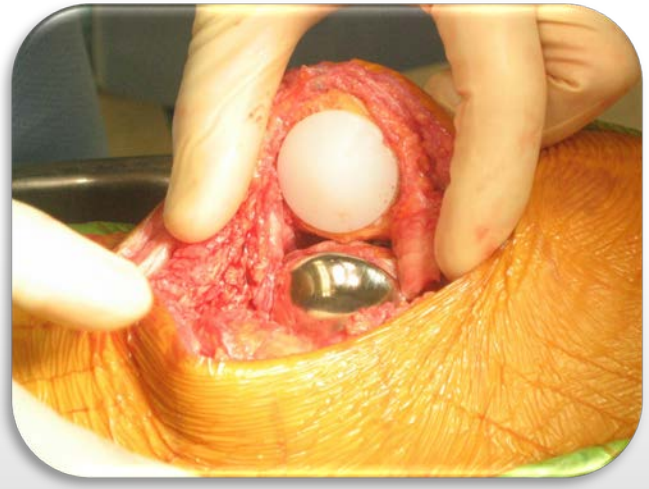
- Restore PF function and mechanics
- Maintain tibio-femoral mechanics
- Address design deficiencies and surgical technique challenges associated with off-the-shelf prostheses

Design Rationale

- Back side matches bony trochlea anatomy
- Precise fit
  - No bony resection
  - Only cartilage removal

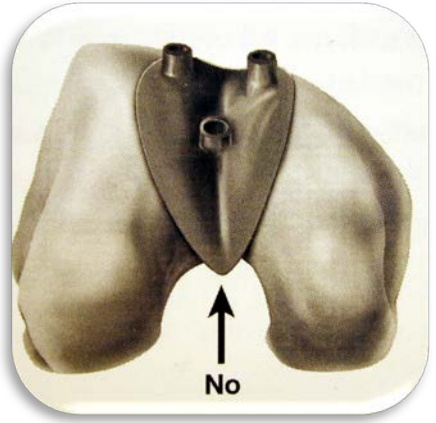
- “Onlay” onto bony trochlea
- “Inlay” into trochlear cartilage





Design Rationale

- Distal margin rests 3 to 5mm from apex of intercondylar notch



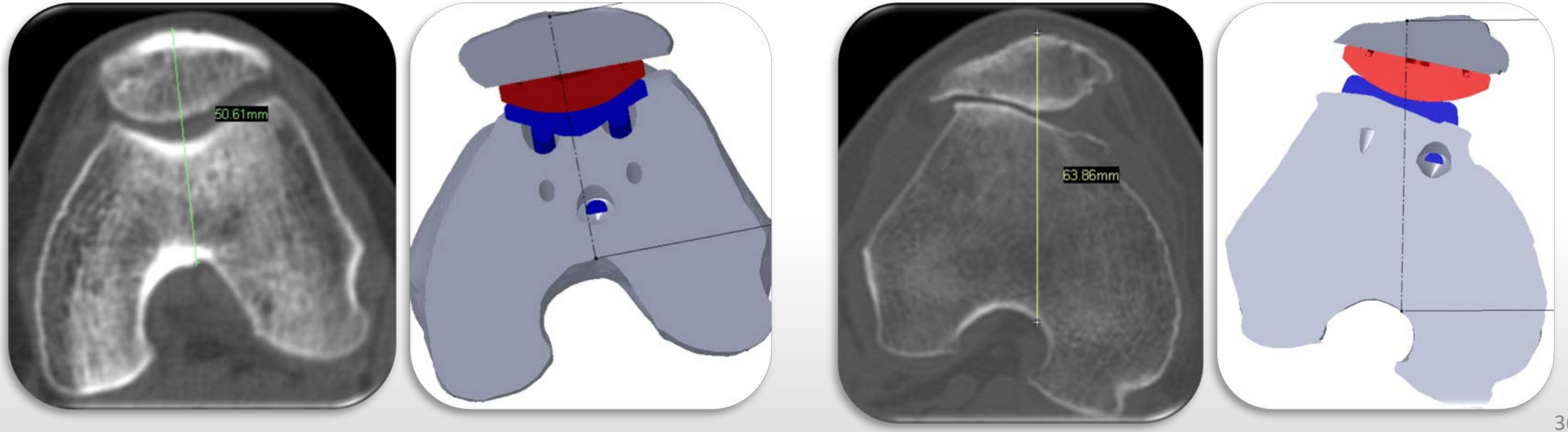
Courtesy of R Grelsamer MD

- Thickened lateral border to:
  - Compensate for bone loss along lateral edge of trochlear groove
  - Provide congruency and tracking stability with mating patella button

Design Rationale

- Articular side has radius of curvature that matches a patellar button

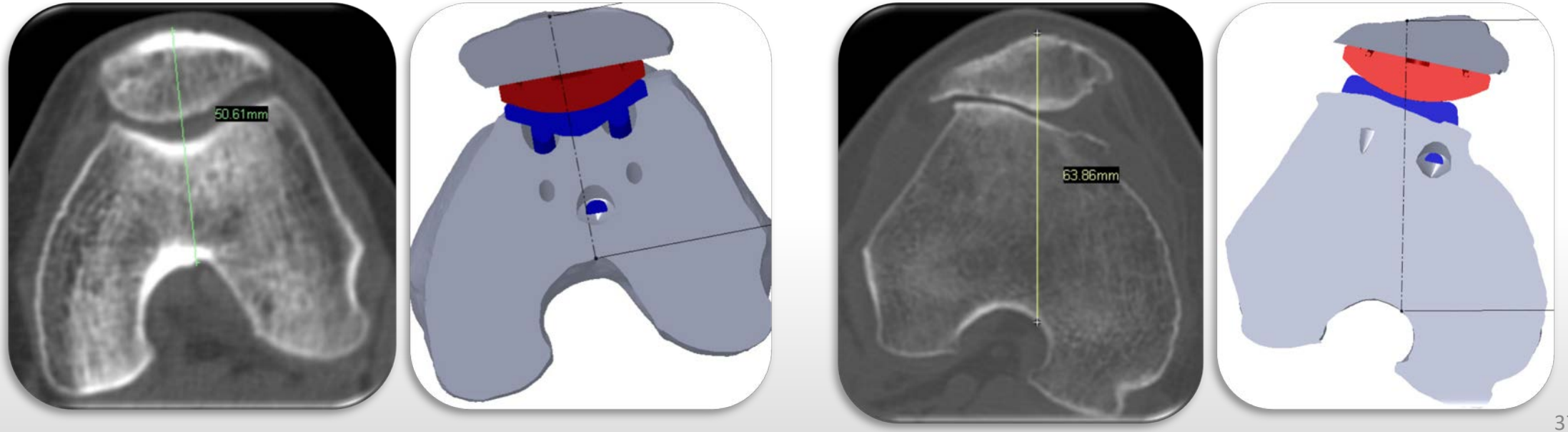
- Design compensates for deficient or dysplastic trochlear groove



Design Rationale

- Bony-contact and articulating surfaces are **decoupled**

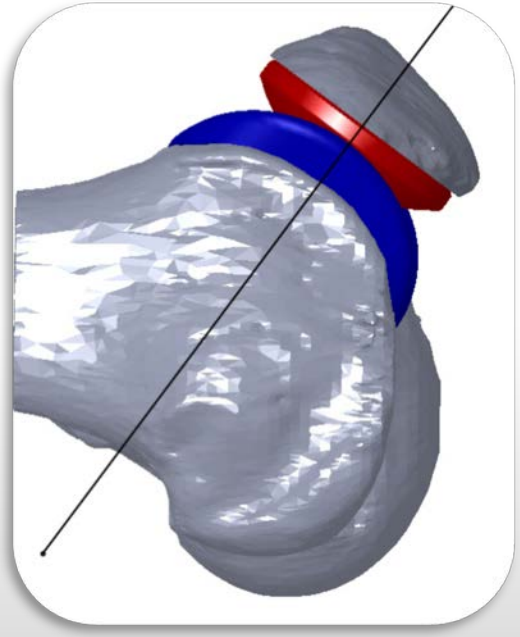
- Patient-Matched design eliminates the **trade-off** between fit and alignment

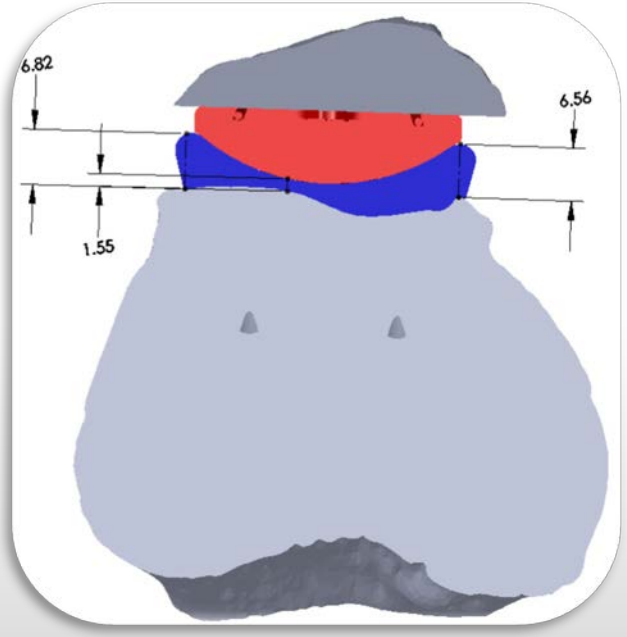


Design Rationale

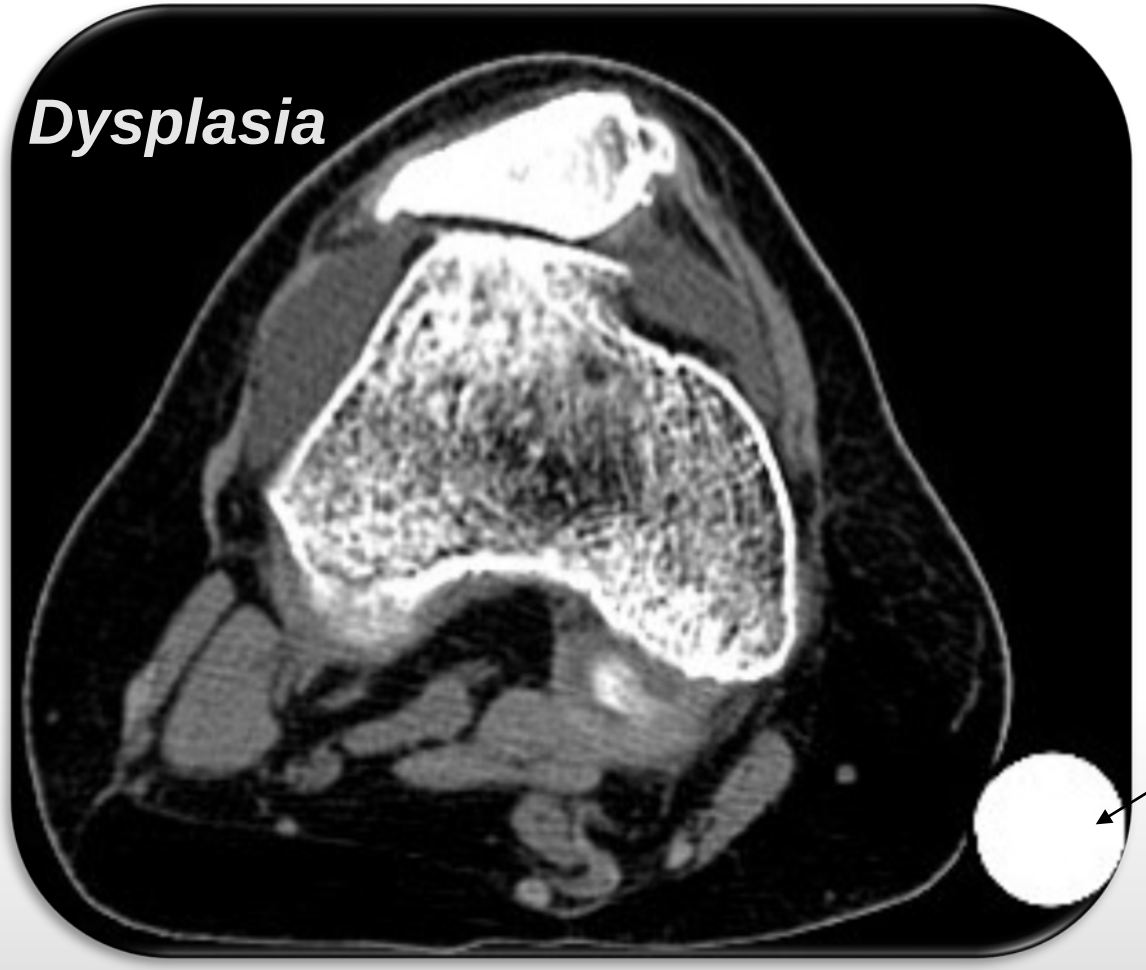
- Patient-Matched trochlea is few mm thick along the tracking arc

- Thicker laterally for PF stability



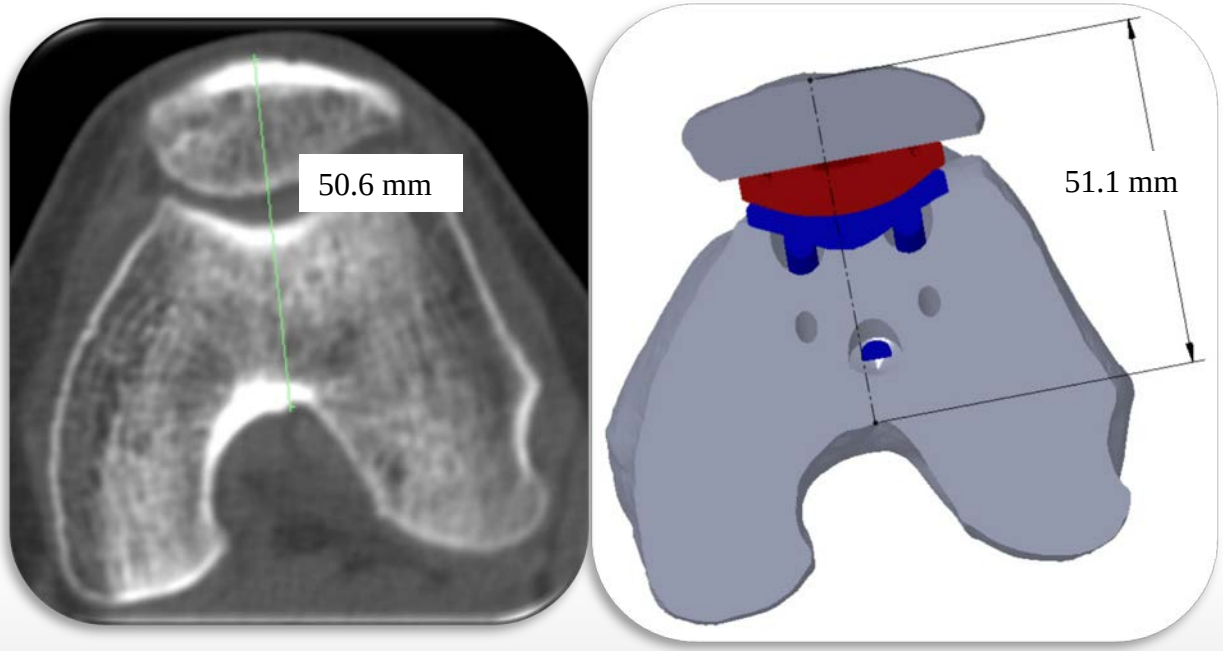


Design Rationale

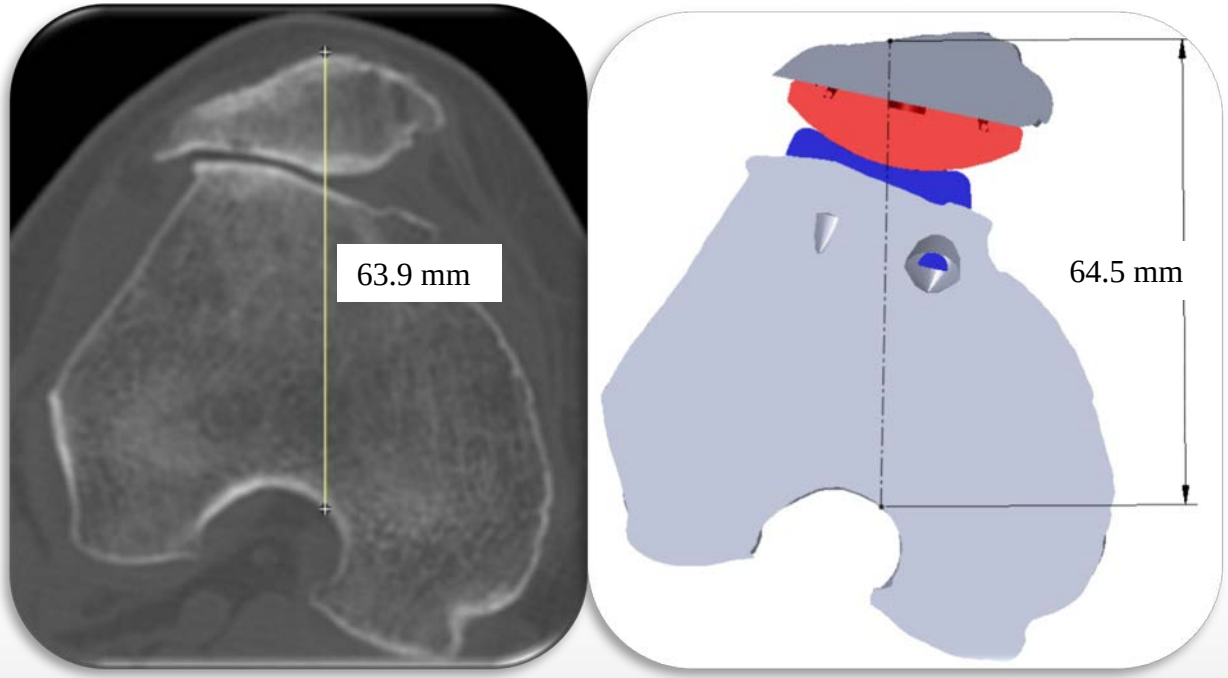


Design Rationale

Patellar Offset

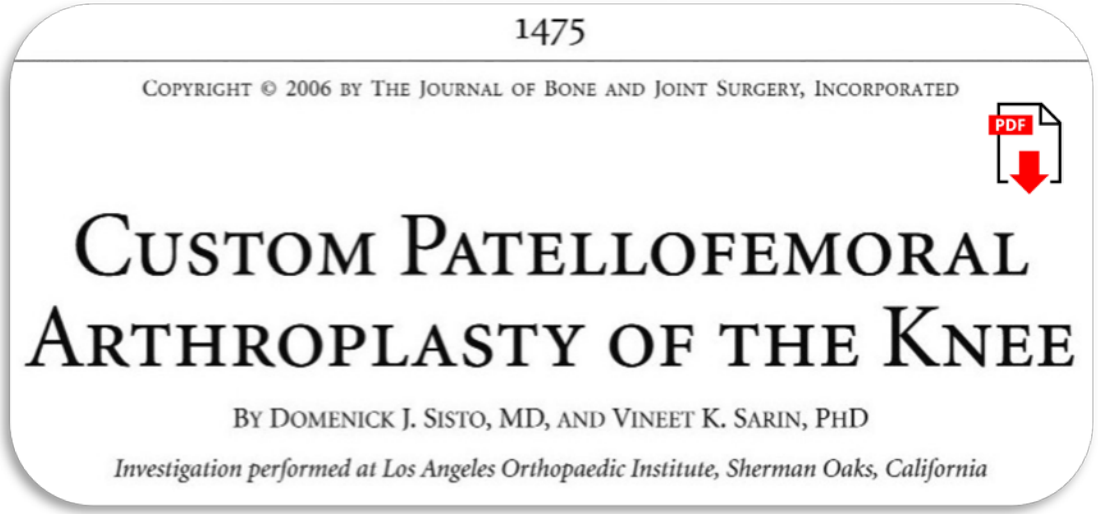


"Normal"



Dysplastic

Clinical Evidence



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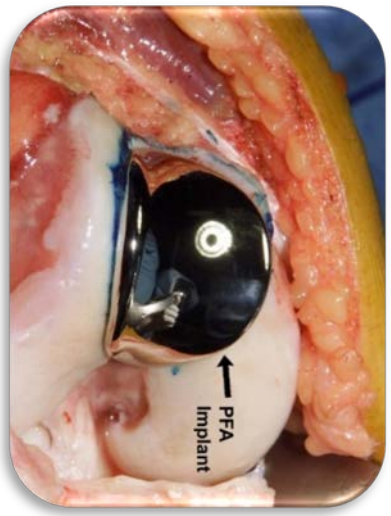
PDF

CUSTOM PATELLOFEMORAL ARTHROPLASTY OF THE KNEE

BY DOMENICK J. SISTO, MD, AND VINEET K. SARIN, PHD

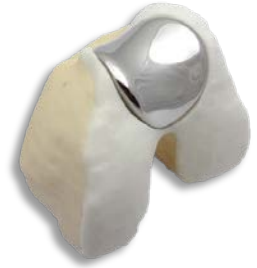
Investigation performed at Los Angeles Orthopaedic Institute, Sherman Oaks, California



Best clinical results published on any PFR device

- **25 PFR in 22 patients**
- **16 female, 6 male**
- **45 years (23 - 51 years)**
- **Mean follow-up 73 months**
- **100% Survivorship**
- **18 “Excellent” & 7 “Good”**
- **No revision, loosening, subsequent surgery**

Clinical Evidence



Custom Patellofemoral Arthroplasty of the Knee: An Eleven Year Follow-Up

Poster No. 1239 • *ORS 2011 Annual Meeting*

- **Clinical Results at 11 years average FU (range 8 to 15 years)**
  - **All implants still in place**
  - **All patients "Very Satisfied"**
  - **No reported weakness, instability, additional surgery**
  - **All patients stated they would do it again**

Custom Patellofemoral Arthroplasty of the Knee: An Eleven Year Follow-Up

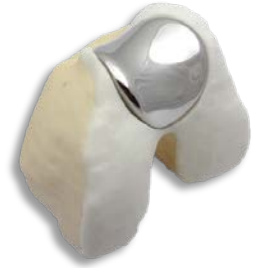
Domenick J. Sisto M.D.[1] and Vineet K. Sarin Ph.D.[2]

[1]Los Angeles Orthopaedic Institute, Sherman Oaks, CA
[2]Kinamed Incorporated, Camarillo, CA

Poster No. 1239 • *ORS 2011 Annual Meeting*

Question	Answer
Has your custom PFA been replaced?	No: 25 out of 25 Yes: 0
Does your PFA keep you from doing anything that you would like to do?	No: 23 out of 25 Yes: 2 out of 25
How satisfied are you with your PFA?	Very Dissatisfied: 0 out of 25 Somewhat Satisfied: 0 out of 25 Very Satisfied: 25 out of 25
Have you had additional surgery on this knee since your PFA?	No: 25 out of 25 Yes: 0
How often do you take pain medication because of pain in this knee?	Never: 25 out of 25 Sometimes (1-2x per week): 0 Often (>1 per day): 0
If you have pain, where is the pain coming from?	Inside of Knee: 3 out of 25 Kneecap area: 21 out of 25 Outside of Knee: 1 out of 25
Does this knee feel weak or unstable?	No: 25 out of 25 Yes: 0
Would you undergo PFA with this custom implant again?	No: 0 Yes: 25 out of 25

Clinical Evidence



Publication	Cases	Years of Follow-Up	Implant (Manufacturer)	Results
Sisto & Sarin[12]	**25**	**2.7 – 9.9**	**Custom (Kinamed)**	**100% good or excellent; No revisions or complications**
Sisto & Sarin[13]	**25**	**7.8 – 14.9**	**Custom (Kinamed)**	**100% not revised, all patients stated they would undergo procedure again**
Ackroyd et al[1]	306	2 – 5	Avon (Stryker)	87% not revised and complication-free
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Tauro et al[15]	62	5 – 10	Lubinus (Link)	45% “satisfactory”; 28% revised
Van Jonbergen et al	185	2 – 30.6	Richards II (Smith & Nephew)	85% survivorship at 10 years, 69% at 20 years
Charalambous et al	51	0.4 – 5	LCS (DePuy)	63% survivorship at 3 years

Clinical Evidence

Complications can include:

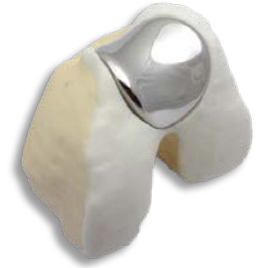
- Arthritis progression
  - More likely with idiopathic arthritis

Patient Selection is critical

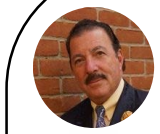
- Patellar maltracking
  - Pre-operative malalignment
  - Pre-operative dysplasia

Soft tissue balance is critical

Clinical Evidence



Endorsed by Leading Surgeons in the US



Adolph V. Lombardi, MD, FACS

- Physician Founder, New Albany Surgical Hospital
- President, Joint Implants Surgeons

Ronald Grelsamer, MD

- Associate Clinical Professor, The Mount Sinai Hospital
- Certified by American Board of Orthopaedic Surgery

Robert J. Greenhow, MD

- Knee and Hip Specialist in Denver, Colorado
- Joint replacement and sports medicine specialist

Tarun Bhargava, MD

- Knee and Hip Specialist in Wichita, Kansas
- Fellowship trained at Johns Hopkins under David Hungerford, one of the fathers of total joint replacement

"This patient-specific design and manufacturing technique ensures accurate and precise anatomic fit while simultaneously providing proper patellofemoral alignment and medial lateral constraint."

Adolph V. Lombardi, MD
New Albany, Ohio

"I have been performing KineMatch custom-fit patellofemoral arthroplasty since 2007. I am very pleased with the rapid pain relief, quick return of range of motion and function, as well as the short operative time and learning curve."

Ronald P. Grelsamer, MD
Chief of Patello-Femoral Reconstruction
New York, NY

"The KineMatch device has offered a remarkable benefit and return to function for a number of my patients with intractable patellofemoral disease who were otherwise facing the prospect of TKR."

Domenick J. Sisto, MD
Sherman Oaks, California

http://www.kinamed.com/products/orthopedic-products/kinematch-pfr/surgeon-finder

Clinical Evidence

Endorsed by Leading Surgeon in the UK

State of the art technology and surgery with 3D pre-op planning, 3D printing and custom-made implants is already in clinical practice today

Mr Ian McDermott, Consultant Knee Surgeon at London Sports Orthopaedics, believes 3D technology is well and truly already here in the field of orthopaedics, and it looks set to evolve and expand significantly in years to come

Symbios and Conformis are not the only companies providing amazing 3D technology in orthopaedics. In our practice we are now using the custom-made KineMatch patellofemoral arthroplasty prosthesis from Kinamed (distributed in the UK by Exactech), and the Episealer custom-made focal resurfacing implant from Episurf, with both giving outstanding clinical results.

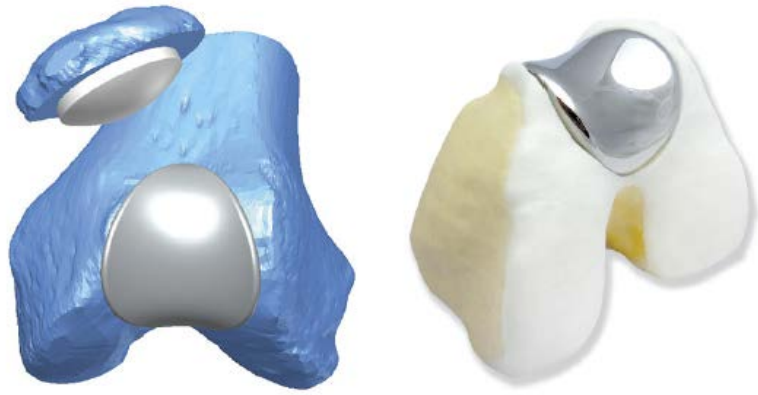
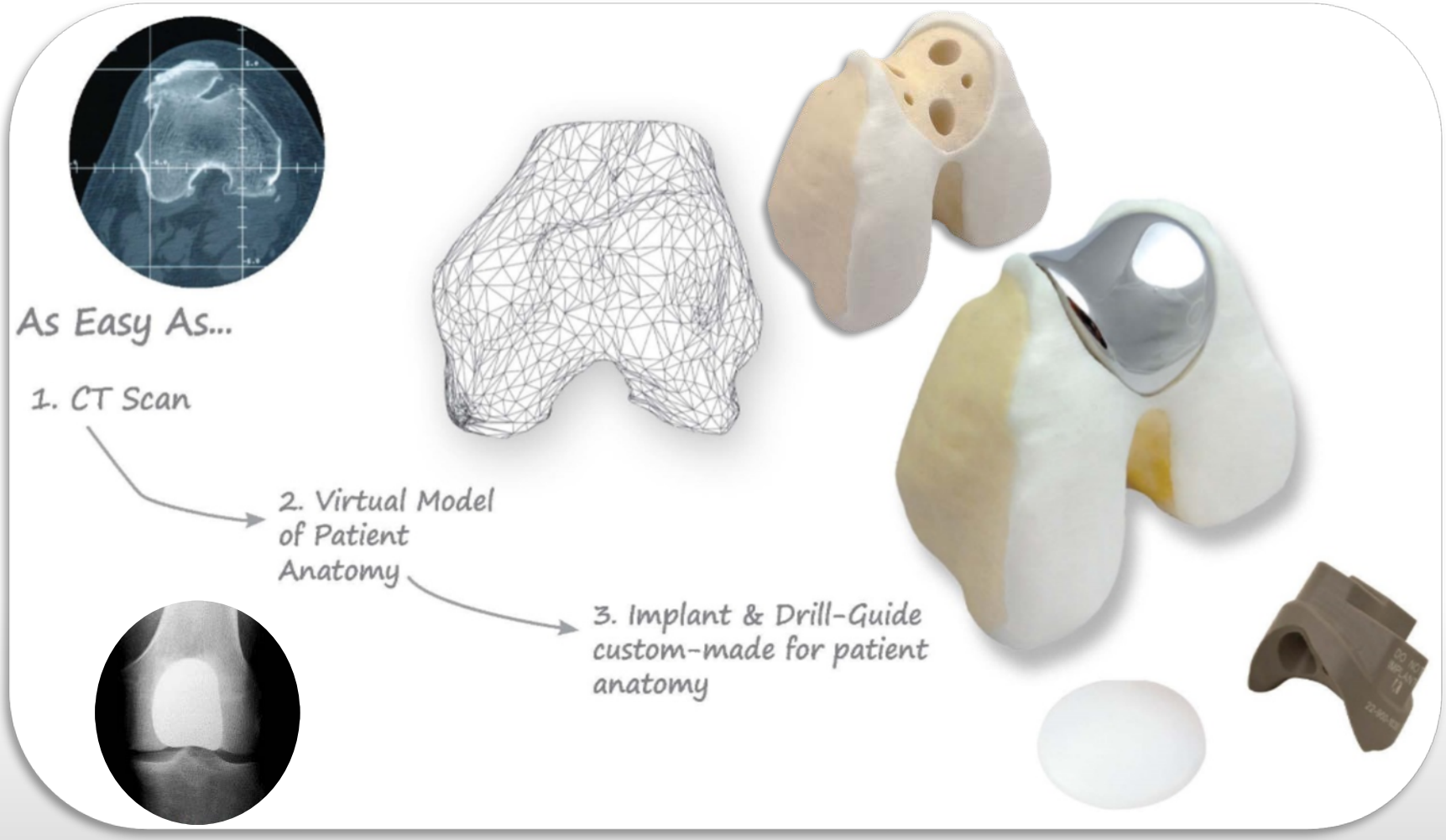
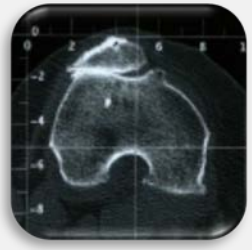


Figure 3: **The Kinematch PFR custom-made patellofemoral implant from Kinamed.**
The Episealer custom-made focal resurfacing implant from Episurf.

The Process


As Easy As...
1. CT Scan
2. Virtual Model of Patient Anatomy
3. Implant & Drill-Guide custom-made for patient anatomy

The Process

Step 1	Knee CT Scan		Patient undergoes CT with motion detection rod to provide data for modeling and manufacture of implant
Step 2	Virtual 3D model of patient anatomy		Algorithm used to analyze and virtually develop custom solution for surgeon approval (plan for osteophytes and/or cysts)
Step 3	Implant and drill-guide custom-made for patient anatomy (~8 weeks)		Custom solution is created from algorithm

The Process

Reconstructed 3D Bone Models

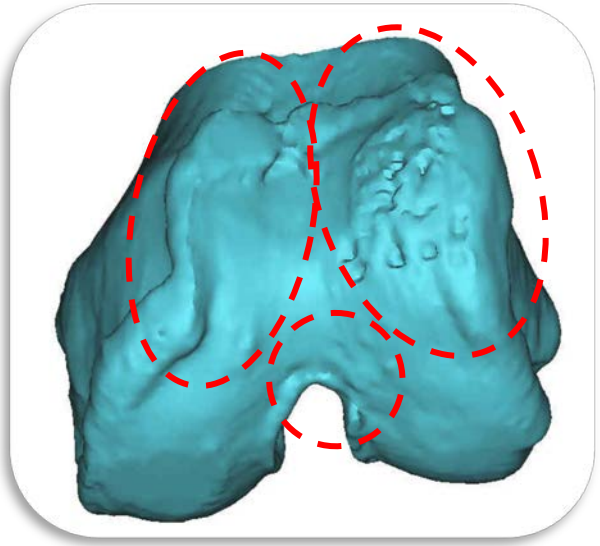
Surgeon: _____, M.D.

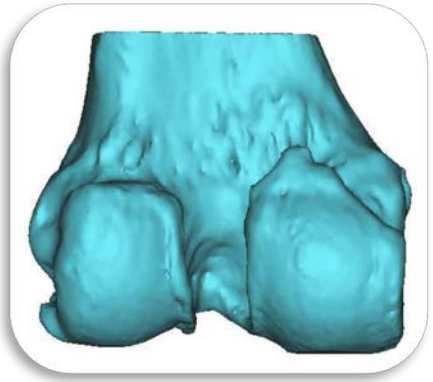
Patient: _____

Date: October 4, 2019

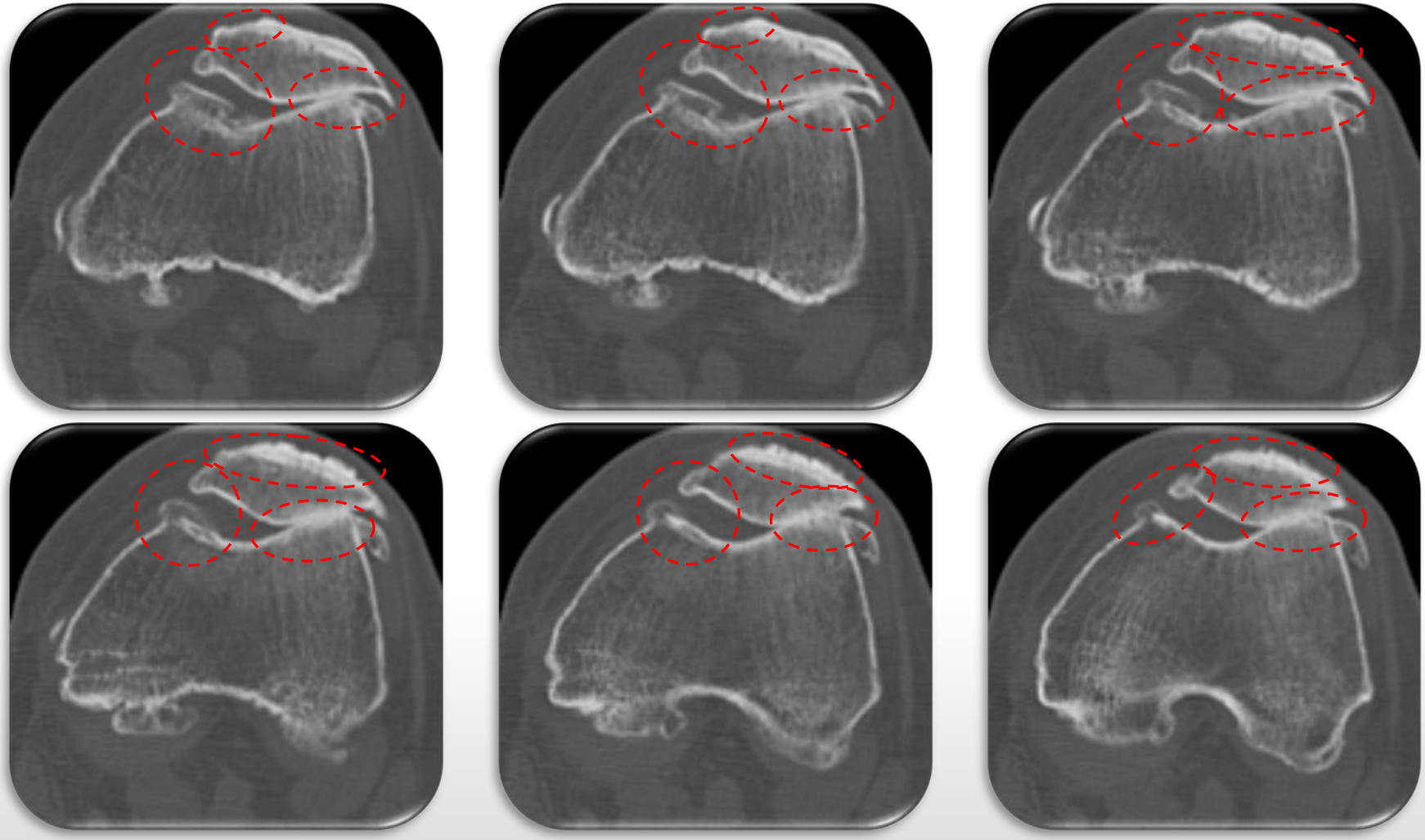
Case: PFR01297

Left Knee





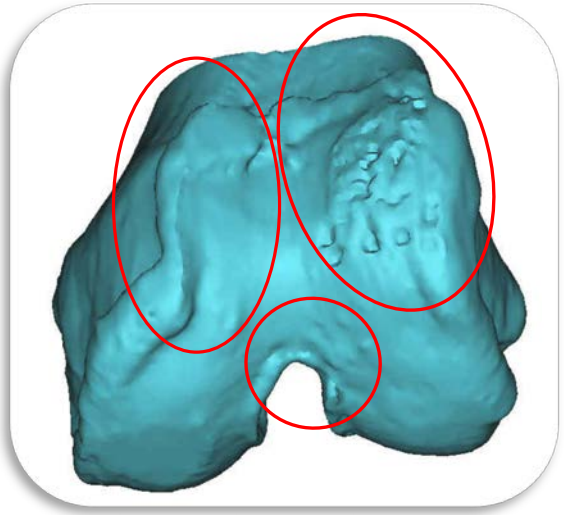
The Process

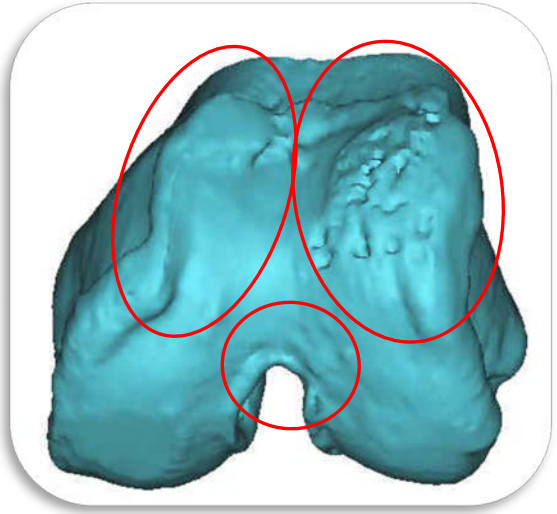


The Process

Native Anatomy:

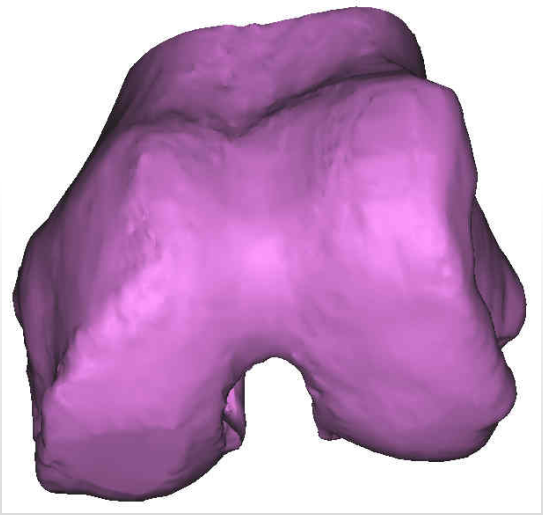
- *Patella Contact*
- *Osteophytes*
- *Cysts*

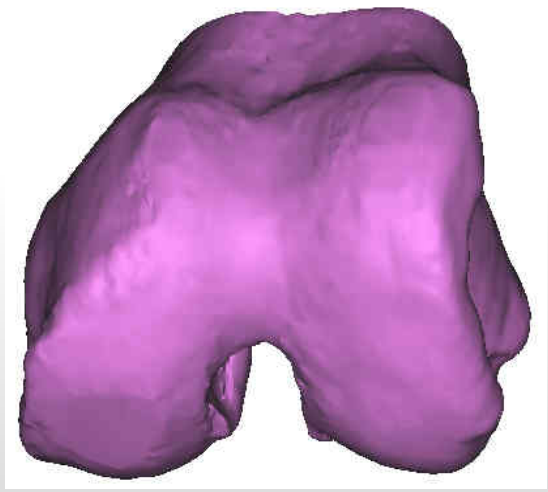




Kinamed Plan:

- *Electronic smoothing of Patella Contact*
- *Electronic removal of Osteophytes*
- *Awareness of Cyst locations*





Surgical Technique

- First, recognize that PFA is not a substitute for patellar realignment
  - Patella Maltracking (instability, imbalance) can be due to:
    - Lateral tightness
    - Medial laxity
    - Distal alignment (Q angle)
    - Patella alta or baja

Surgical Technique

How to ensure the case goes smoothly

- Go over the instrumentation with the surgeon BEFORE the case, preferably the day before, so that you can go through a “hands-on” of the instruments with them in a more relaxed setting
- As soon as you arrive for the case, CONFIRM that they have sterilized the drill guide

During the case

- Bring the patient’s femur model with you to the O.R.

Surgical Technique

Custom Patellofemoral Arthroplasty of the Knee

Surgical Technique

By Domenick J. Sisto, MD, and Vineet K. Sarin, PhD

Investigation performed at Los Angeles Orthopaedic Institute, Sherman Oaks, California

The original scientific article in which the surgical technique was presented was published in JBJS Vol. 88-A, pp. 1475-80, July 2006

Patient-specific Patellofemoral Arthroplasty

Domenick J. Sisto, MD, Jon Henry, MD,† Marco Sisto, BA,* and Vineet K. Sarin, PhD‡*

Abstract: In the past few years, there has been renewed interest in patellofemoral arthroplasty. Although the results of off-the-shelf patellofemoral prostheses have varied, the researchers' results with patient-specific patellofemoral arthroplasty are encouraging. Our experience shows that patient-specific patellofemoral arthroplasty is a safe and effective treatment option for patients who have isolated end-stage patellofemoral arthritis. The surgical technique for patient-specific patellofemoral arthroplasty is straightforward because positioning and alignment of the patient-specific trochlear prosthesis are determined preoperatively, thus eliminating intraoperative guesswork. This paper describes the technique of patellofemoral arthroplasty that incorporates a custom-designed patient-specific prosthesis for resurfacing of the patellofemoral trochlea.

Key Words: patellofemoral, arthroplasty, knee, arthritis, patient-specific

Contraindications include but are not limited to:

- Medial and lateral tibiofemoral Ahlback scores[8] greater than
- The lack of an attempt at nonoperative care or to rule o sources of pain
- Systemic inflammatory arthropathy
- Uncorrected patellofemoral instability or malalignment

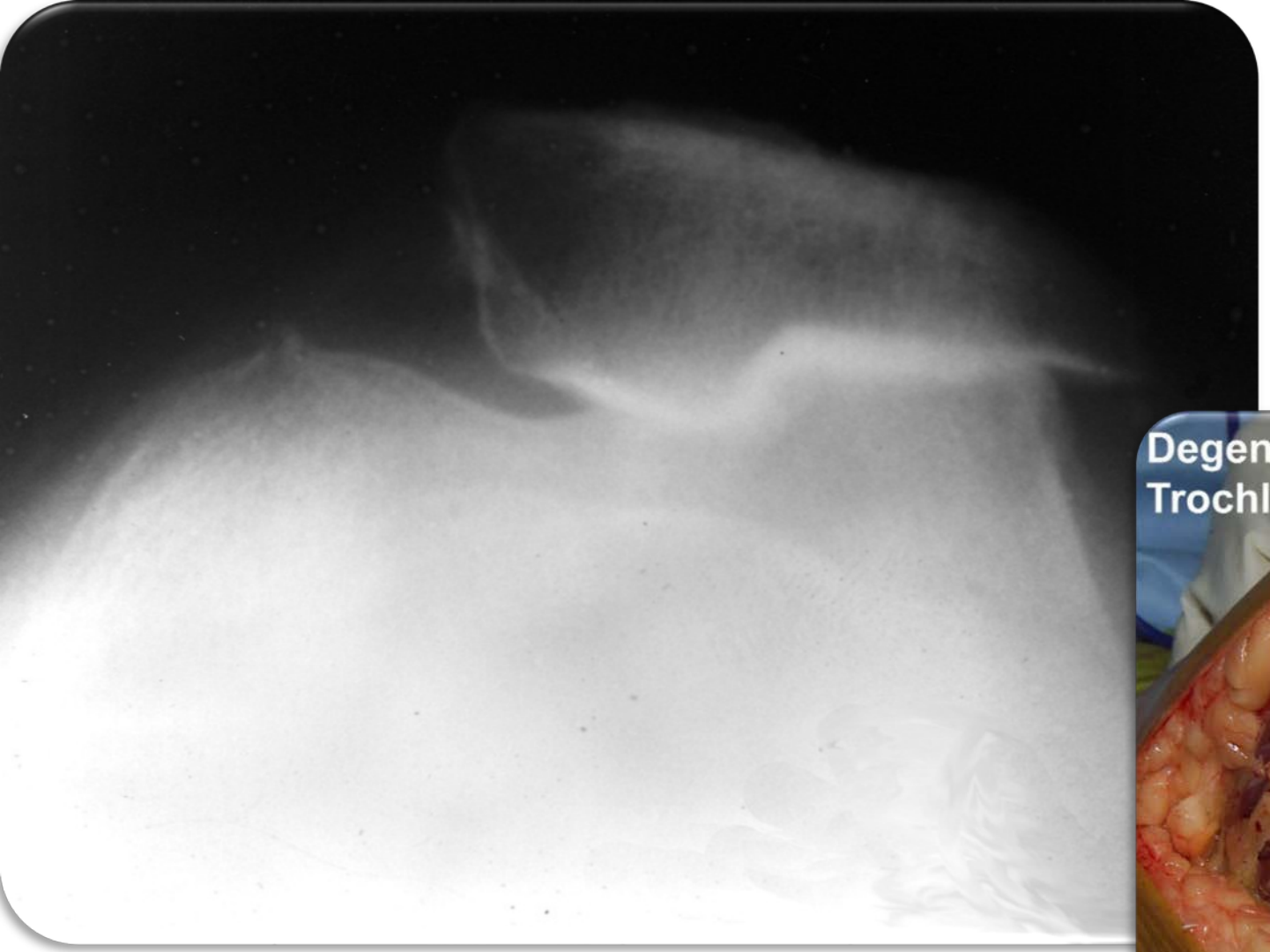
DESIGN RATIONALE

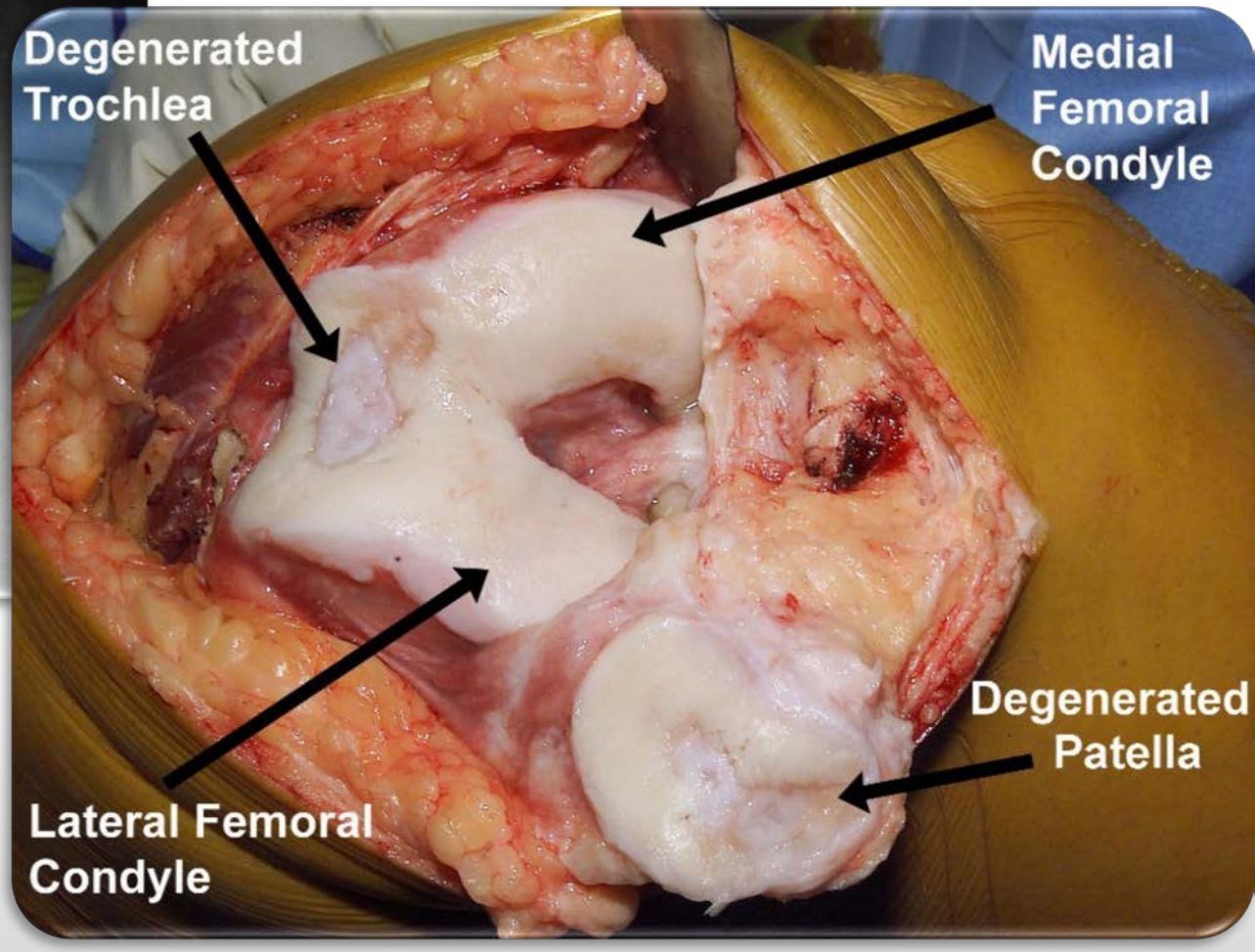
The design goal of patient-specific patellofemoral plasty is to restore the mechanics of the patello compartment and maintain the native mechanics tibiofemoral compartments.[6,7,9] Progression of arthritic into the medial and lateral knee compartments often con to the need for patellofemoral arthroplasty revision.[10]

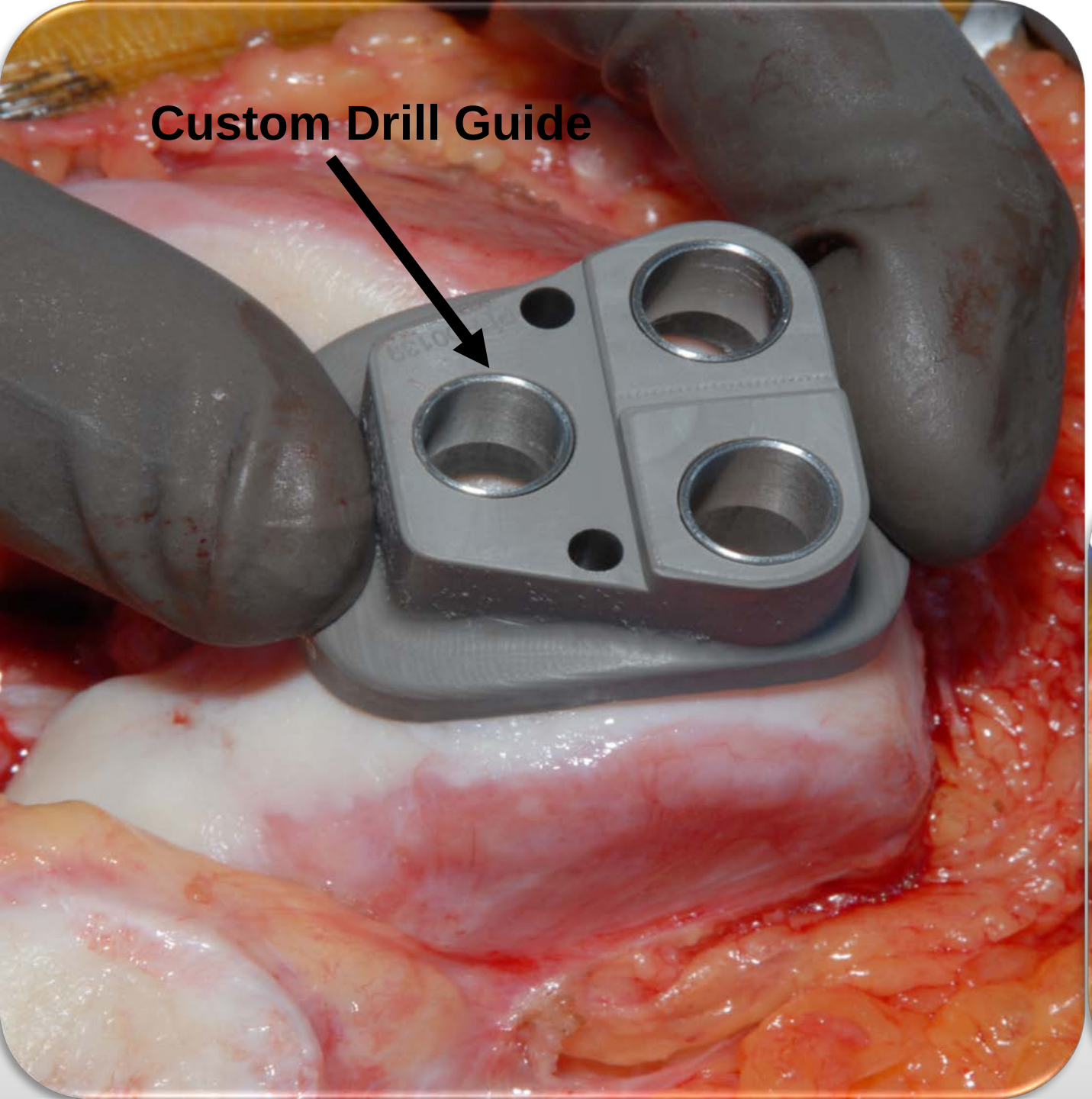
Surgical Technique

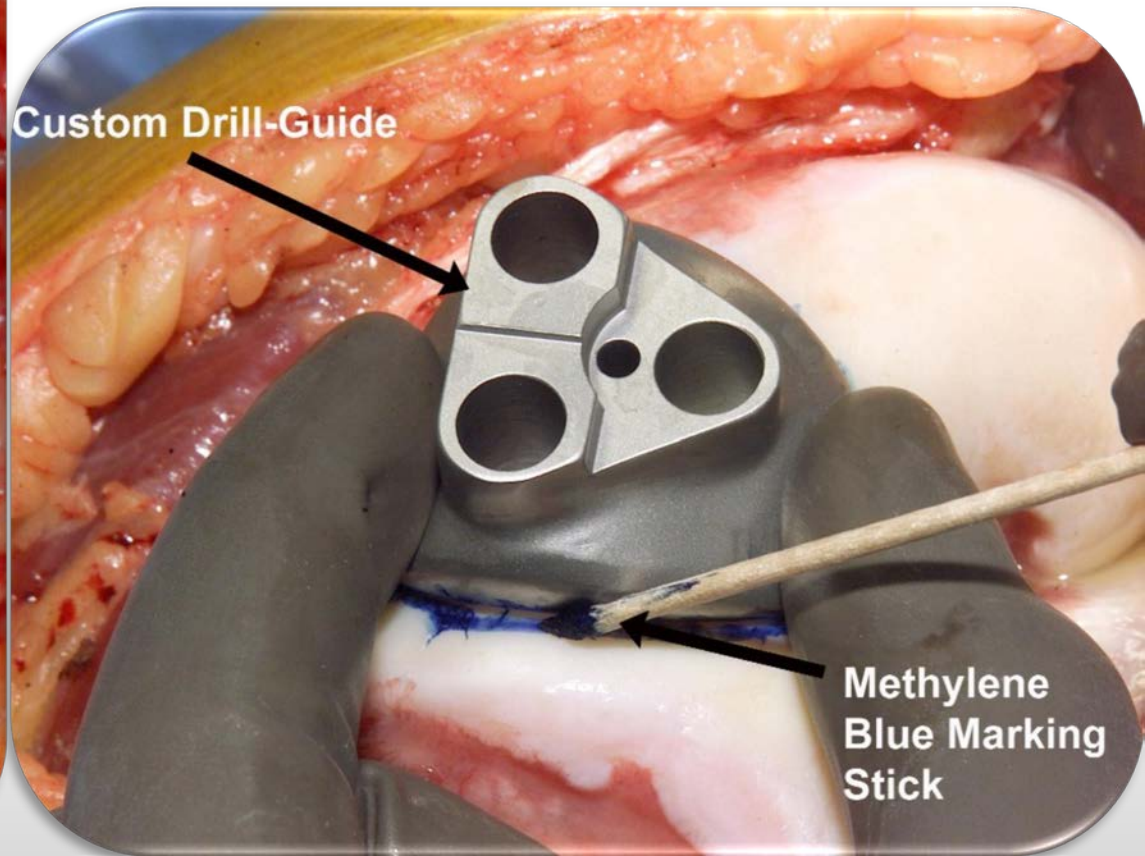
VIDEO

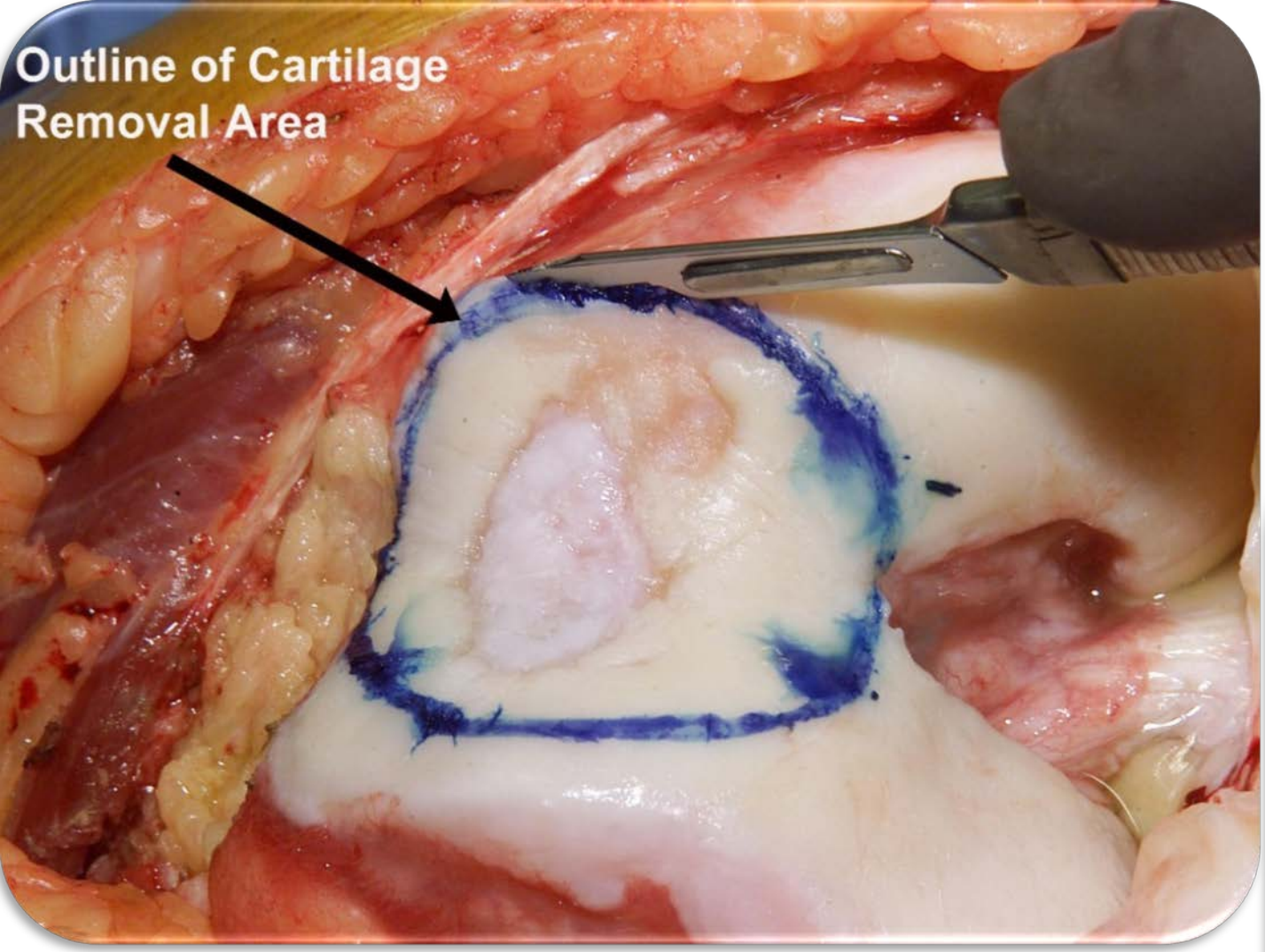
Courtesy of A Lombardi MD

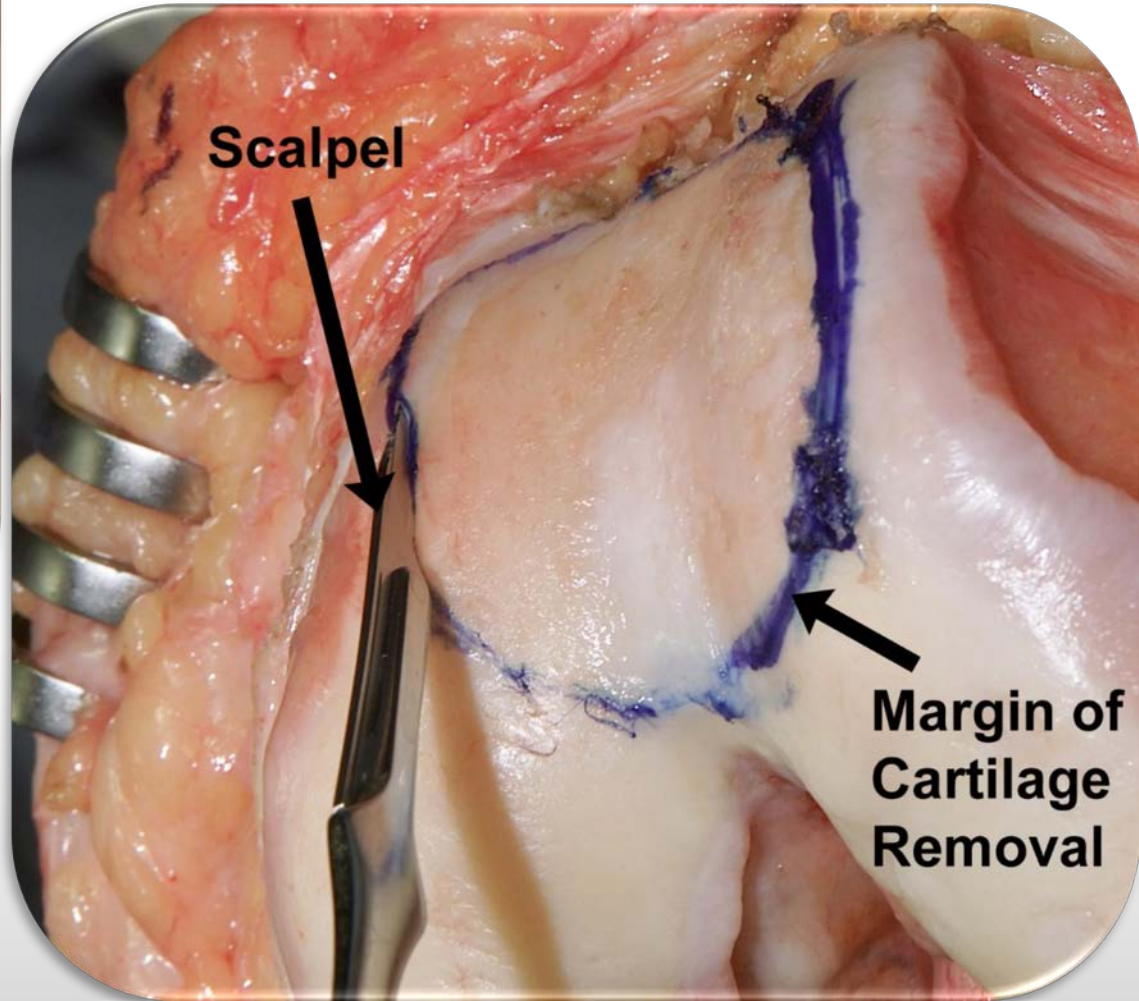


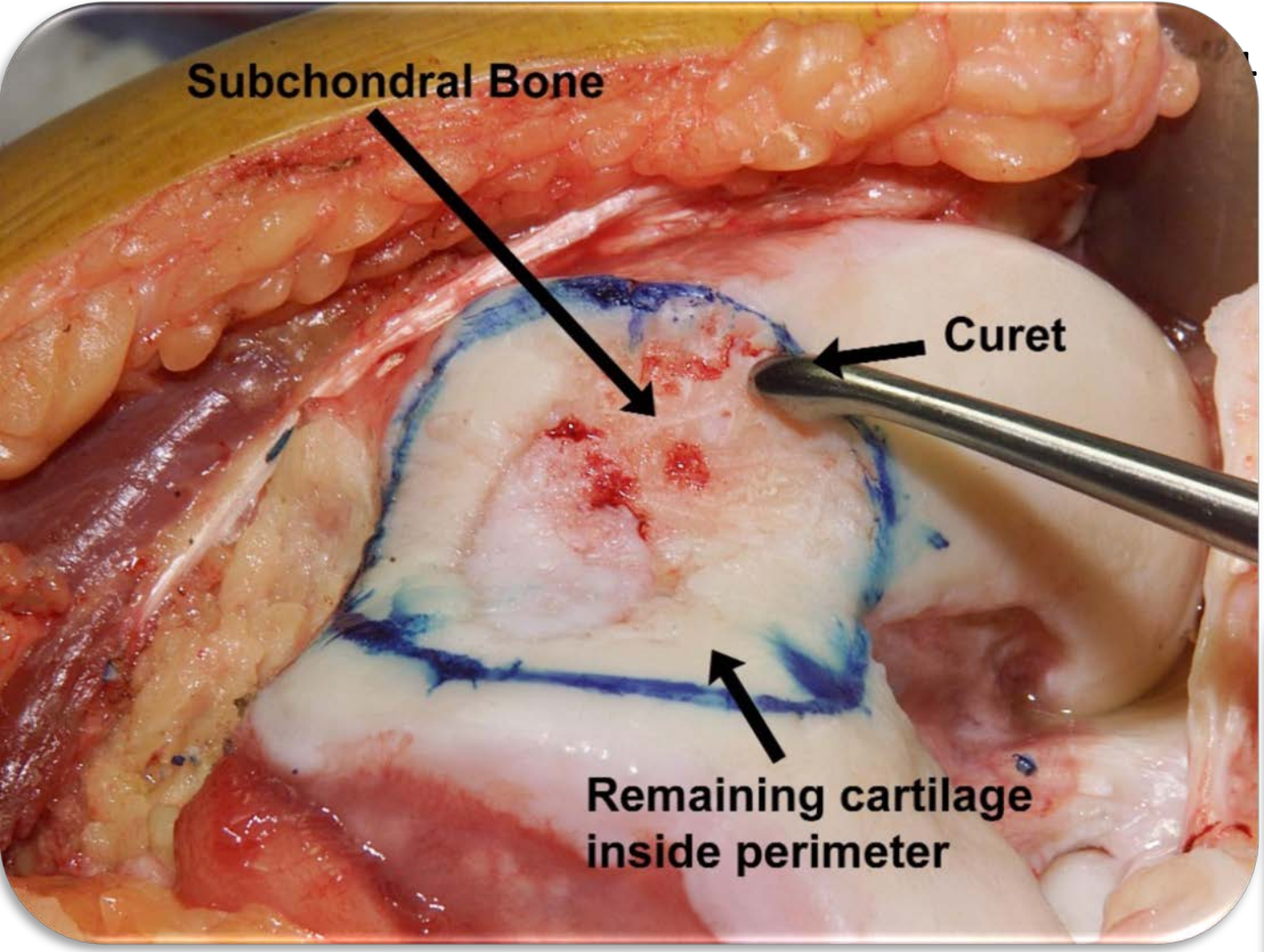

Degenerated
Trochlea
Medial
Femoral
Condyle
Degenerated
Patella
Lateral Femoral
Condyle


Custom Drill Guide

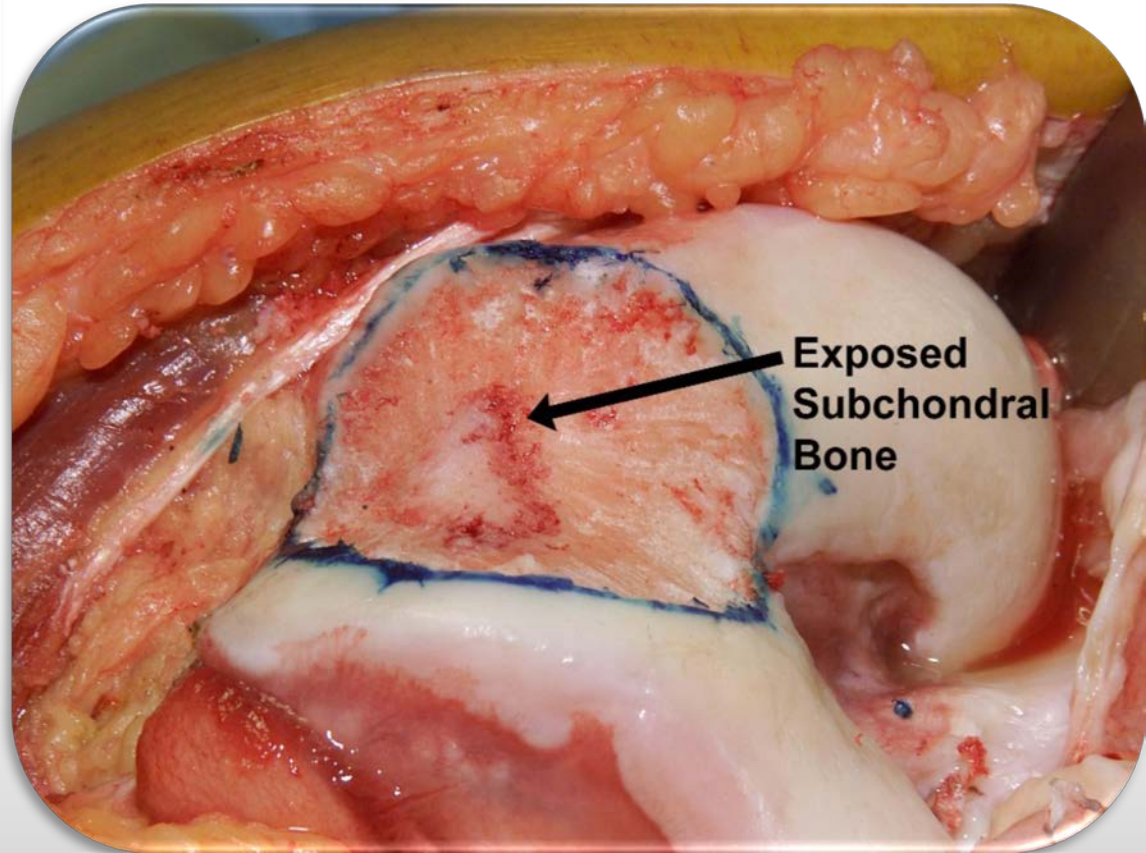

Custom Drill-Guide
Methylene
Blue Marking
Stick


Outline of Cartilage
Removal Area


Scalpel
Margin of
Cartilage
Removal



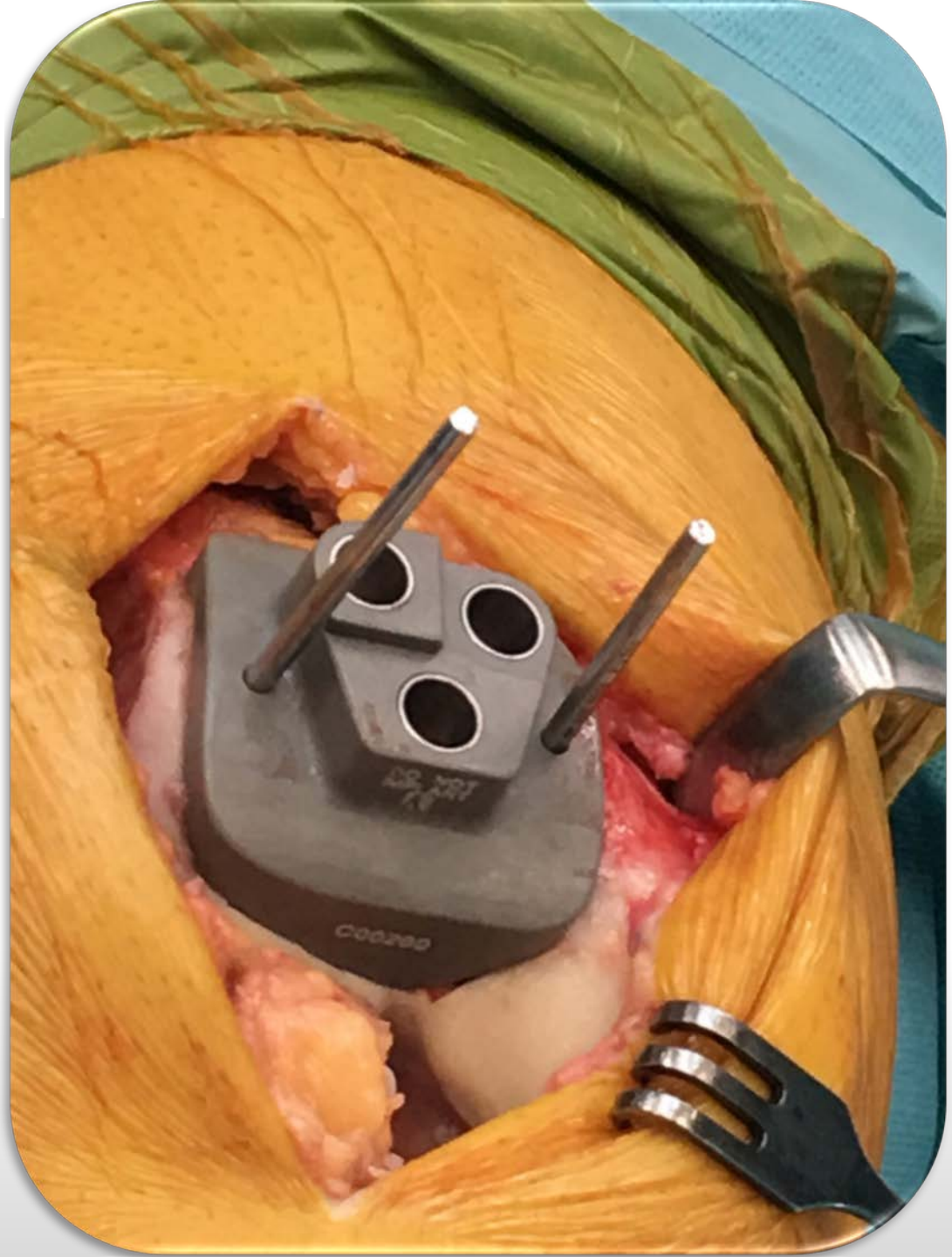
Ring Curette is preferable

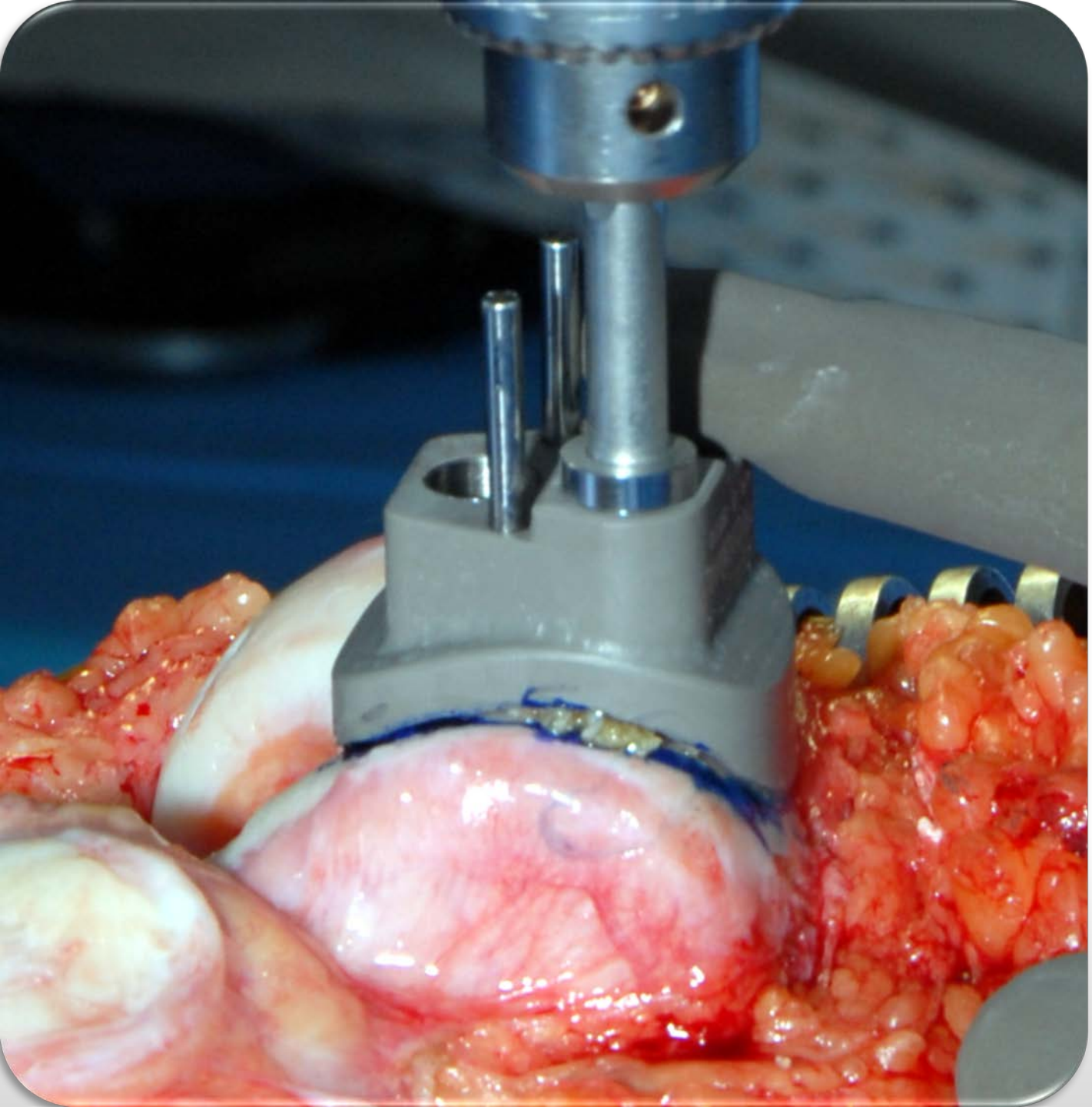


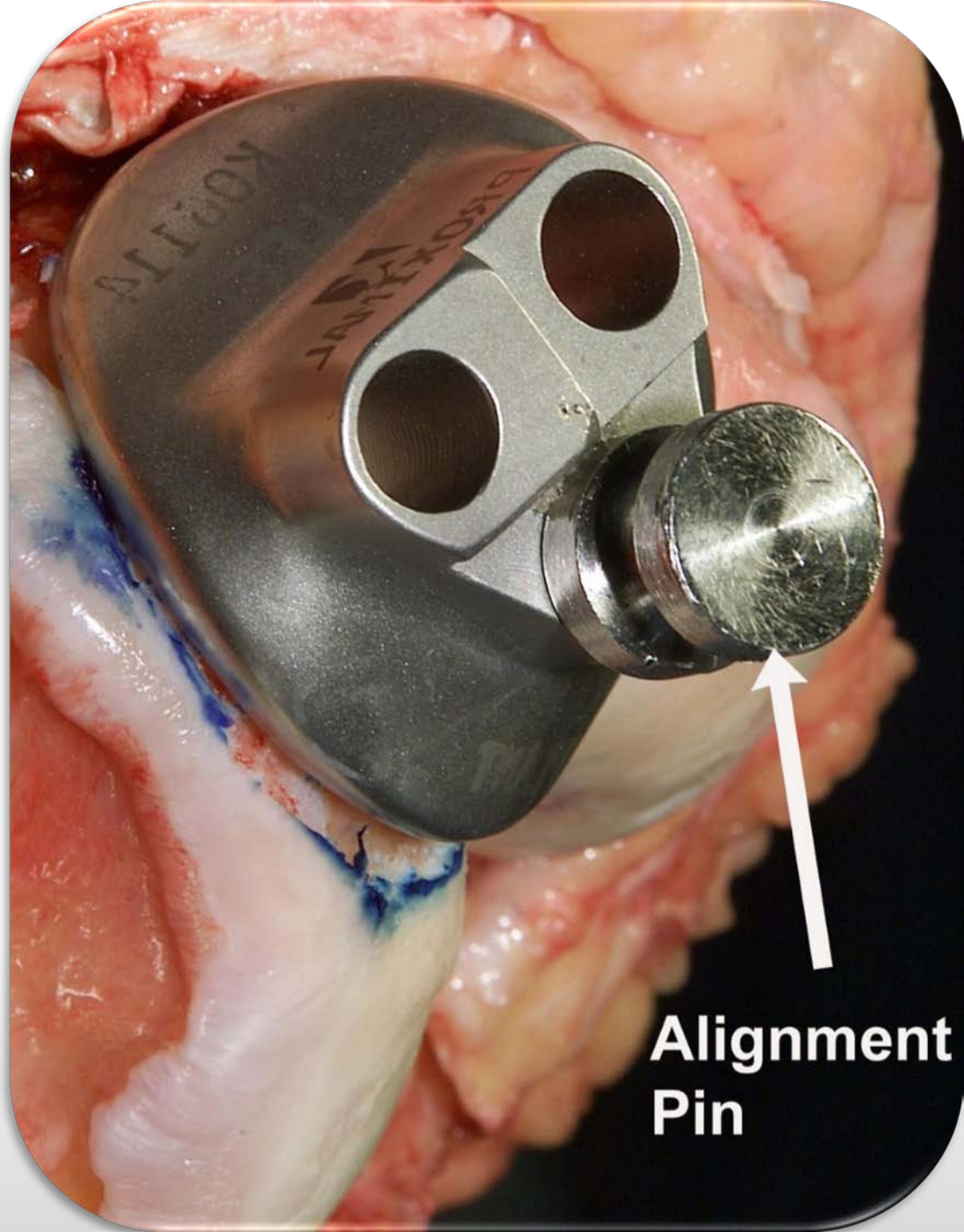
- At this point in the procedure, proper contact between the drill guide and the femoral surface must be verified.

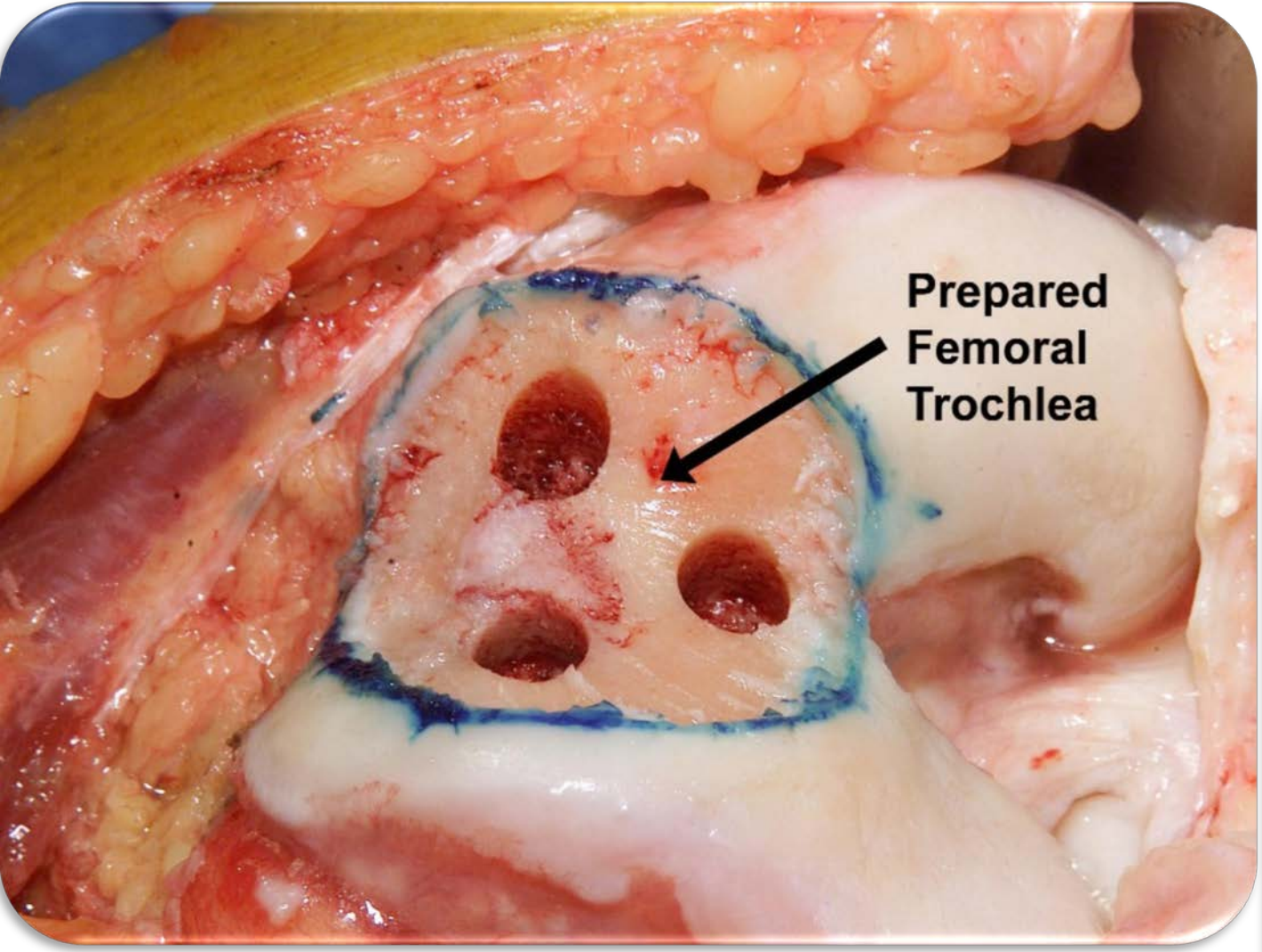
- BEFORE putting in the two small guide pins, it must be verified that there is NO gapping around the periphery of the guide.
  - If there is, it must be determined where to move the guide slightly in order to find its proper location.
  - If there is any cartilage remaining under the guide in that location, it must be removed, and the guide fit re-checked for any gapping.

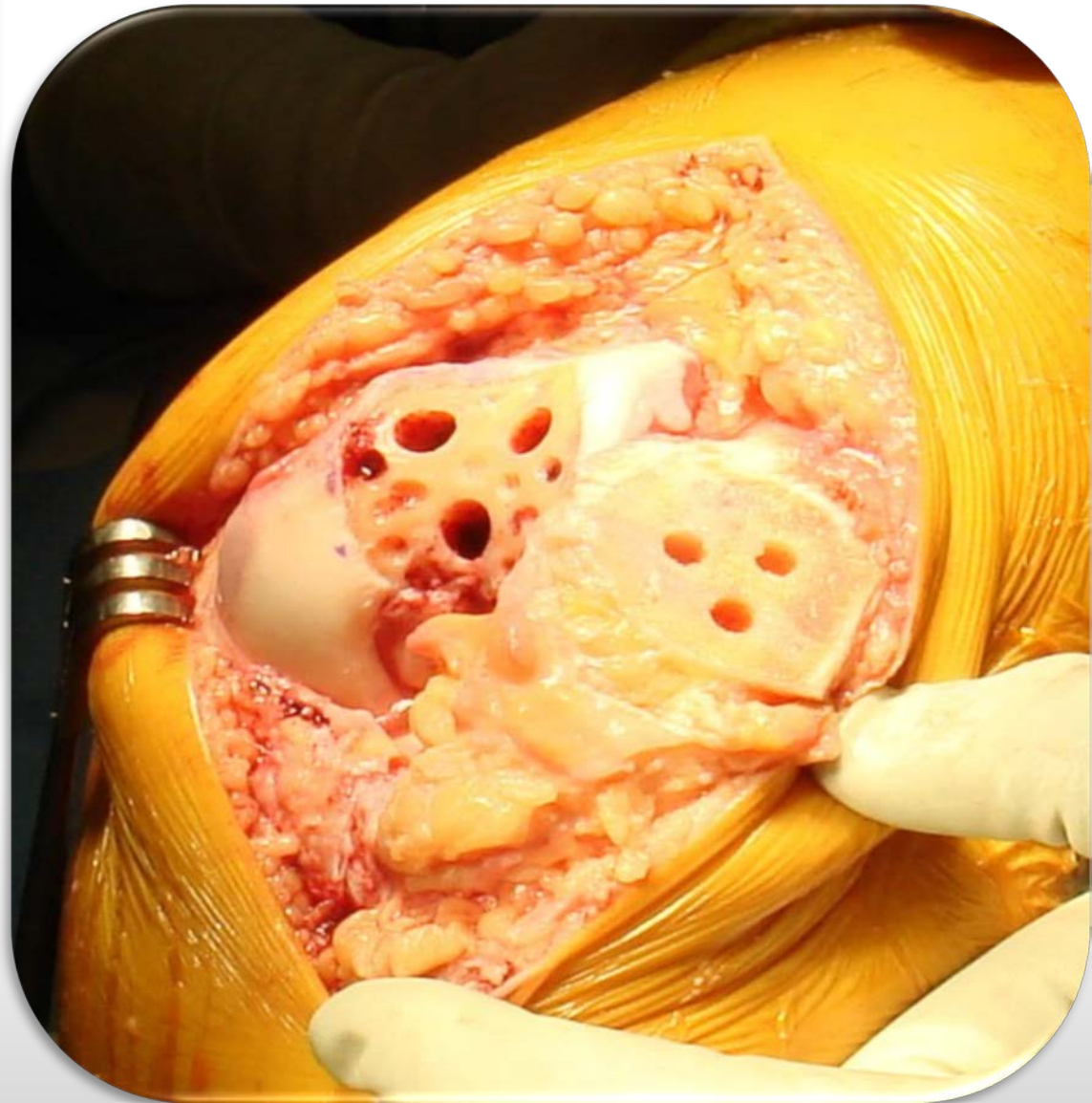
- Once the guide is well seated around its entire circumference, it can be affixed with pins and the bone drilled.

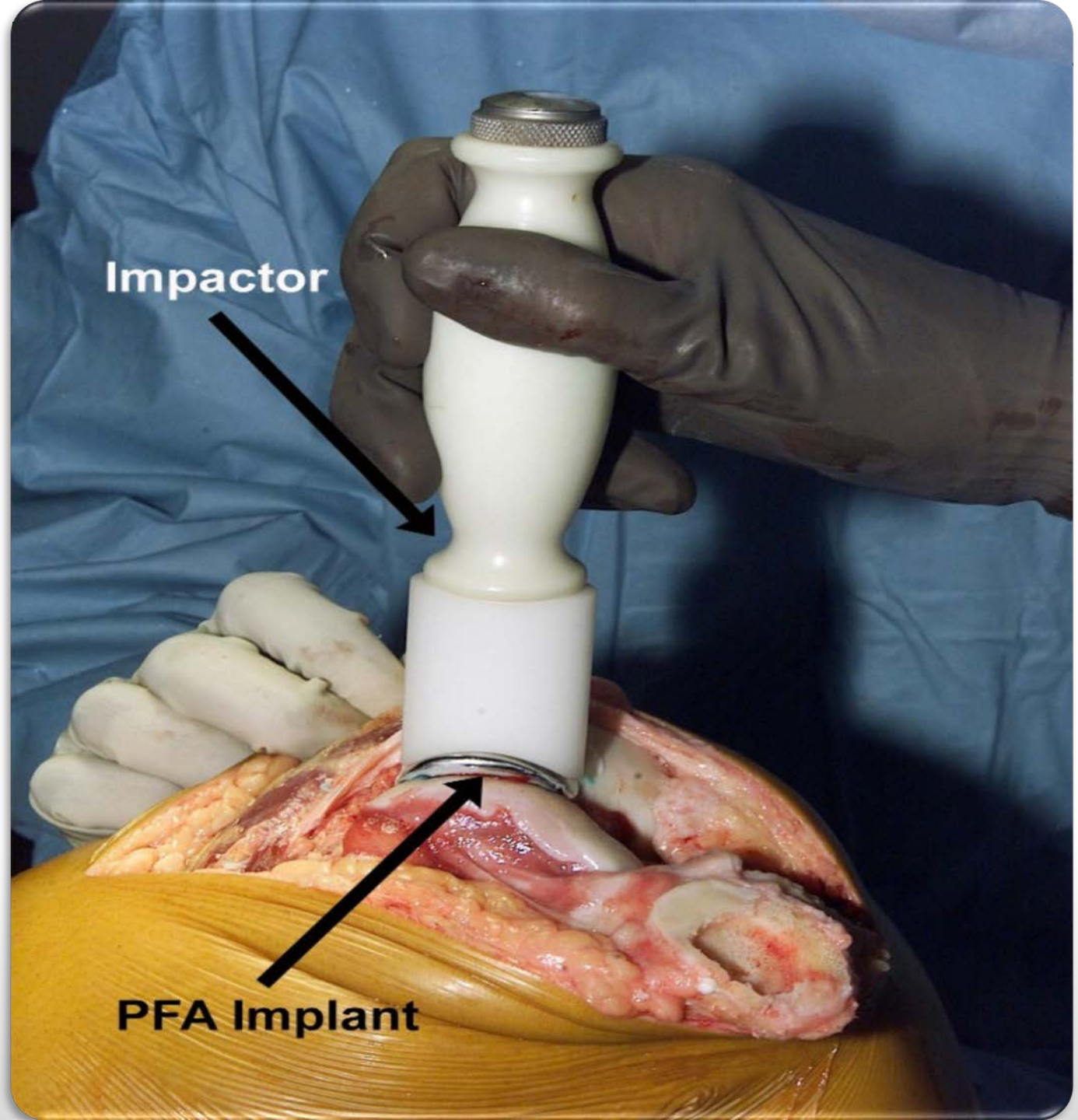


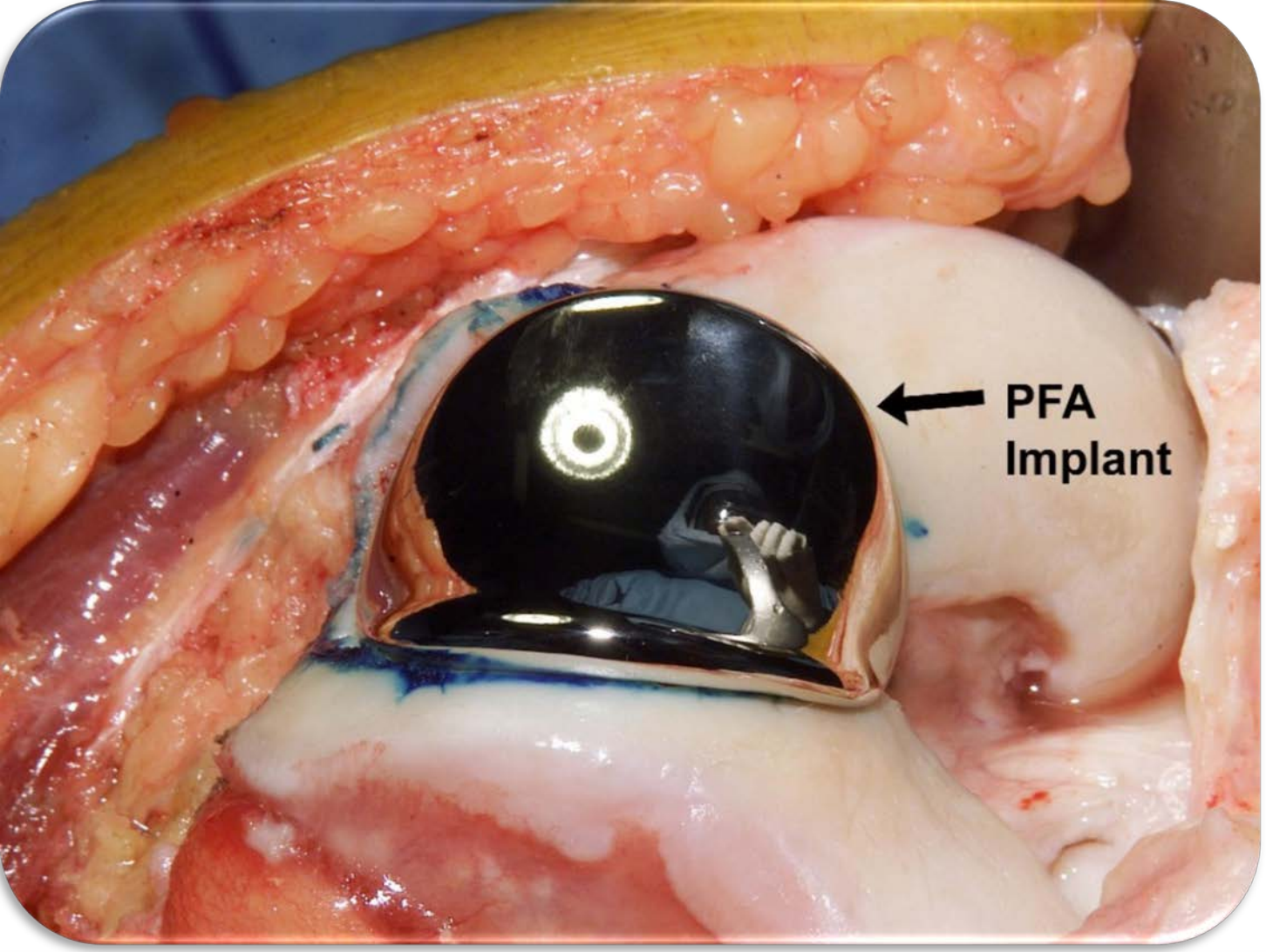


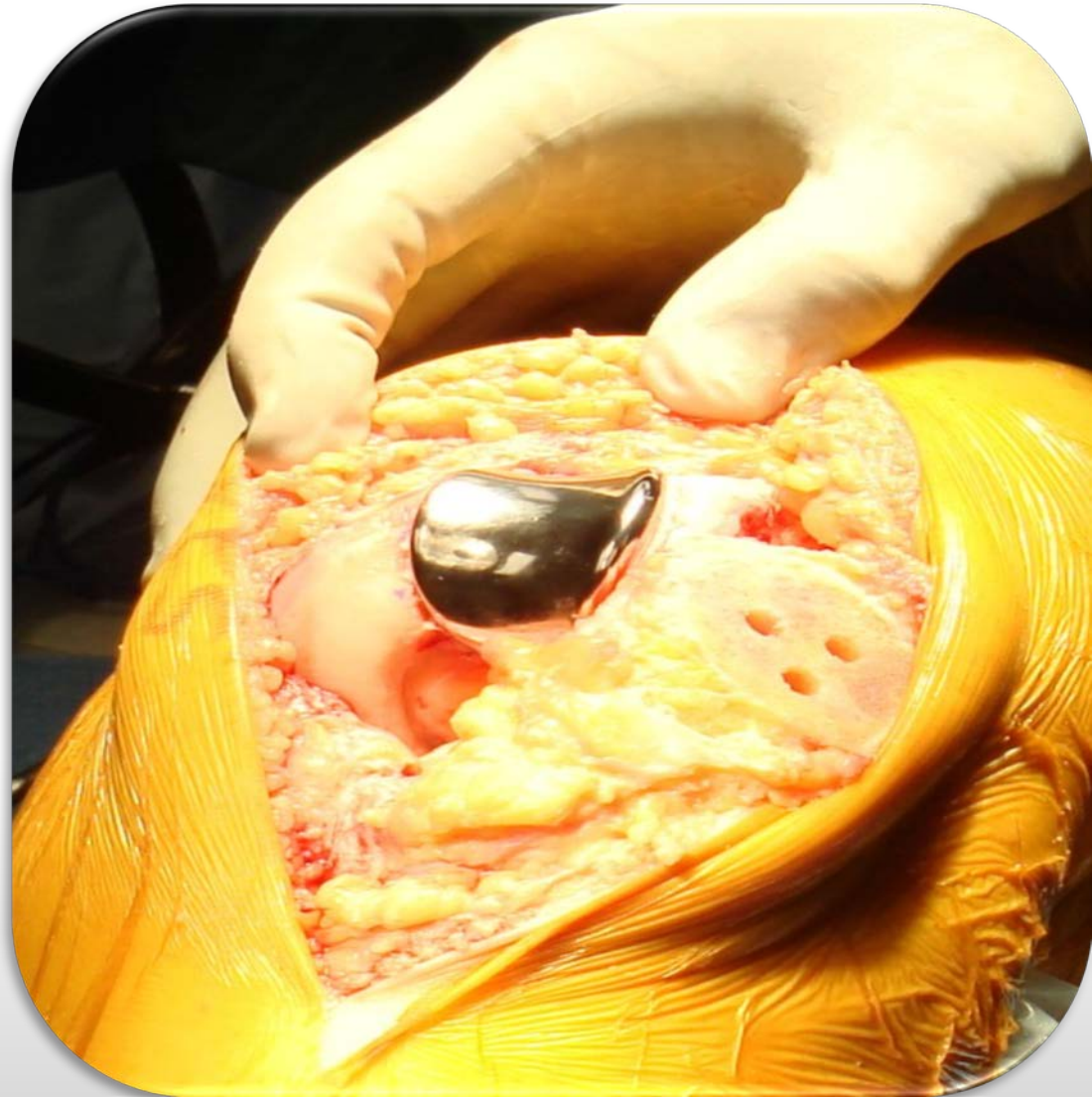

Alignment
Pin


Prepared
Femoral
Trochlea




Impactor
PFA Implant


PFA
Implant

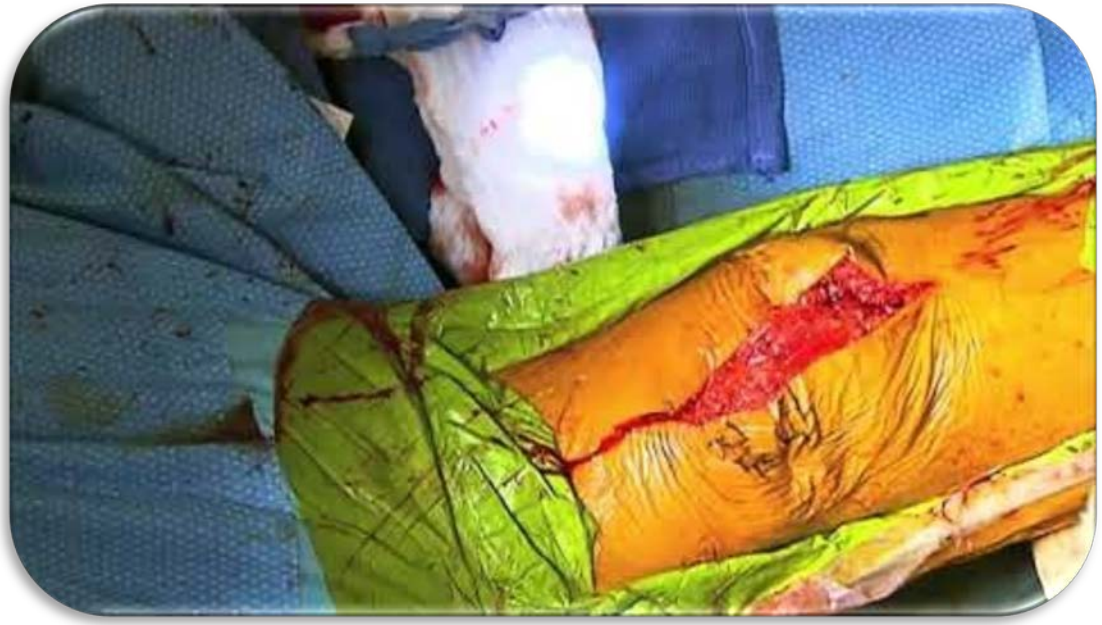


Surgical Technique

Before closing

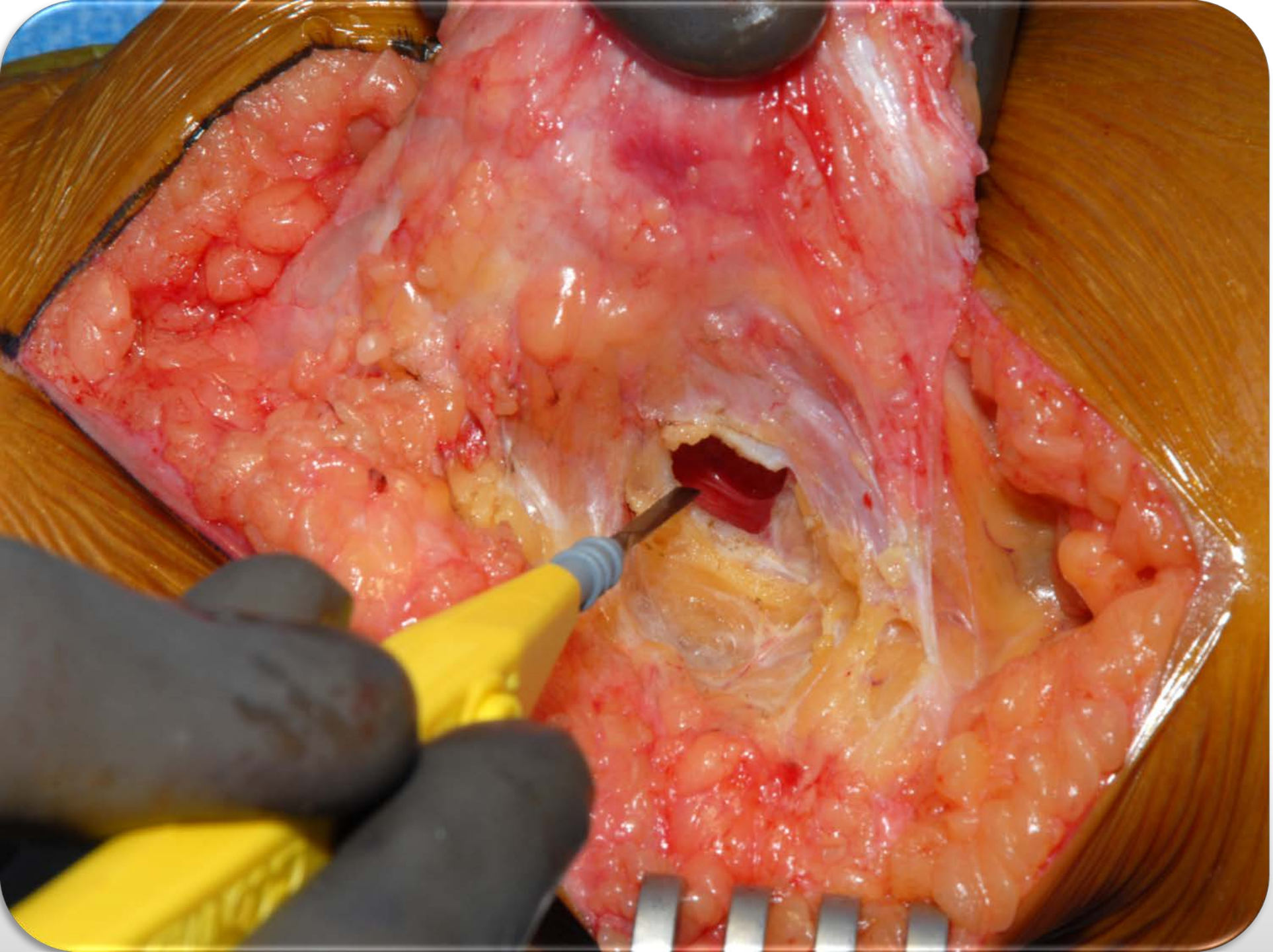
TRACKING IS KEY

- A perfect fit is a Beautiful thing
- Don’t trade cartilage/bone wear for poly wear
- Range of motion testing tells the tale
- Lateral releases may be required
    - Lateral wear is very common, often seen pre-operatively

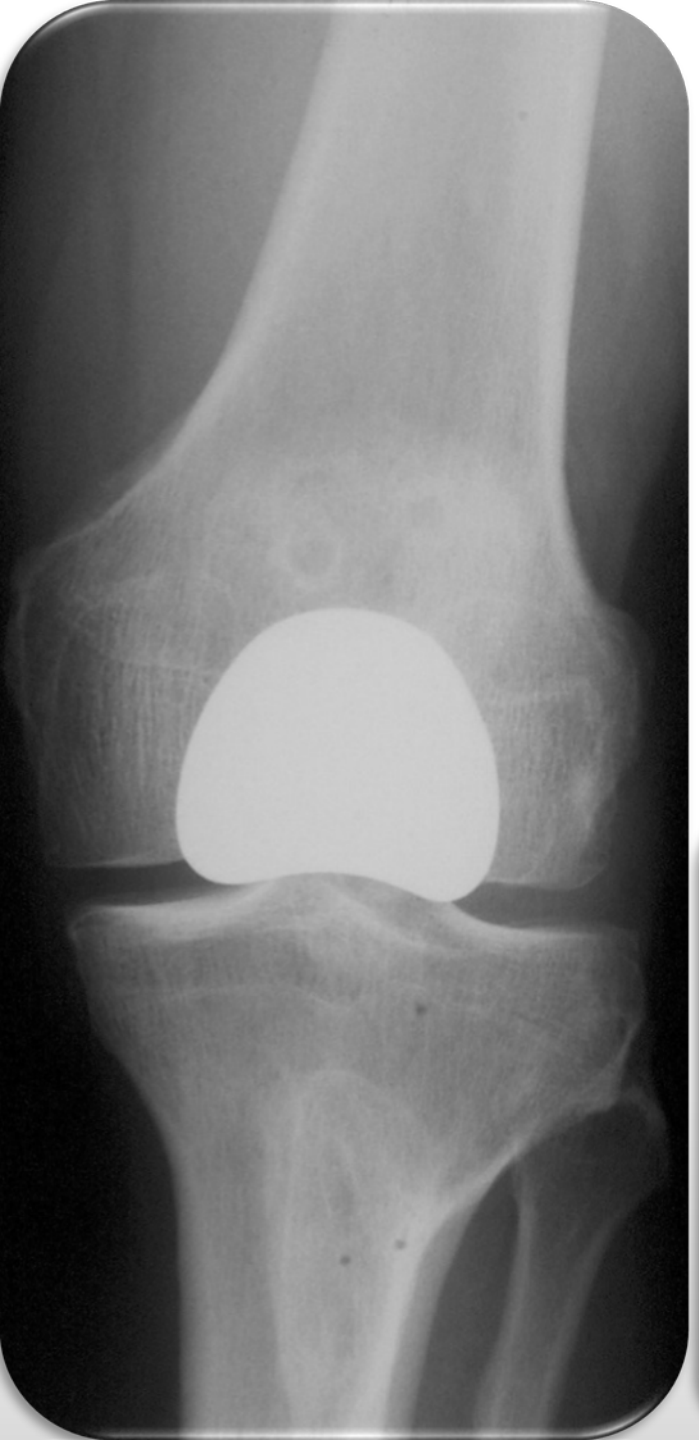


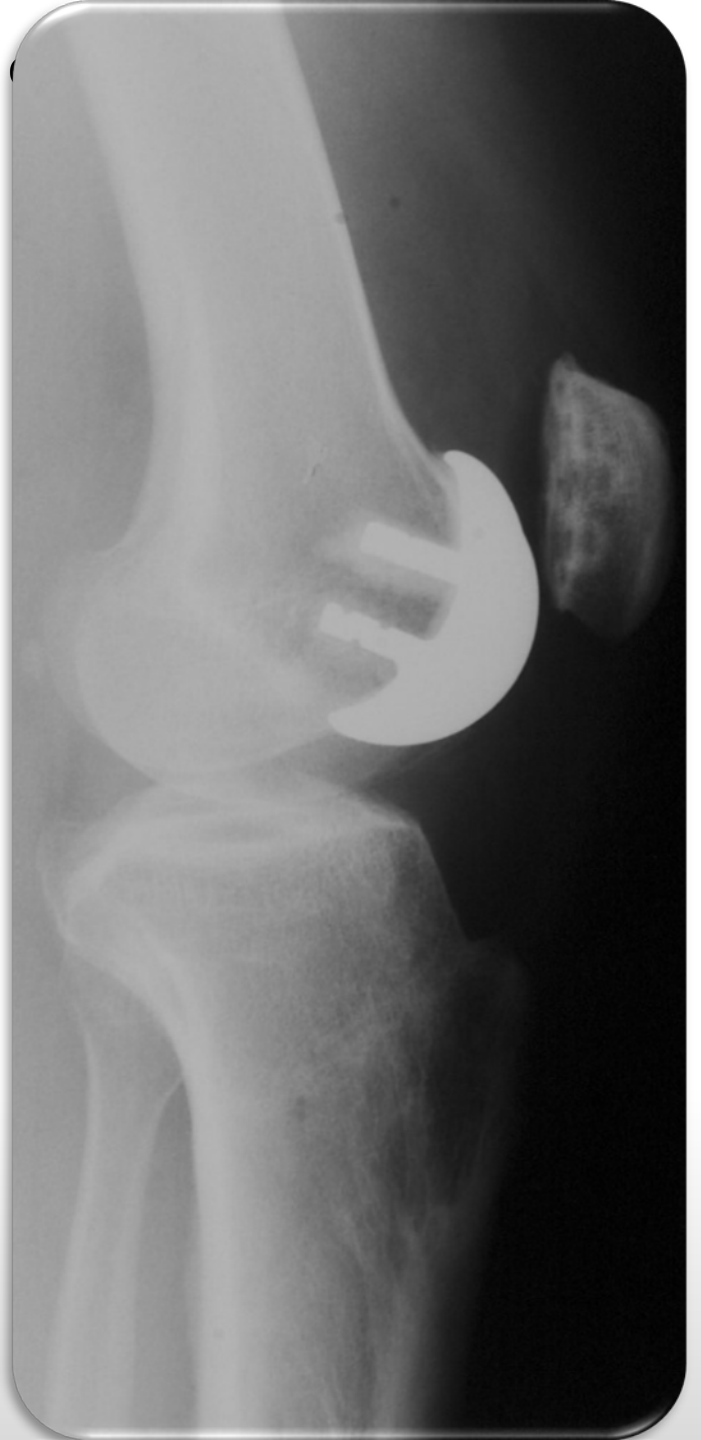
VIDEO

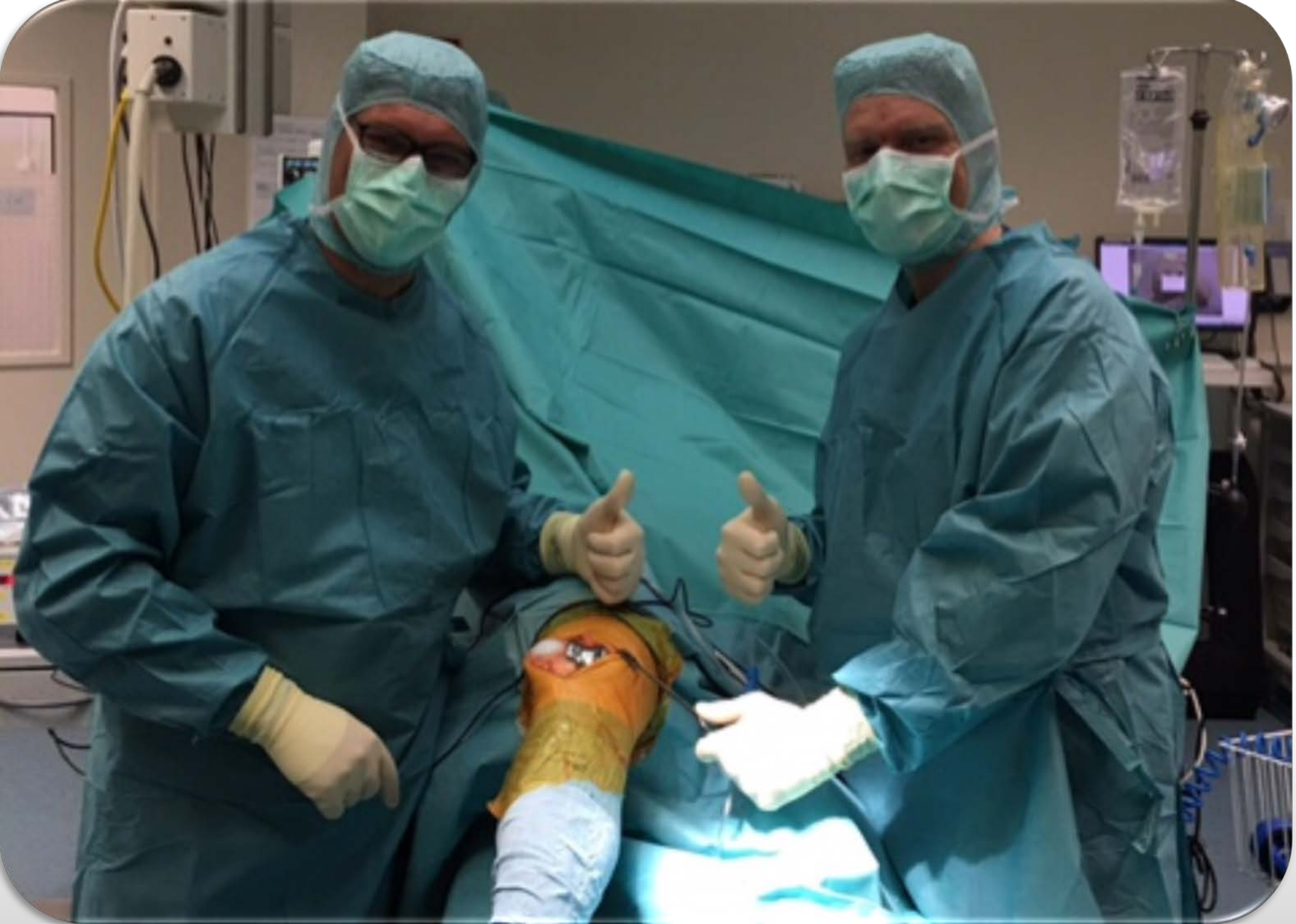
Courtesy of A Lombardi MD



Lateral Release







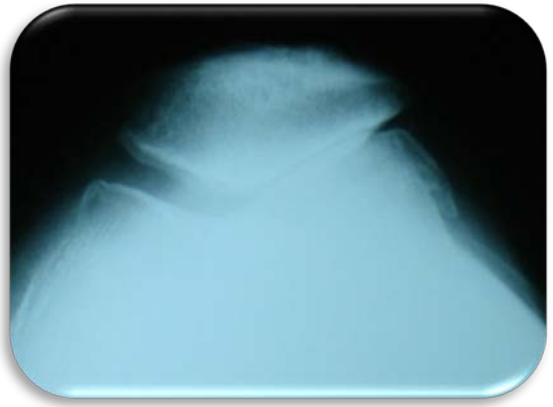
Surgical Technique

- Post-Operative Management

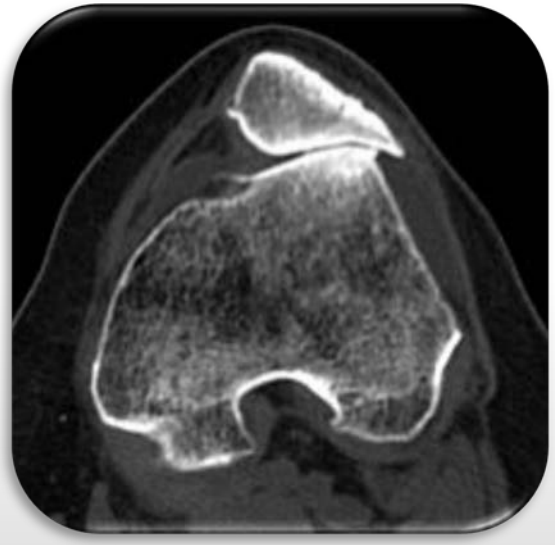
  - No demonstrated need for DVT prophylaxis
  - Rehabilitation is critical and much quicker than with TKA
  - Immediate full-weight bearing allowed
  - Physical therapy to restore quad strength

Illustrative Cases

- Case 1: “Normal” trochlea
- Case 2: Dysplastic trochlea
- Case 3: Surgeon Testimonial
- Case 4: Surgeon Testimonial



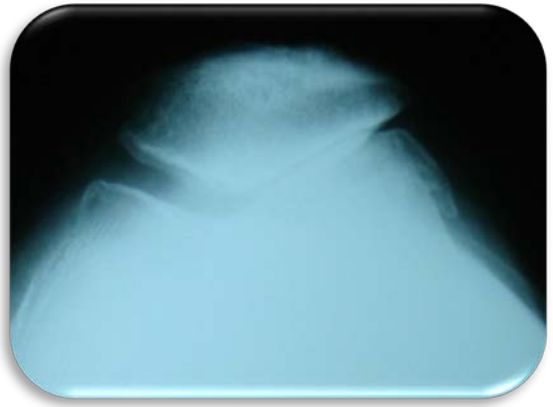
Courtesy of D Sisto MD



Courtesy of R Grelsamer MD

Case Study 1

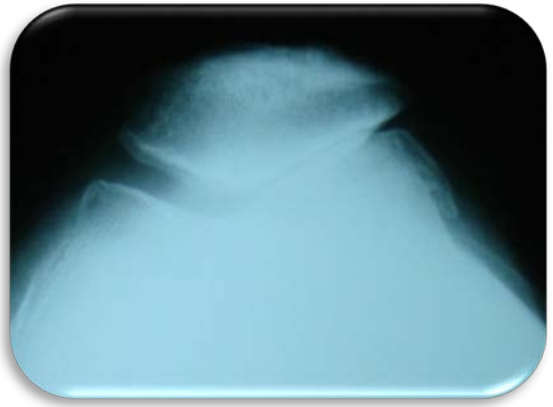
- Normal Trochlea



  - History
    - 49 year old male, post-traumatic twist injury
    - Arthroscopy and distal realignment (TTO)
    - Progressed to disabling PF disease
    - Could not do stairs, kneel, squat, or climb without severe pain

Case Study 1

- Physical Exam
  - Severe anterior tenderness, crepitus, grinding
  - No meniscal injury, no ligamentous instability
  - No medial/lateral tenderness
  - Radiographs positive for unicompartmental PF arthritis

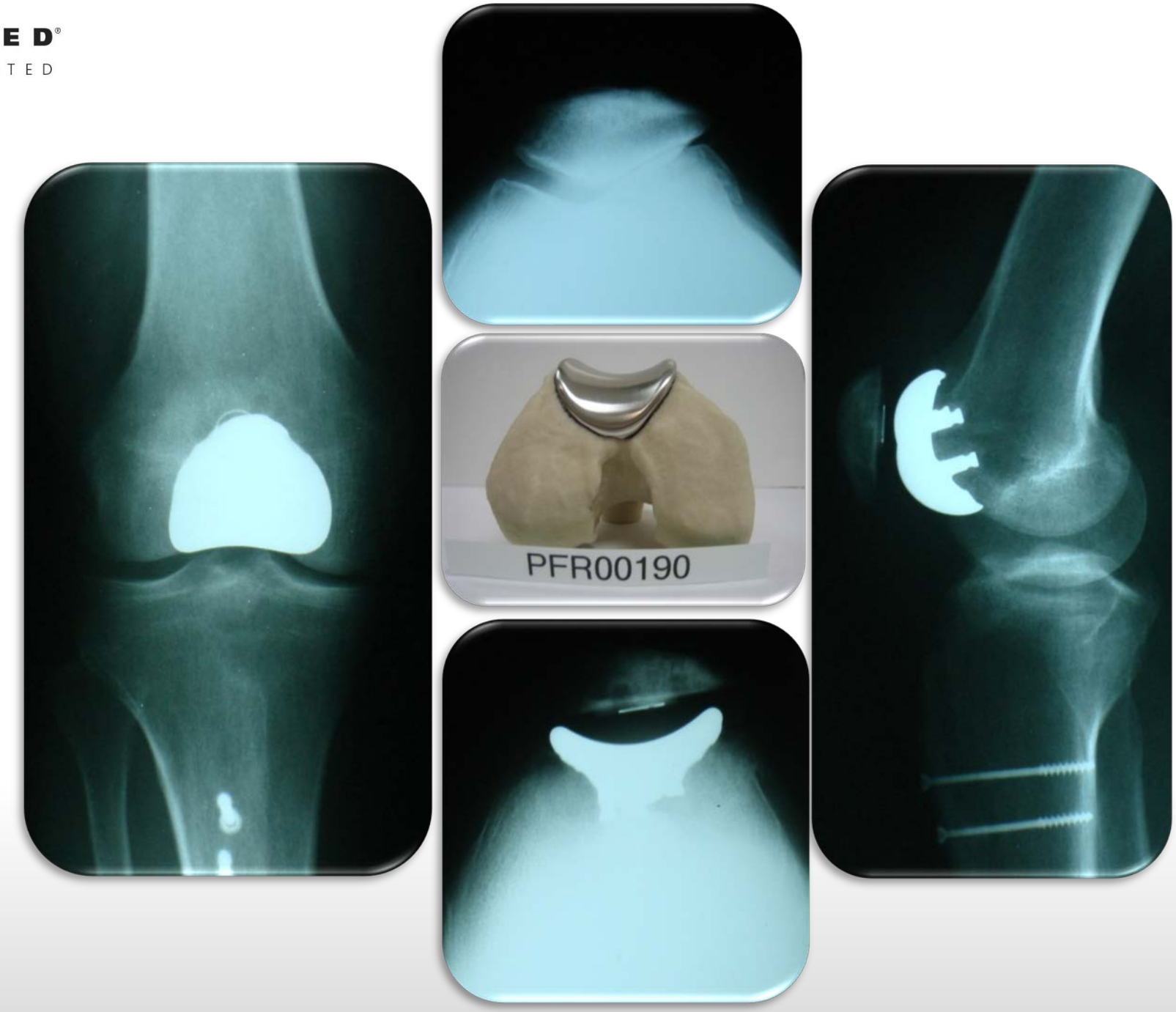


Case Study 1

- Conservative treatment was unsuccessful
  - Medications, heat, physical therapy
  - Hyalgan injections

- PFA with patient-matched implant

KINAMED®
INCORPORATED



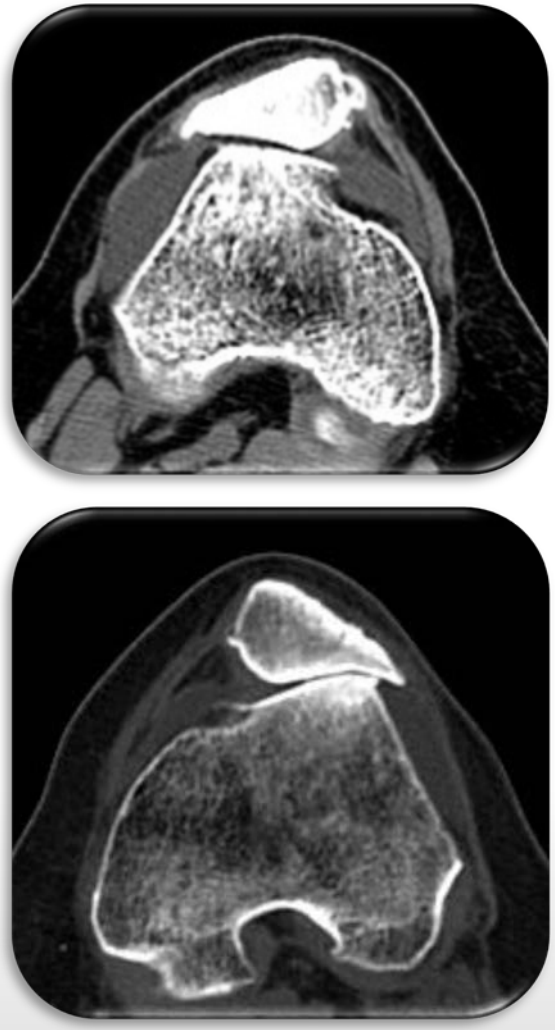
Case Study 1

- Post-Op (2 years out)
  - Has returned to full-time active work
  - No pain
  - No meds
  - Ambulates up/down stairs without assistance
  - Kneel, squat, climb without pain

Case Study 2

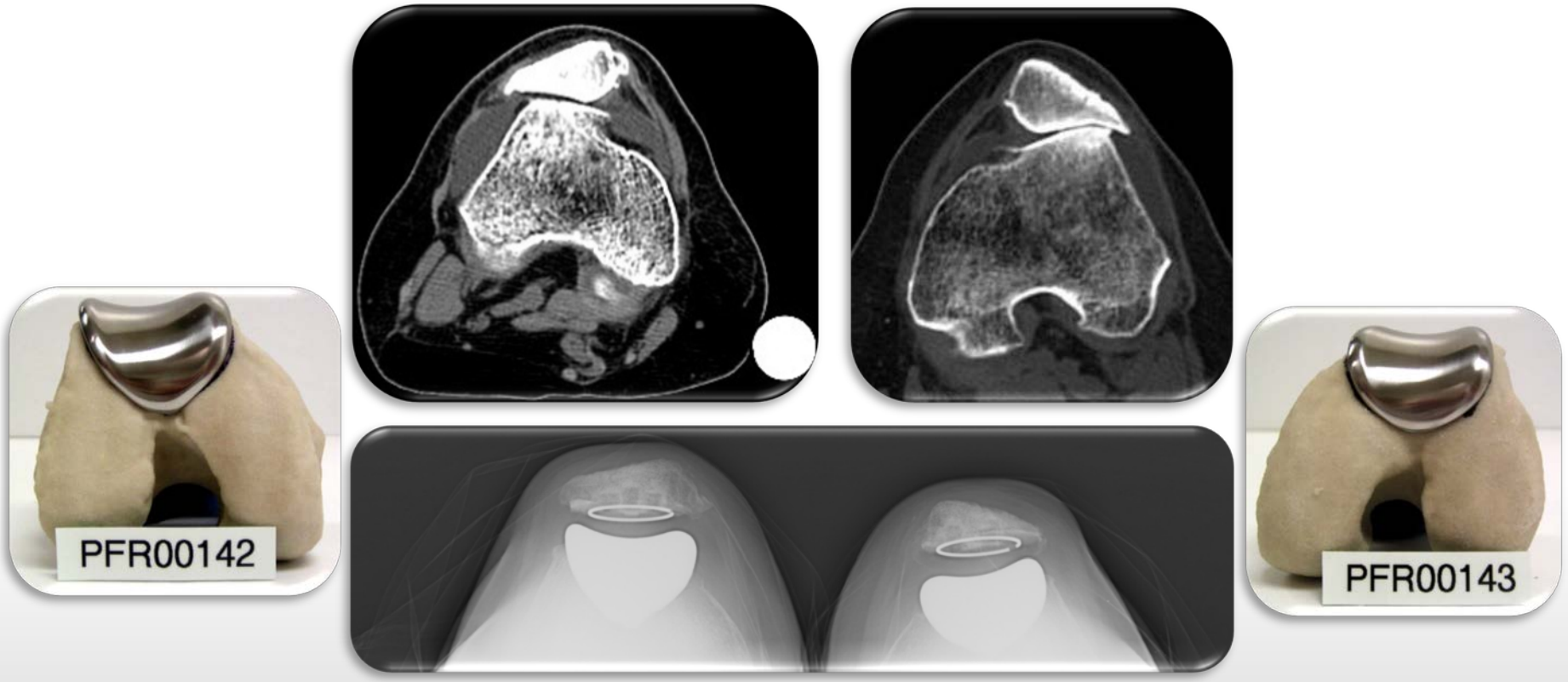
- Trochlear Dysplasia

  - History
    - 56 year old female, anterior knee pain since teenager
    - Failed non-operative treatments
      - Activity modification, pain meds, steroid, visco-supplementation, injection, nutritional supplements, physical therapy
    - Negative for inflammatory arthritis
    - Imaging reveal severe bilateral PF dysplasia
      - Dejour Type C/D with chronically subluxed patellae



Case Study 2

Staged (3 months apart) bilateral PFA with patient-matched implants

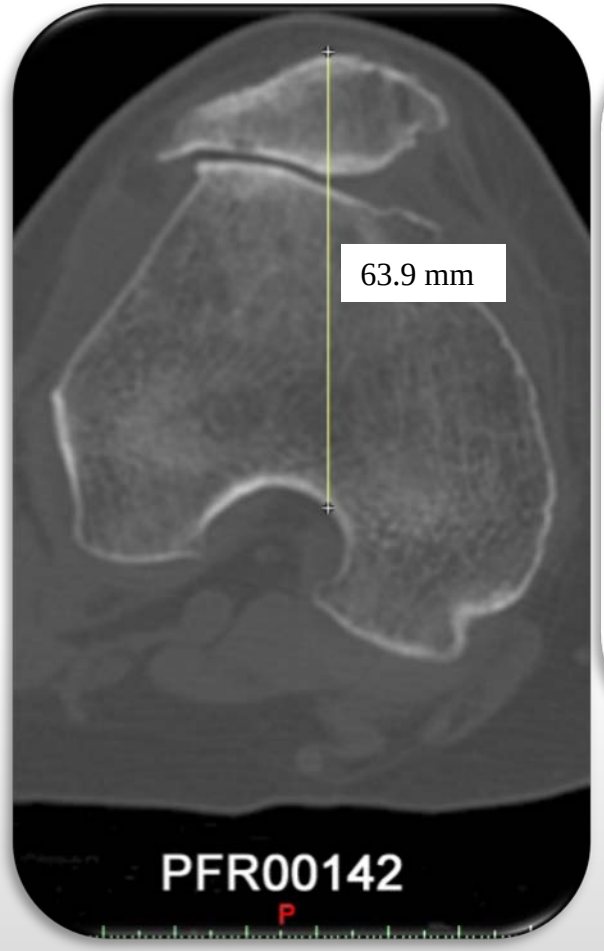


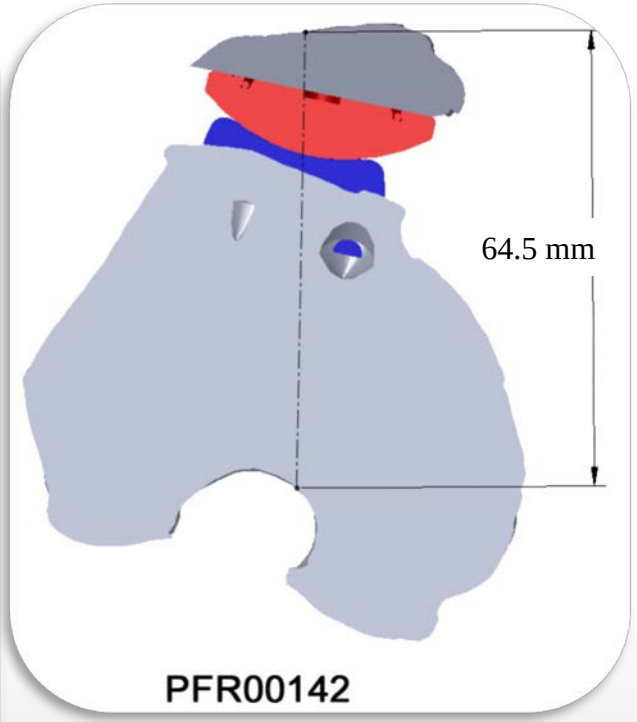
Case Study 2

- Post-Op (3 years out)
  - Patellae centered within patient-matched trochleas
    - Extensive lateral release, medial plication
  - Flexes easily to 120°
  - Patient considers the procedure a success

Case Study 2

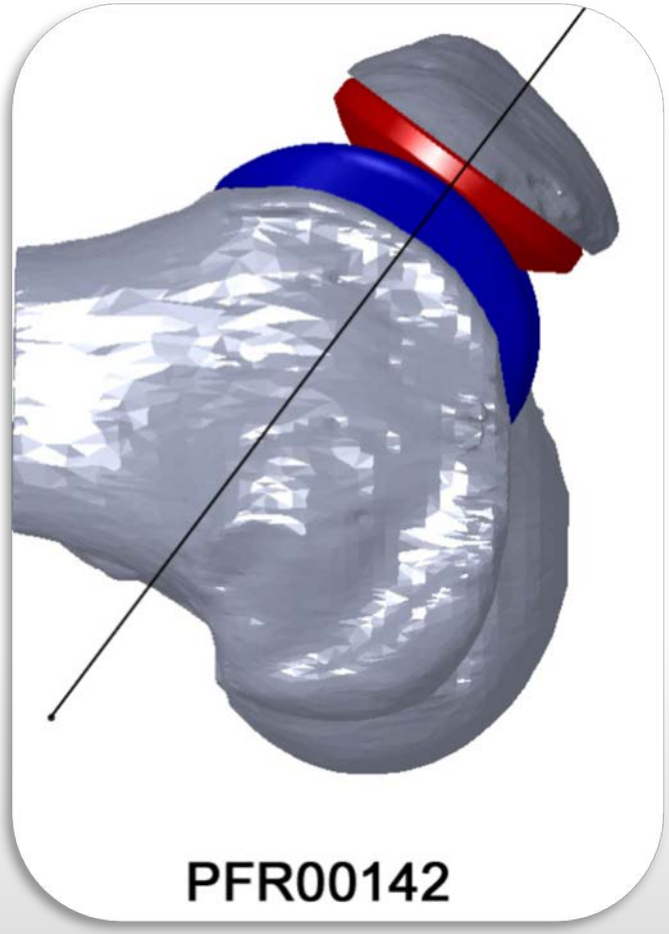
Patellar Offset

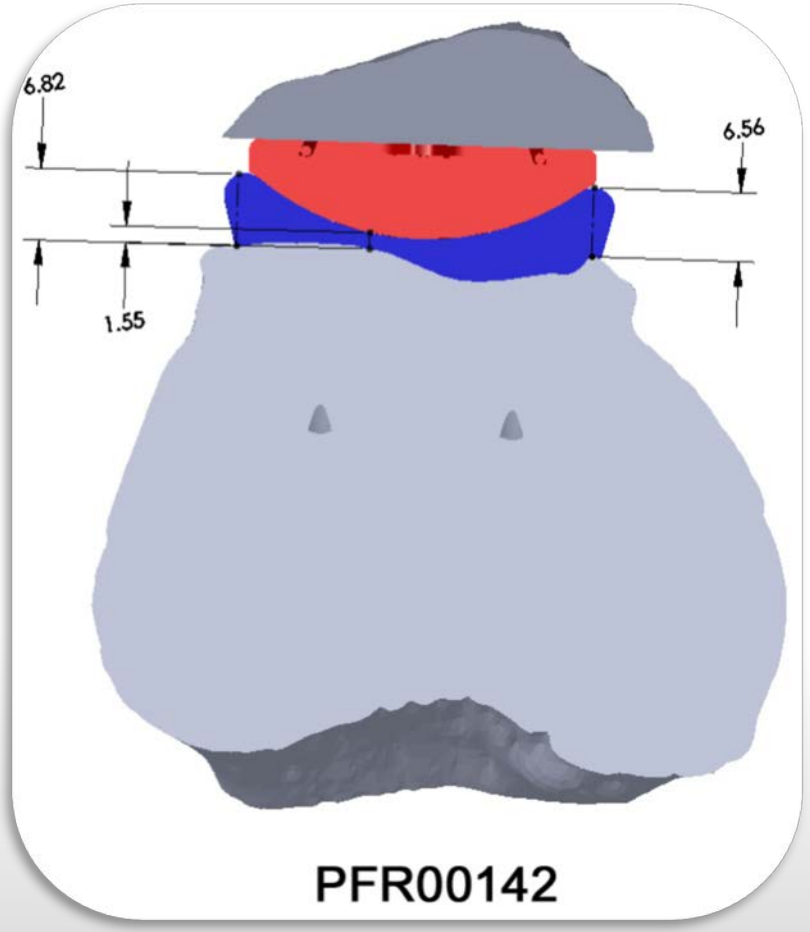




Case Study 2

Thickness





Case Study 3

Joint Preservation with *KineMatch*®
Patient-Matched Patellofemoral Replacement (PFR)

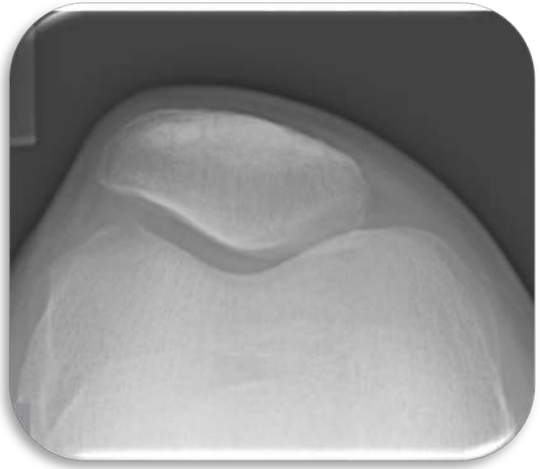
Jon Henry, MD
Aurora BayCare Orthopedic & Sports Medicine Center, Green Bay, WI, USA

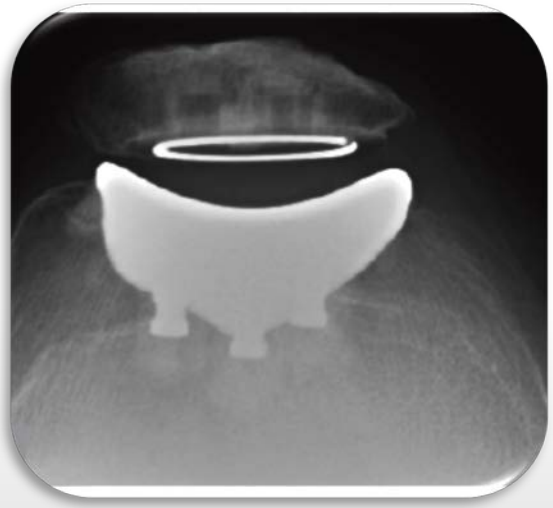
44 year old female with bilateral custom KineMatch PFR for progressive knee pain

Right Knee KineMatch PFR (DOS: May 2014)

An active, previously athletic 44 year old female with longstanding progressive right anterior knee pain was seen in December 2013. Clinical and radiographic studies showed moderately advanced osteoarthritis isolated to the patellofemoral joint. Conservative treatment measures (previous arthroscopic chondroplasty, NSAIDS, cortisone and visco-supplementation injections, physical therapy, activity modification) had been exhausted and a CT-based KineMatch PFR was offered.

In my experience the KineMatch PFR has been an excellent option for younger (<55 year old) patients with end-stage OA isolated to the PF joint. We have used the KineMatch system with success on more than 60 patients in our practice since 2007. With proper patient selection this has been a reliable and powerful tool to restore quality of life, even in individuals with very active lifestyles.





VIDEO

Patient Testimonial

Case Study 4

Getting A Patient Back "In The Game" with *KineMatch®* Patient-Matched Patellofemoral Replacement (PFR)

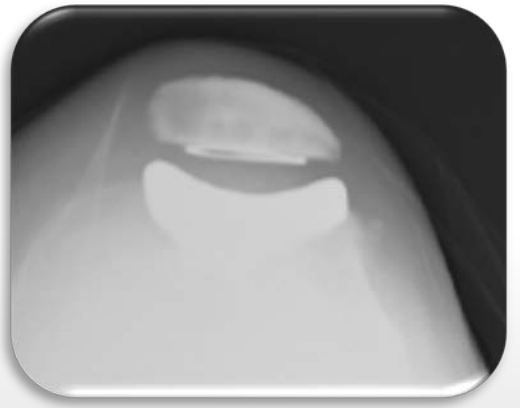
Robert J. Greenhow, MD, FRCSC, Diploma Sports Medicine

Peak Orthopedics and Spine (a division of Orthopedic Centers of Colorado)
Englewood, Colorado, USA

An active, athletic 67 year old male presented with bilateral anterior knee pain and grinding under his knee caps during flexion and extension. An avid golfer, he reported significant difficulties bending down to place a tee and when reading his putts. Previous conservative treatment measures (activity modification, physical therapy, NSAIDS, and bilateral knee viscosupplementation injections) had proven ineffective.

On a recent phone interview at more than five years post-op, the patient has no knee pain and is "delighted" with his outcome. He currently works as a Marshall at a golf course and is able to play regularly. He can bend down to read putts and place his tee with no pain or grinding.

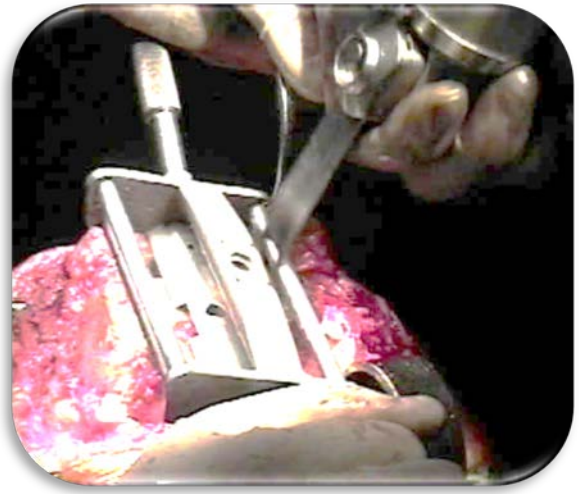
I began using the KineMatch PFR in 2011 and have performed over 90 cases to date. I have found this device to be an excellent solution for patients with isolated end-stage patello-femoral disease.

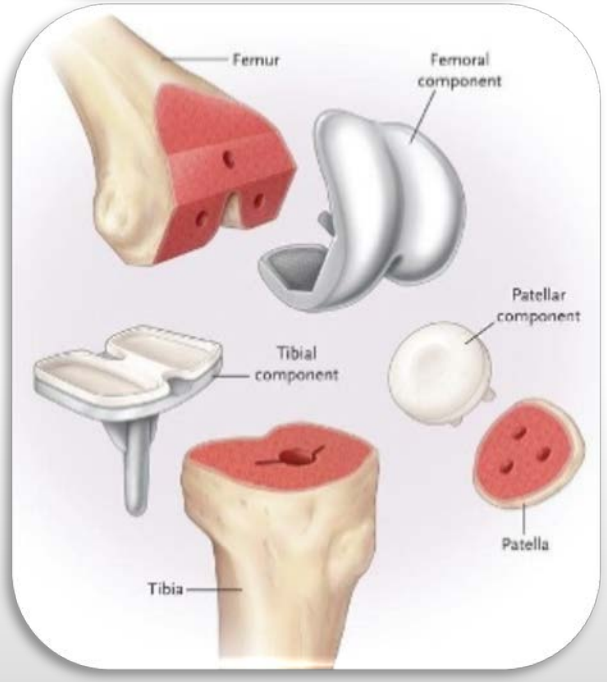


Advantages

PFR advantages versus TKR

- Typically young, active patients (Too young for TKR)
- Preserves ACL and natural, healthy femoro-tibial compartments
- PFR is a much less invasive than TKR with 1/3 the morbidity, rehab and recovery time
- PFR with patient-matched device is a quicker surgical procedure than TKR





Advantages

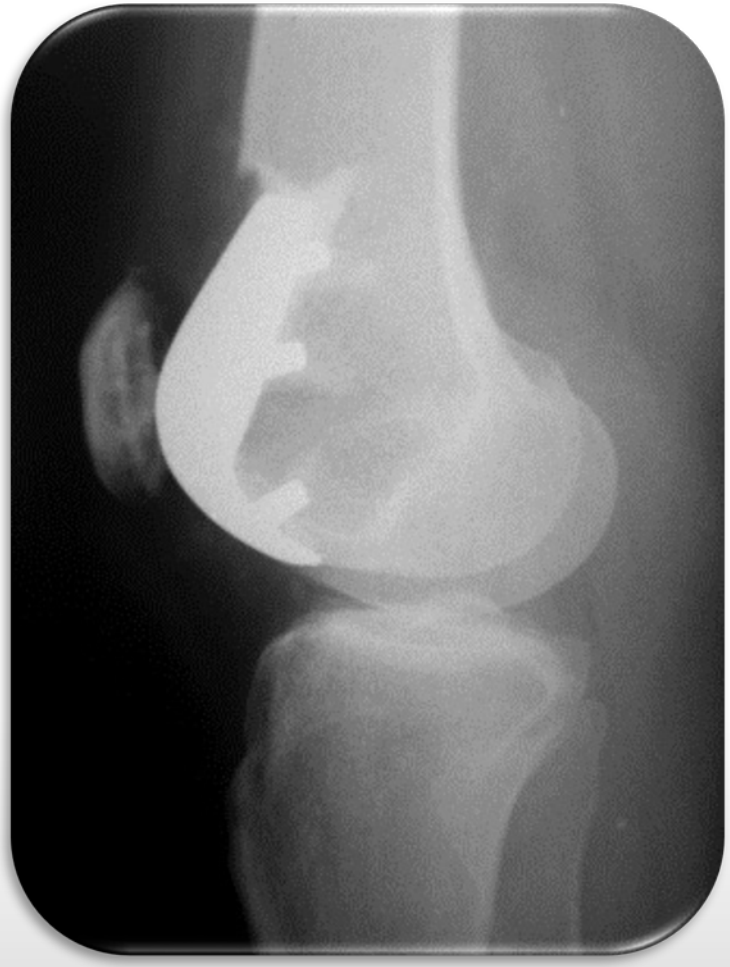
Patient-Matched PFR advantages versus TKR

- Eliminates IM invasion with an alignment rod and thus embolization of fat and marrow.
- Patient-Matched PFR is a bone sparing, temporizing procedure, even if the disease ultimately progresses to other joint compartments.
- Look at the X-rays to the right – does it make sense to saw off all the bone required for TKR when the natural femoro-tibial articulations are healthy and a proven solution is available?

Advantages

KineMatch Custom PFR versus off-the-shelf (OTS) PFR products

- OTS designs have given PFR a “bad name”
- Because of fit problems associated with OTS designs, most surgeons have experienced frustratingly inconsistent results
- OTS PFR devices are difficult and tricky to implant
- KineMatch is a quick easy surgical procedure



Advantages

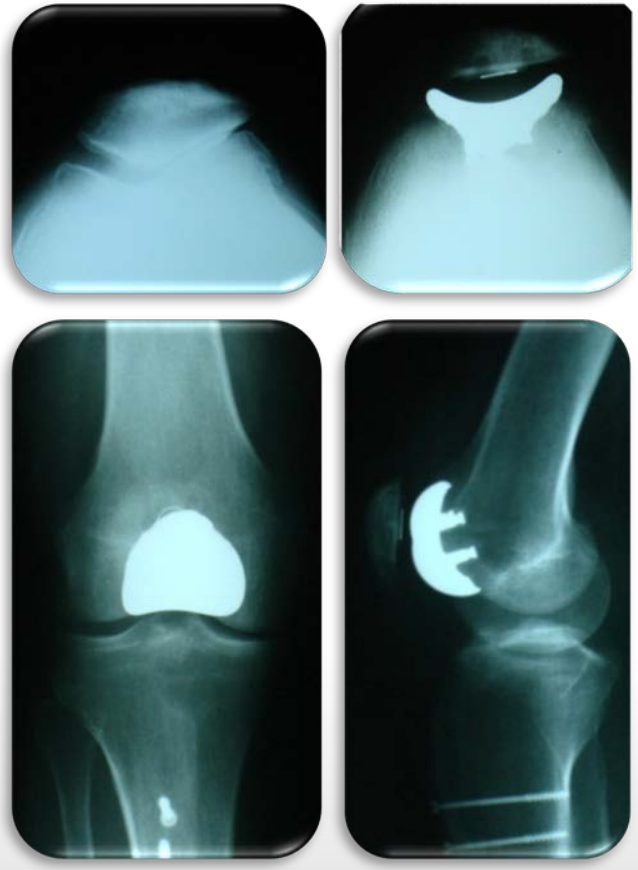
KineMatch Patient-Matched PFR versus off-the-shelf PFR products

- Customization solves the problems inherent in OTS designs
- KineMatch provides a precise fit in the trochlear groove to address problems of:
  - patellar catching
  - soft tissue impingement and pain
  - poor patellar tracking and stability

Advantages

KineMatch Custom PFR versus off-the-shelf PFR products

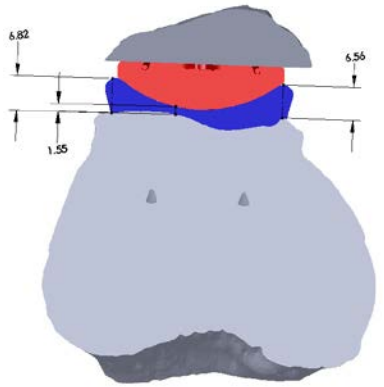
- It is believed that poorly fitting OTS implants can lead to disease progression in the femoro-tibial articulations.
- Poor fit will negatively affect the mechanics of all knee compartments (including medial and lateral compartments).
- The KineMatch PFR is designed to restore the mechanics of the PF compartment and therefore maintain the native mechanics of the tibio-femoral compartments.



Advantages

KineMatch Custom PFR versus off-the-shelf PFR products

- Customization provides a perfect fit without bone resection
- No IM rods, bone cuts or sculpting required with KineMatch
- Four KineMatch cases below show variable anatomy of the trochlea



FAQ

The implant looks thick – won't this "overstuff" the joint?

- The PFR femoral component thickness in the base of the groove is typically only about 3 to 4 mm.
- The normal articular cartilage on the patella is approximately 4 to 5 mm and in the trochlea it is approximately 2 to 3 mm, yielding a combined total cartilage thickness of 6 to 8 mm.
- Since this cartilage is removed prior to placement of the implants, there is little net change to the A-P position of the articulating surface and overstuffing of the joint is avoided.
- Also, the PFR femoral component tends to look thicker than its effective thickness in terms of patellar positioning.
- This is because the implant is typically thicker at the medial and lateral margins, where it is built up to provide stability for proper patella tracking, than in the base of the groove portion. These patients have often suffered from patellar subluxation and even dislocation.
- Clinical Results do not support this notion.

FAQ

The implant looks thick – won't this "overstuff" the joint?

Reconstructive Review
Volume 4, Number 1, March 2014

Original Article

Does the Kinematch® Prosthesis Impair Knee Flexion in Patients with Trochlear Dysplasia?

Ronald Grelsamer, MD§, Paul Cavallaro, BS†

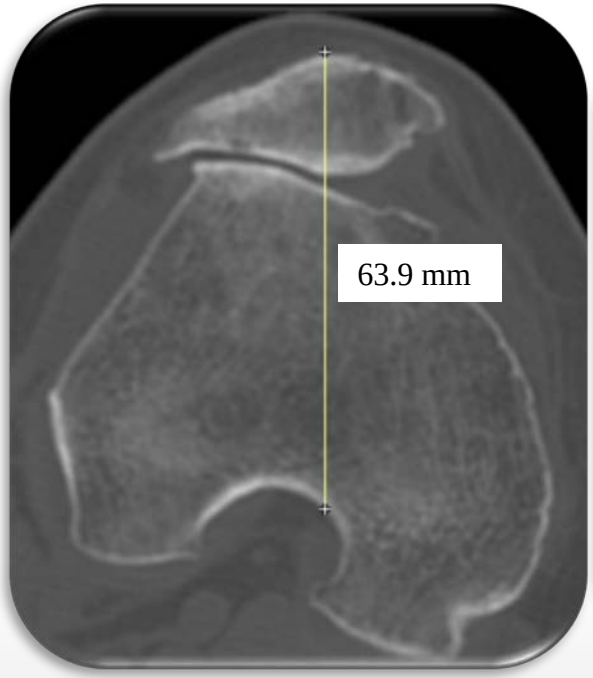
Abstract

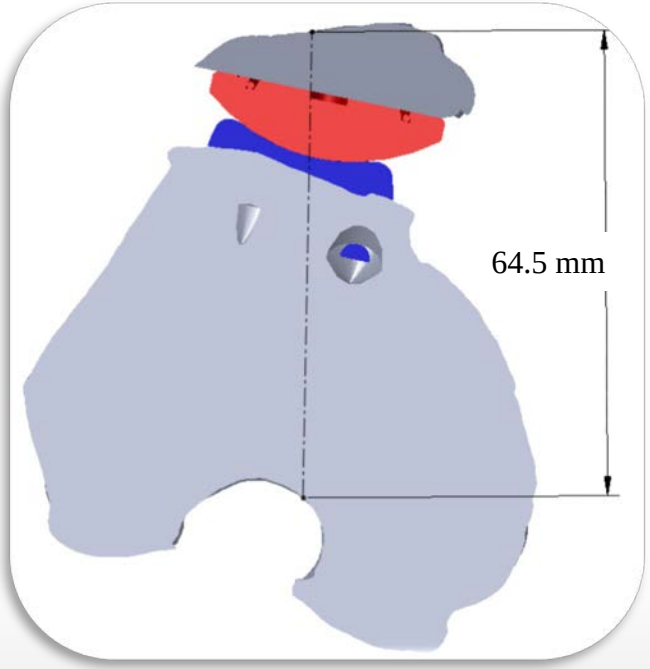
Background: Patellofemoral replacements are used to treat isolated patellofemoral arthritis in carefully selected patients. The Kinematch® custom-designed implant is placed directly on subchondral bone, leading critics of the device to believe that this results in overstuffing and limitation of flexion in cases of trochlear dysplasia; the current study aims to evaluate this premise.

Methods: A retrospective analysis of a consecutive series of 24 patients (32 knees) was conducted. Trochlear dysplasia was evaluated using pre-operative axial CT scans, and knees were categorized as having minimal or moderate/severe dysplasia (moderate = flat trochlea, severe = convex trochlea). The primary outcome was post-operative knee flexion.

Results: There was no statistical or clinical difference in post-operative knee flexion between the minimal (120°+12) and the moderate/severe dysplasia (117°+9) groups (p=.34).

Conclusions: Use of the Kinematch® patient-specific custom trochlear component does not significantly limit flexion in cases of trochlear dysplasia, and although the surgeon has the ability to deepen the trochlea by way of the pre-operative model, this is not necessary.

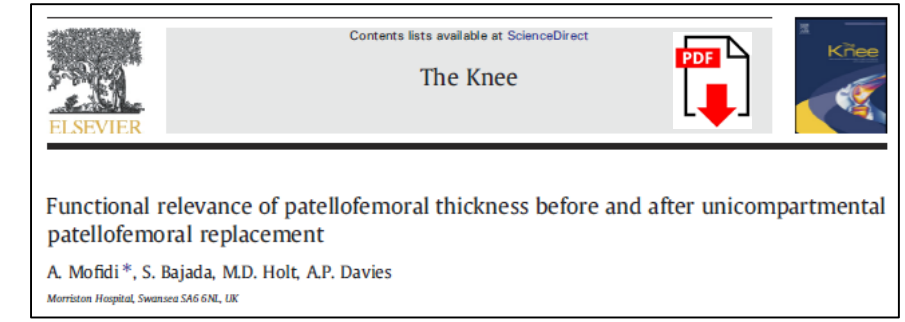




FAQ

What about “Overstuffing”?

- 28 pts (34 knees) with isolated PFA
- Trochlear height, patellar thickness compared pre and post
- ROM and functional outcomes measured at 1 yr
- AP height of knee increased by 6mm on average
- ROM and clinical outcome not affected



Mofidi et al (2011) Functional relevance of PF thickness before and after PFA

FAQ

What about “Overstuffing”?

The concept of overstuffing the patellofemoral joint has been simply and uncritically transferred from the femorotibial joint with no confirmatory studies. Because the capsule and inelastic ligaments secure the femorotibial joint, it is extremely important to balance these ligaments carefully during TKA and avoid a tibial insert that is too large. This will certainly overstuff this joint and lead to a poor result with decreased range of motion. The patellofemoral joint is a totally different articulation. Although the patellar ligament is inelastic, the quadriceps muscles are elastic and stretchable. This explains why the investigation by Bengs and Scott [5] not only failed to support the claim of overstuffing by Conley et al. [11], but actually refuted it. More recently, Pierson et al. [27] reviewed 830 primary TKAs to determine the effects of so-called overstuffing the patellofemoral joint. Their findings did “not support the widely held belief that stuffing of the patellofemoral joint results in adverse outcomes after total knee arthroplasty.”

Clin Orthop Relat Res (2008) 466:3059–3065
DOI 10.1007/s11999-008-0536-5

SURVEY

The Female Knee

Anatomic Variations and the Female-specific Total Knee Design

Alan C. Merchant MD, Elizabeth A. Arendt MD, Scott F. Dye MD, Michael Fredericson MD, Ronald P. Grelsamer MD, Wayne B. Leadbetter MD, William R. Post MD, Robert A. Teitge MD

Received: 14 May 2008 / Accepted: 10 September 2008 / Published online: 27 September 2008

Abstract The concept and need for a gender-specific or female-specific total knee prosthesis have generated interest and discussion in the orthopaedic community and the general public. This concept relies on the assumption of a need for such a design and the opinion that there are major anatomic differences between male and female knees. Most of the information regarding this subject has been disseminated through print and Internet advertisements, and through direct-to-patient television and magazine promotions. These sources and a recent article in a peer-reviewed journal, which support the need for a female-specific implant design, have proposed three gender-based anatomic differences: (1) an increased Q angle, (2) less prominence of the anterior medial and anterior lateral femoral condyles, and (3) reduced medial-lateral to anterior-posterior femoral condylar aspect ratio. We examined the peer-reviewed literature to determine whether women have had worse results than men after traditional TKAs. We found women have equal or better results than men. In addition, we reviewed the evidence presented to support these three anatomic differences. We conclude the first two proposed differences do not exist, and the third is so small that it likely has no clinical effect.
Level of Evidence: Level IV, systematic review. See the Guidelines for Authors for a complete description of levels of evidence.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

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Wayne State University, Warren, MI, USA

Introduction

Female-specific total knee implants have been marketed and promoted to orthopaedic surgeons and their patients despite a paucity of evidence-based, peer-reviewed information. Of two recent medical journal articles that advocated a female-specific knee design, one was an interview with the implant’s designer or consultant [6] and the other was a news release authored by a reporter quoting

Merchant, Arendt, Dye, Grelsamer, Leadbetter, Post, Teitge (2008)

FAQ

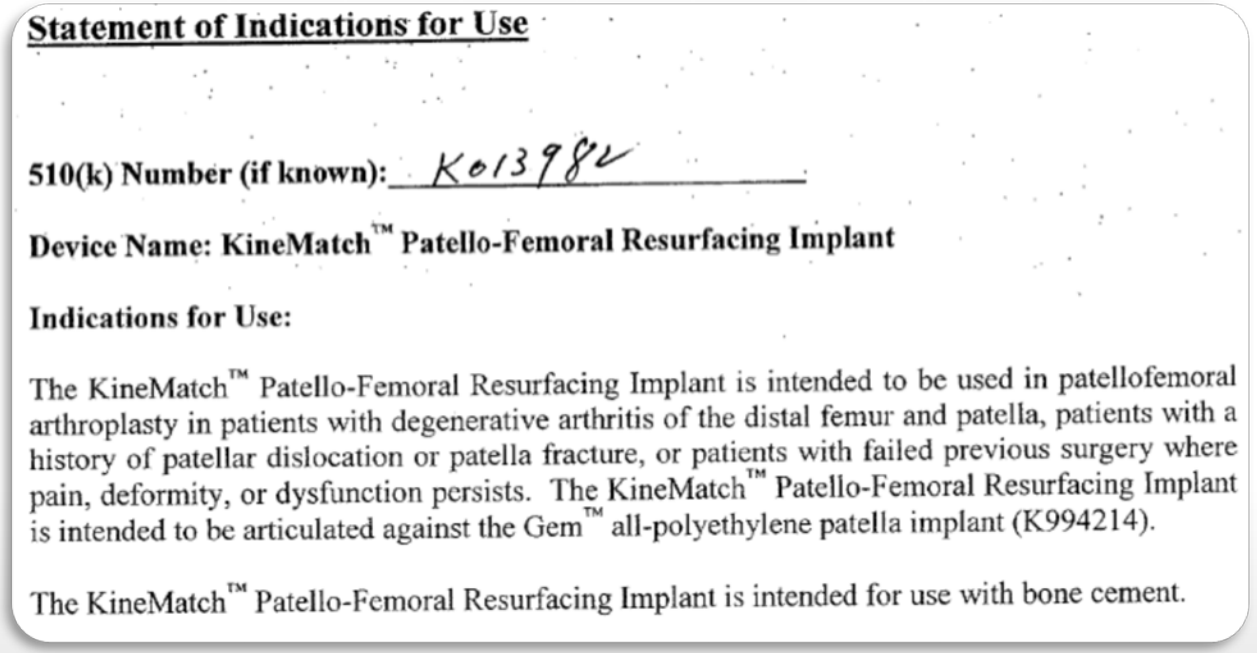
How do I determine if the patient has isolated PF disease?

- Radiographic evaluation using the Ahlbäck Score has proven to be a reliable diagnostic tool for identifying patients with isolated PF disease.
- This is a radiographic analysis of each individual compartment of the knee.
- An Ahlbäck Score worksheet is provided with the brochure
- It is also common that these patients have had fairly recent prior open or arthroscopic procedures performed where the condition of each compartment of the knee has been evaluated.

FAQ

Is the KineMatch system FDA cleared?

- **Yes, it has marketing clearance via 510(k) K013982**



Statement of Indications for Use

510(k) Number (if known): K013982

Device Name: KineMatch™ Patello-Femoral Resurfacing Implant

Indications for Use:

The KineMatch™ Patello-Femoral Resurfacing Implant is intended to be used in patellofemoral arthroplasty in patients with degenerative arthritis of the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery where pain, deformity, or dysfunction persists. The KineMatch™ Patello-Femoral Resurfacing Implant is intended to be articulated against the Gem™ all-polyethylene patella implant (K994214).

The KineMatch™ Patello-Femoral Resurfacing Implant is intended for use with bone cement.

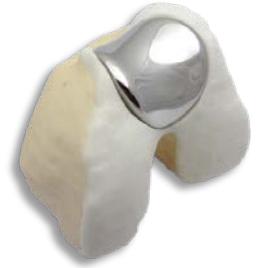
MDD Annex VIII. Per Article 4, Part 2, these devices (including patella) specifically do not bear the CE mark.

FAQ

Isn’t ordering a custom-made implant a hassle?

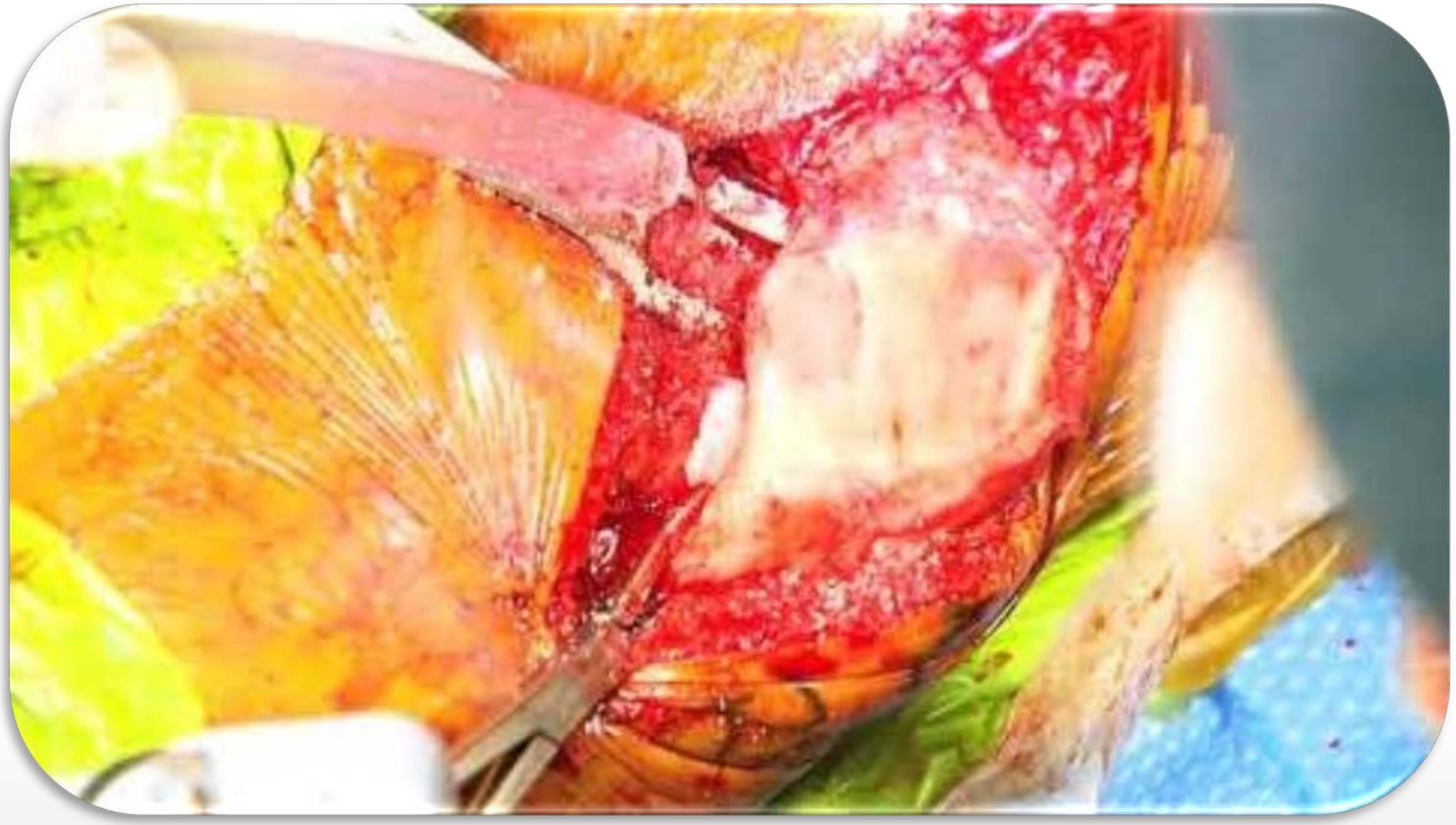
- After the surgeon signs the initial order form in the folder, s/he turns the process over to you and his scheduler – that’s it!
- CT protocol, including motion detection rod, assures proper scan.
- Kinamed produces the build plan and patient model.
- You ask the surgeon to sign off on the plan.
- Kinamed begins the manufacturing process, after receipt of PO.
- Kinamed coordinates implant delivery with you or the surgeon’s scheduler to plan date of surgery.
- Implant is shipped to you along with instruments.

Conclusions



- Patient-Matched PFA is safe and effective
  - Bone Preservation
  - Reproducible
  - No Guessing on Alignment
- Results compare very favorably with off-the-shelf prostheses
- Key elements for PFA success
  - Strict inclusion criteria based on pre-op imaging
  - Meticulous soft-tissue balancing and tracking assessment
  - Patient-Matched design for precise anatomic fit with proper alignment and medial-lateral constraint

CCJR Presentation



Courtesy of A Lombardi MD

VIDEO

Thank You!