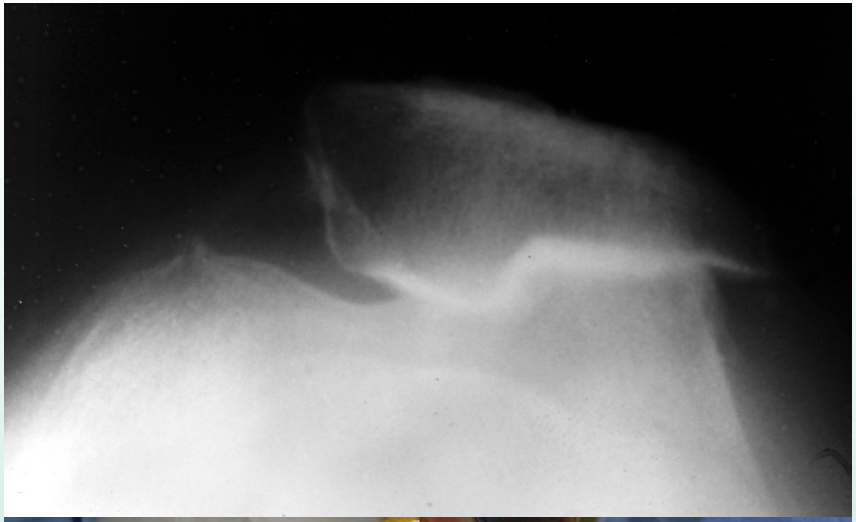
KINAMED®
INCORPORATED

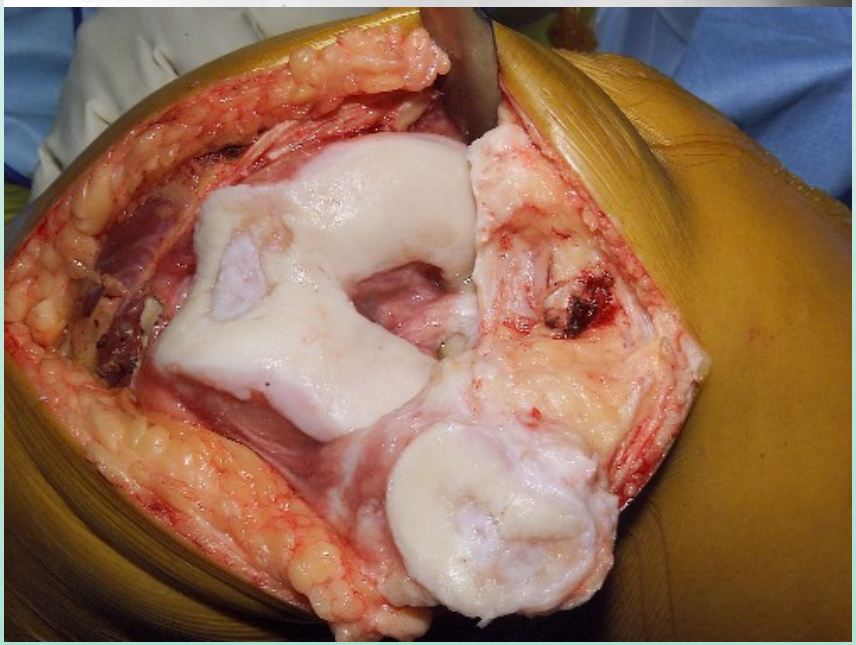
KineMatch® Custom-Fit Patello-Femoral Replacement

Indications

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.
- Much more common in women who comprise 75% of PFA patients.

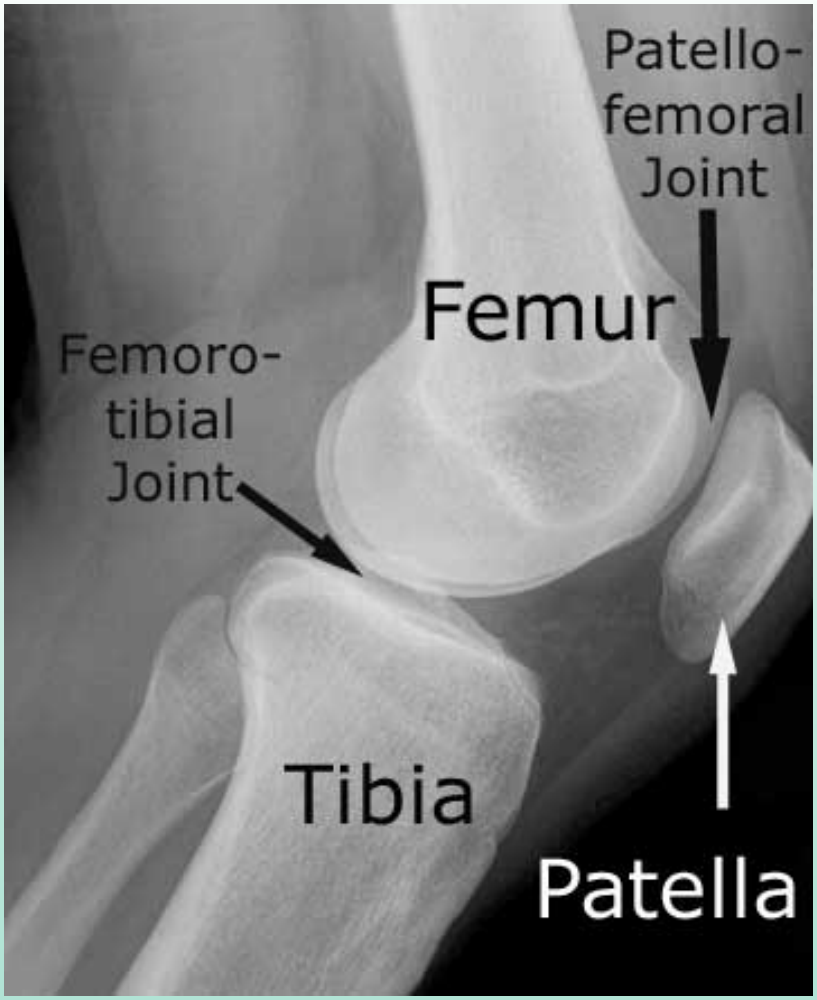




Some Basics

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 of line of pull of the quadriceps and patellar tendons. This creates a valgus or lateral vector in the patella as it tracks.



The Market

We estimate this to be a $100 million market in the US!

- Conservatively 3-5% of all knee arthroplasty patients are best treated with a PFR. An estimated 12,000-20,000 patients per year are candidates in the US.

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 bills at $X,XXX including the patella implant

- 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 Workmen's Comp patient.

The Market

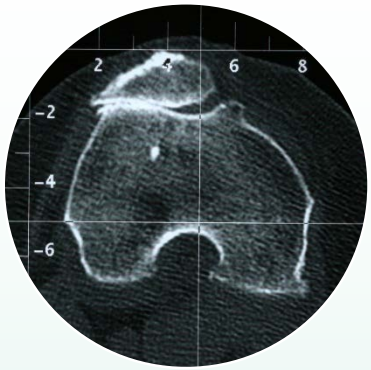
The 3 types surgeon classes

- Surgeons already using PFR (often unicondylar users also)
- Surgeons who go right to TKR
- Sports medicine surgeons that are not doing joints

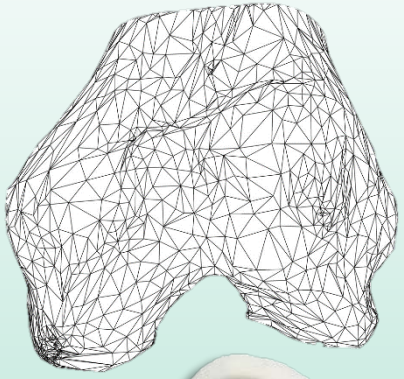
Your approach to each may be different

Our Product

A brief introduction to the KineMatch System



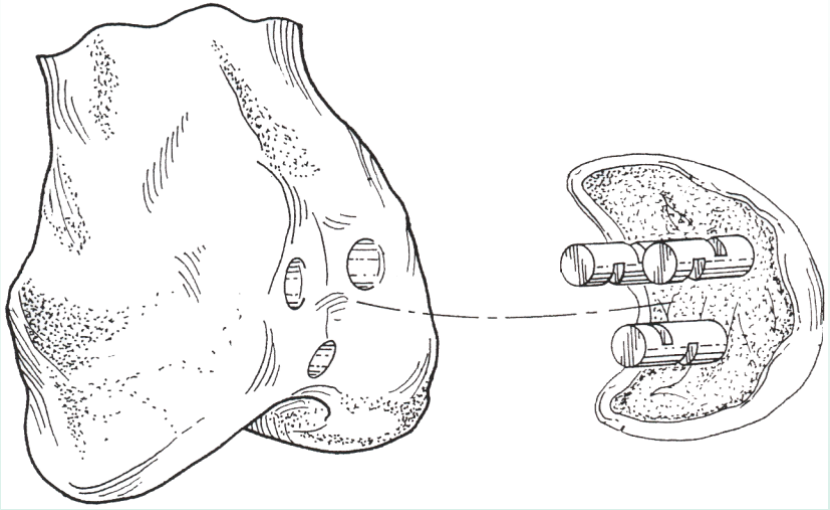
- Custom device based on CT data acquired per our CT scan protocol
- We provide:
  - **CT bone model**
  - **Custom Femoral Implant**
  - **Custom Drill Guide**
  - **Standard 3-peg dome patella**
  - **Loan of a simple instrument set**
- Delivery is 6 weeks after we receive proper CT scan data



Our Product

A brief introduction to the KineMatch System

- Femoral implant has fixation pegs on the backside and is fixed with bone cement (see Surgical Technique Guide).

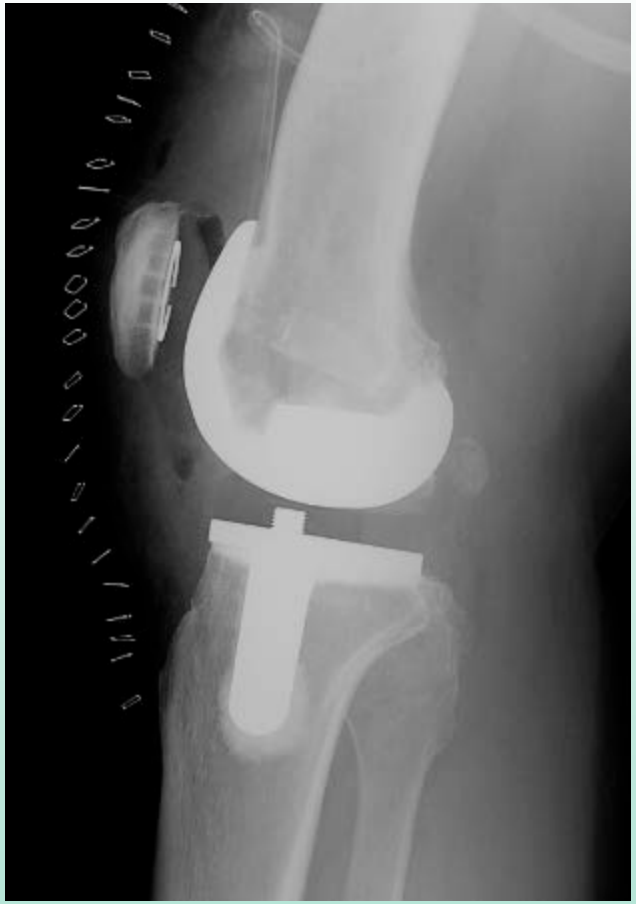


- Patella implant is an “all poly”, symmetrical dome, 3-peg design that is also cemented.

The Competition

Who is our competition?

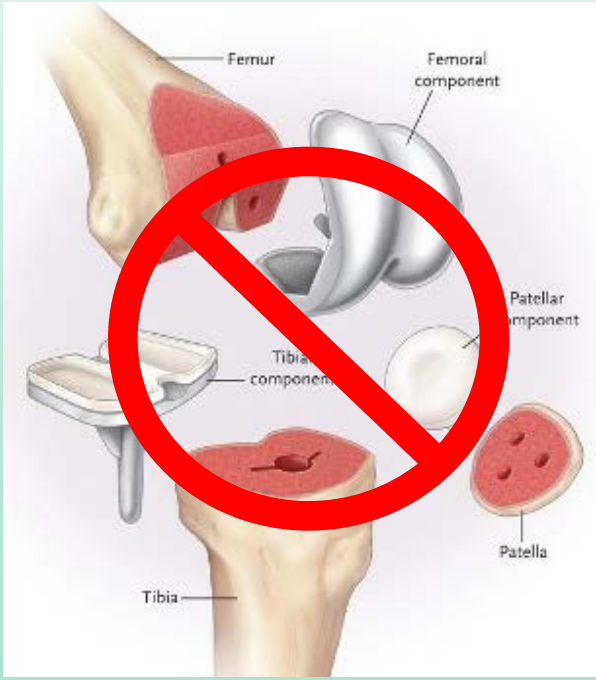
- Total Knee Replacement (works but not the best procedure for these patients!)
- Off-the-shelf PFR devices (poor results)
- Soft tissue and re-alignment procedures (poor results)
- Patellectomy (poor results – rarely performed nowadays)



The Competition

PFR advantages versus TKR

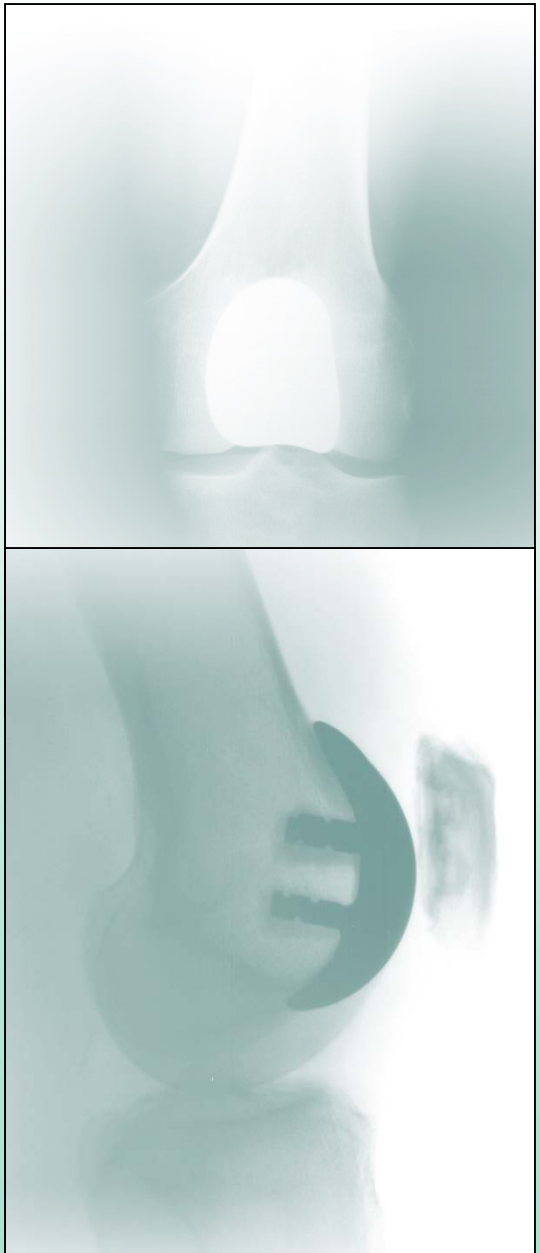
- Typically young, active patients – too young for TKR
- Patient functions better on their natural, healthy femoro-tibial articulations.
- PFR is a much less invasive than TKR with 1/3 the morbidity, rehab and recovery time.
- PFR with custom device is a quicker surgical procedure than TKR.



The Competition

Custom PFR advantages versus TKR

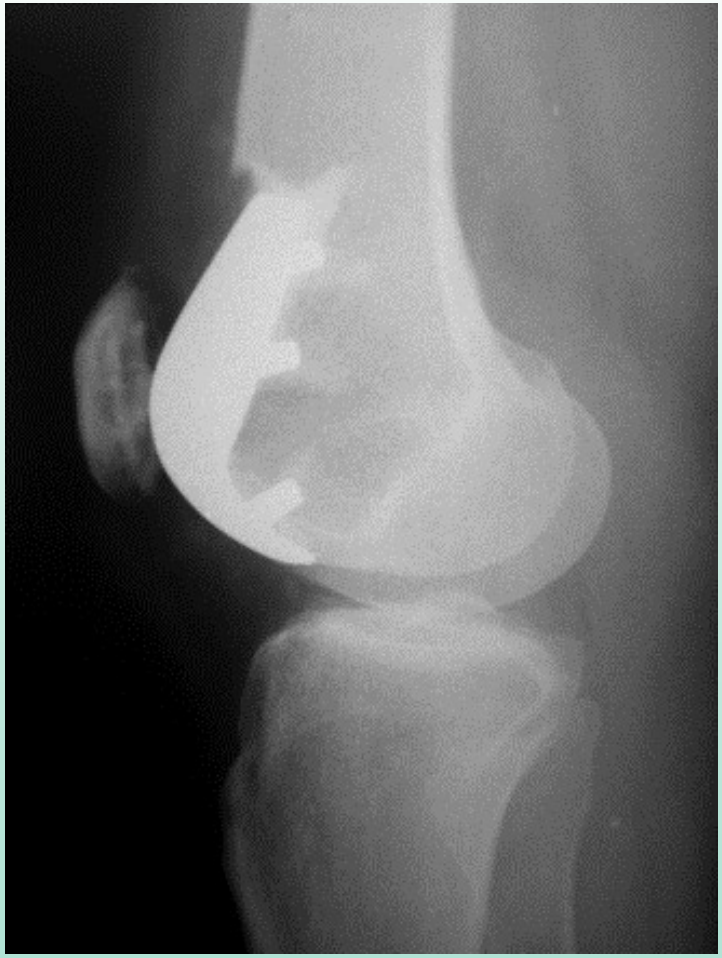
- Eliminates IM invasion with an alignment rod and thus embolization of fat and marrow.
- Custom PFR is a bone sparing, temporizing procedure, even if the disease ultimately progresses to other joint compartments.
- Look at the X-rays to the right – does it make sense to saw off all the bone required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



The Competition

KineMatch Custom PFR versus off-the-shelf 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 Custom is a quick easy surgical procedure.

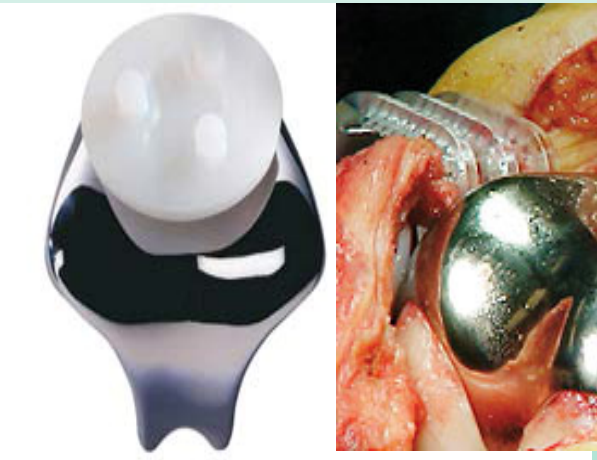


The Competition

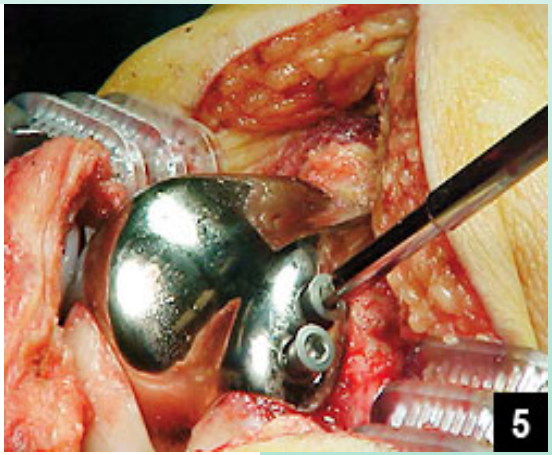
Companies & PFR Product Brand Names

- Arthrosurface – HemiCap
- Biomet – Vanguard OTS, Performa custom
- ConforMIS – iDuo (actually 2 compartment)
- DePuy – LCS
- Smith & Nephew - PFJ
- Stryker / Howmedica – Avon
- Zimmer – NexGen, Natural Knee II
- Link – Glide (still available?)

Zimmer NexGen



DePuy LCS



Biomet Performa

The Competition

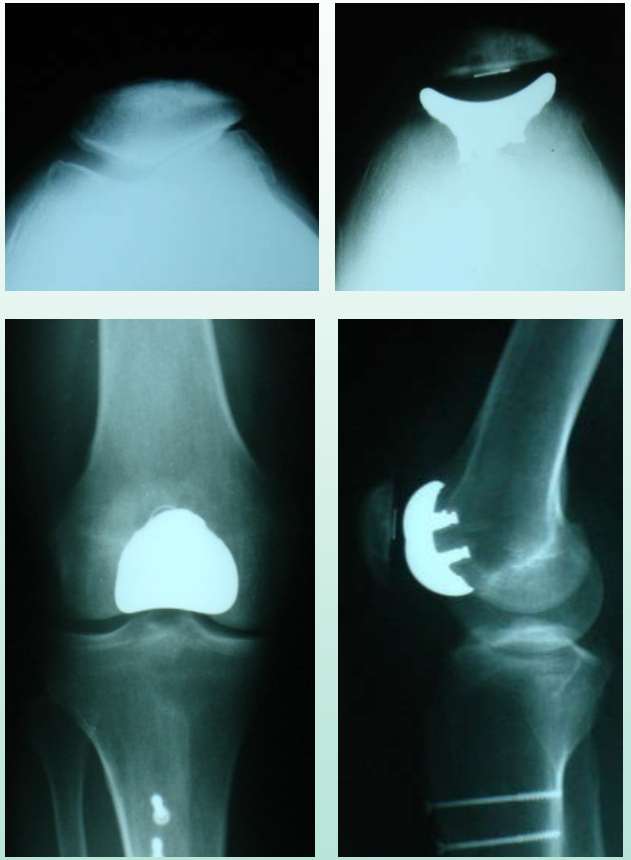
KineMatch Custom PFR versus off-the-shelf PFR products

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

The Competition

KineMatch Custom PFR versus off-the-shelf PFR products

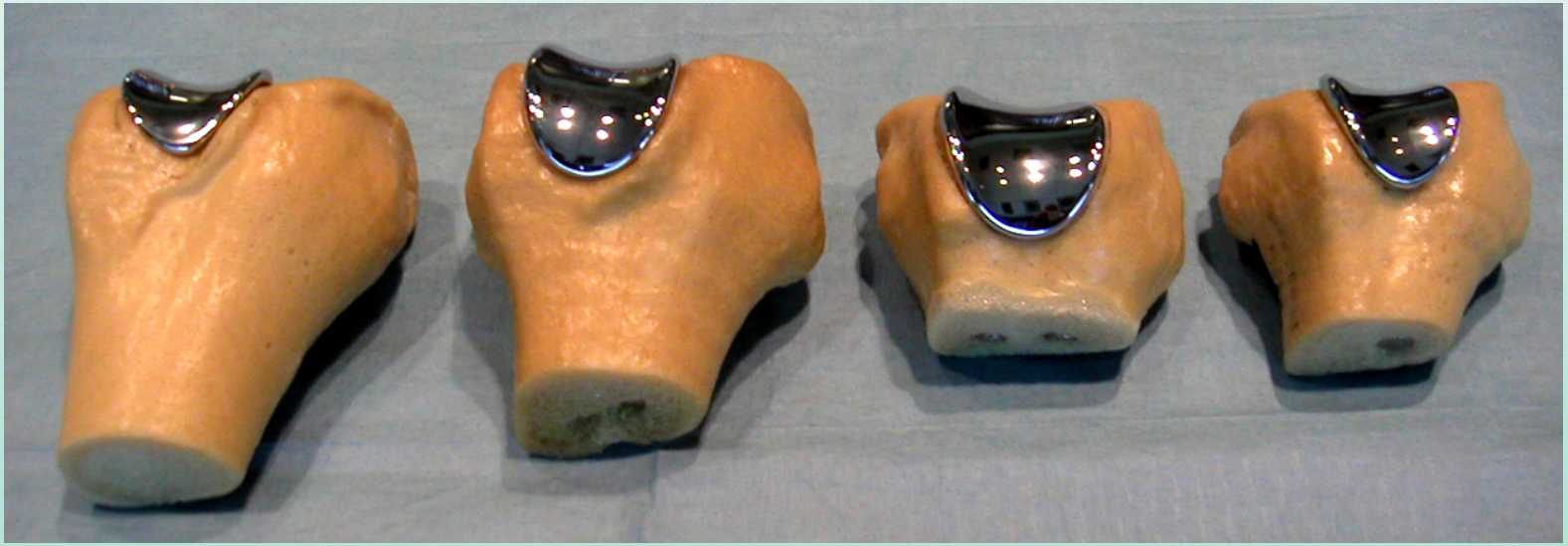
- It is believed that poorly fitting OTS implants can lead to disease progression in the femoro-tibial articulations.
- Poor fit will negatively affect the mechanics of all knee compartments (including medial and lateral compartments).
- The custom PFR approach is designed to restore the mechanics of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



The Competition

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



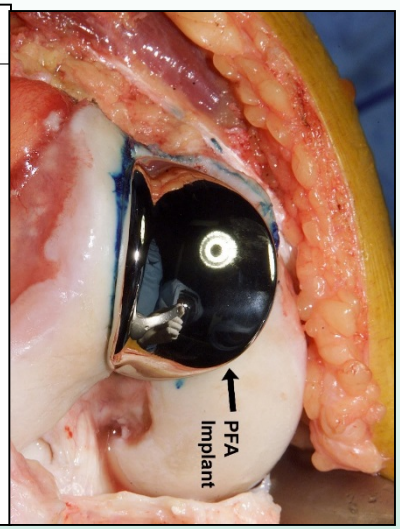
KineMatch PFR Clinical Data

J. Bone Joint Surg. Am 88:1475-1480, 2006

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**

Results:

- **100% Survivorship**
- **18 “Excellent” & 7 “Good”**
- **No revision, loosening, subsequent surgery**

Patello-Femoral Replacement Clinical Results

Author	#	FU (years)	Implant	Result
Ackroyd 2005	306	2 - 5	Stryker	87% not revised and complication-free
Arciero 1988	25	3 - 9	Richards	72% good or excellent, 12% revised
Argenson 1995	66	2 - 10	Medinov	85% not revised
Argenson 2005	66	12 - 20	DePuy	56% not revised
Blazina 1979	57	1 – 3.5	Richards	78% “much improved”
Cartier 1990	72	2 - 12	Richards	85% good or excellent, 8% complications
De Winter 2001	26	1 - 20	Richards	61% good or excellent, 19% reoperations
Kooijman 2003	45	15 - 21	Richards	62% not revised
Krajca 1996	16	2 - 18	Richards	88% good or excellent, 19% reoperations
Lubinus 1979	14	0.5 - 2	Link	“All improved”
Merchant 2004	15	2.2 – 5.5	DePuy	93% good or excellent on ADL scale
Smith 2002	45	0.5 – 7.5	Link	64% good or excellent, 19% revised
Tauro 2001	62	5 - 10	Link	45% “satisfactory”, 28% revised
Sisto 2006	**25**	**2.7 – 9.9**	**Kinamed**	**100% good or excellent, No complications**
Sisto 2011	**25**	**7.8-14.9**	**Kinamed**	**100% not revised, all patients stated they would undergo procedure again**

KineMatch PFR Clinical Data

Domenick J. Sisto, MD

- **Los Angeles Orthopaedic Institute, Sherman Oaks, CA**
- **Completed Orthopaedic Residency at Hospital For Special Surgery, NYC, 1984**
- **Completed Sports Medicine Fellowship at Kerlan-Jobe Orthopaedic Clinic, LA, 1985**
- **Dr. Sisto is not a paid “consultant” for Kinamed**

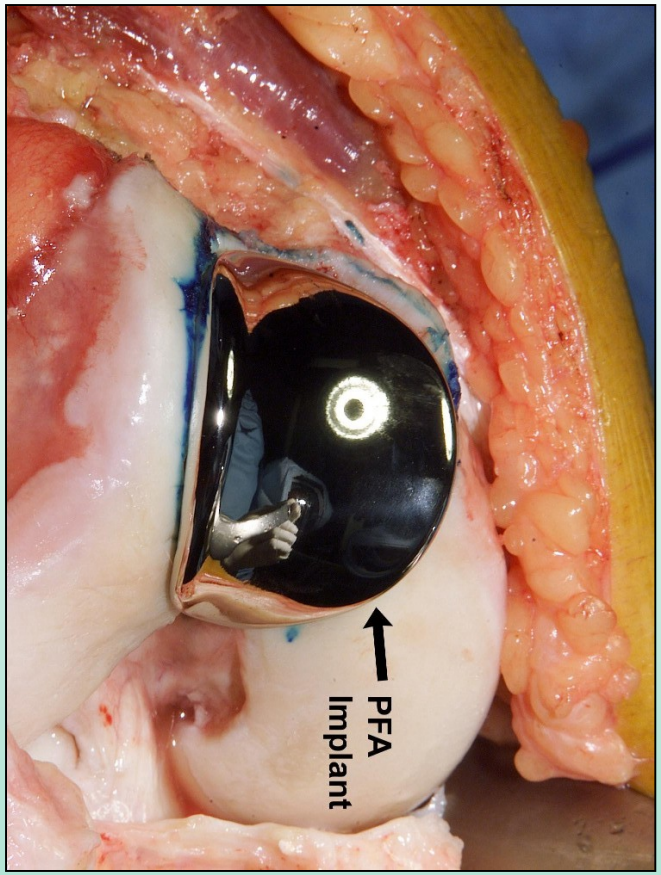
FAQs - Frequently Asked Questions

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.

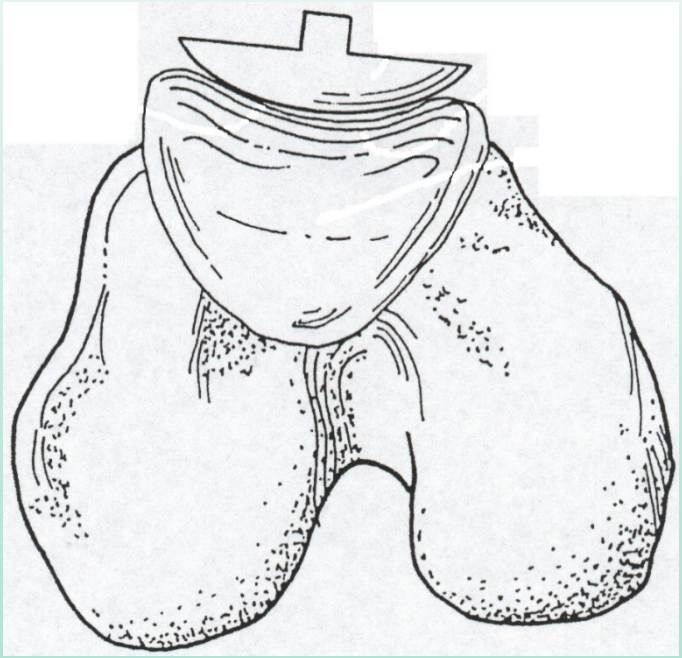
FAQs - Frequently Asked Questions

The implant looks thick – won't this cause "overstuffing" of the joint?



Note the even depth to medial/lateral compartment cartilage in the x-ray

Note the congruency at the edges of the dome patella.



Femoral implant is typically thinner in the central portion and thicker medially and laterally to provide congruency and tracking stability with the patella implant.

FAQs - Frequently Asked Questions

The implant looks thick – won't this cause "overstuffing" of 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.

FAQs - Frequently Asked Questions

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

- **Radiographic evaluation using the “Albach 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 Albach Score worksheet is provided with the brochure (back pocket)**
- **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.**

FAQs - Frequently Asked Questions

Is the KineMatch system FDA approved?

- **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.

FAQs - Frequently Asked Questions

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

- **“Abbreviate” the KineMatch ordering process**
- After the surgeon signs the initial order form in the folder, he turns the process over to you and his scheduler – that’s it!
- Kinamed assures proper the CT protocol is followed by contacting the scan site directly – providing everything - CT protocol, motion detection rod and optical data storage disk.
- Kinamed produces the build plan, patient model and assistance with insurance payment clearance.
- You get surgeon to sign off on plan, and a PO from hospital
- Kinamed begins the manufacturing process – usually after receipt of PO from the hospital.
- Kinamed coordinates implant delivery with surgeon’s scheduler to plan date of surgery.
- Implant is shipped to you along with loaner instrument set.

FAQs - Frequently Asked Questions

Isn't it too expensive? My hospitals limit knees to $"X"

- Most patients are young – covered by insurance
- Review codes – equipment code = L5700 CPT code = 27446.
- Review list of insurance companies having covered the procedure
- The hospital is not exposed to a revenue-losing procedure once the insurance company clears the patient for the procedure

How to ensure the DOS goes smoothly

Pre-op

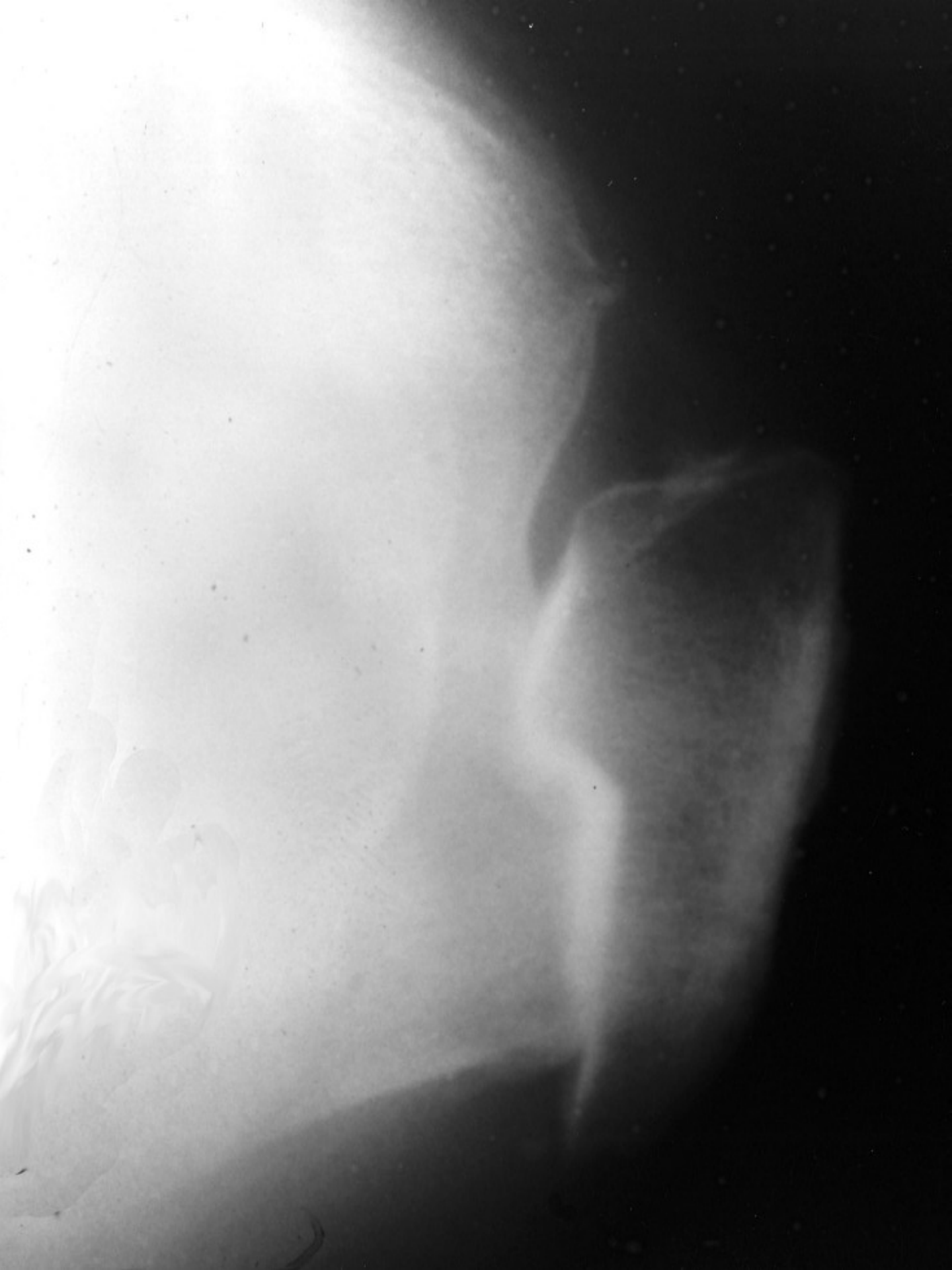
- Go over the instrumentation with the surgeon BEFORE the case – preferably the day before - so that you can go through a “hands-on” of the instruments with them when they are not sterile
- Make SURE that they have sterilized the drill guide as soon as you arrive the day of the surgery

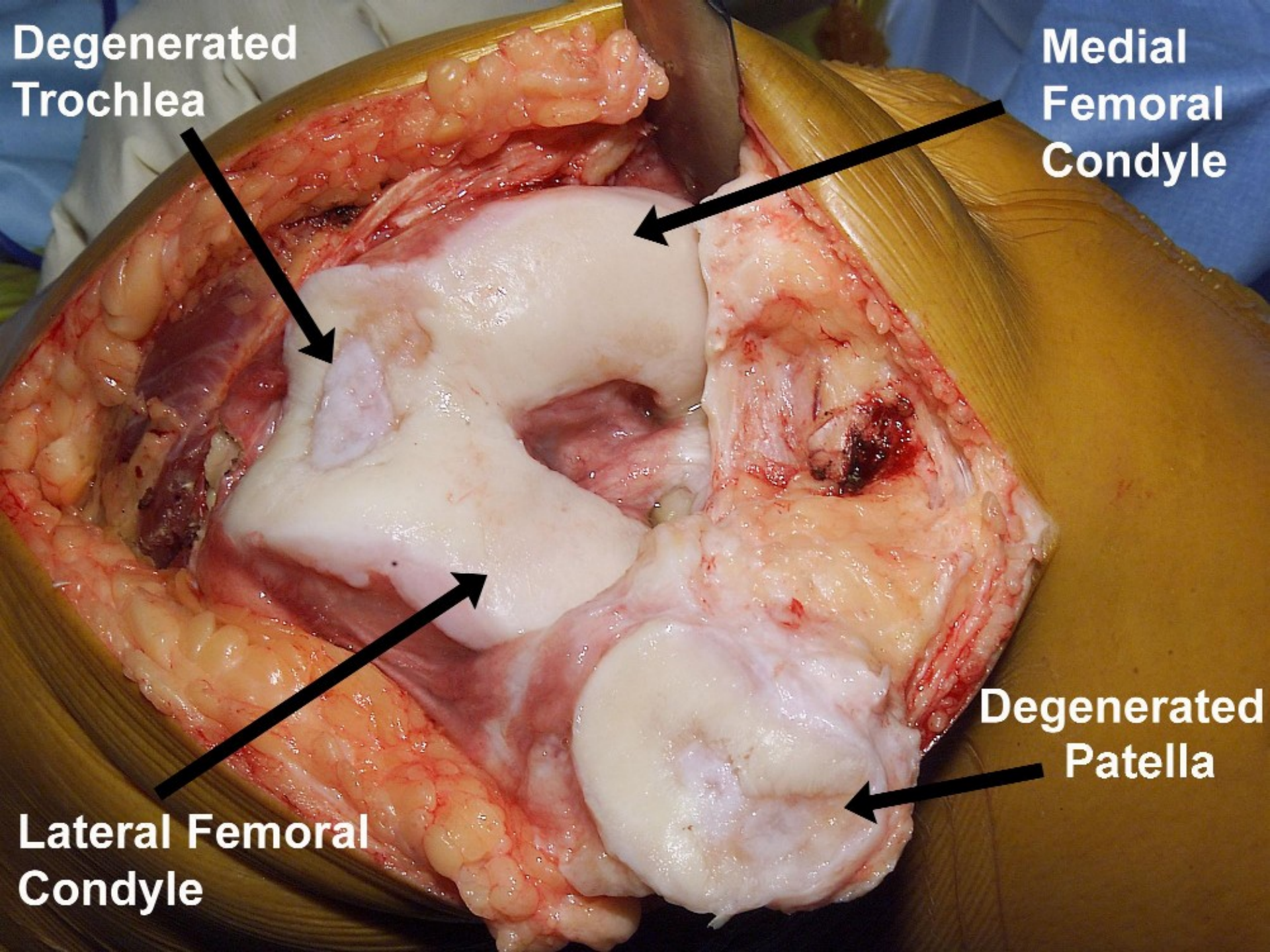
During the case

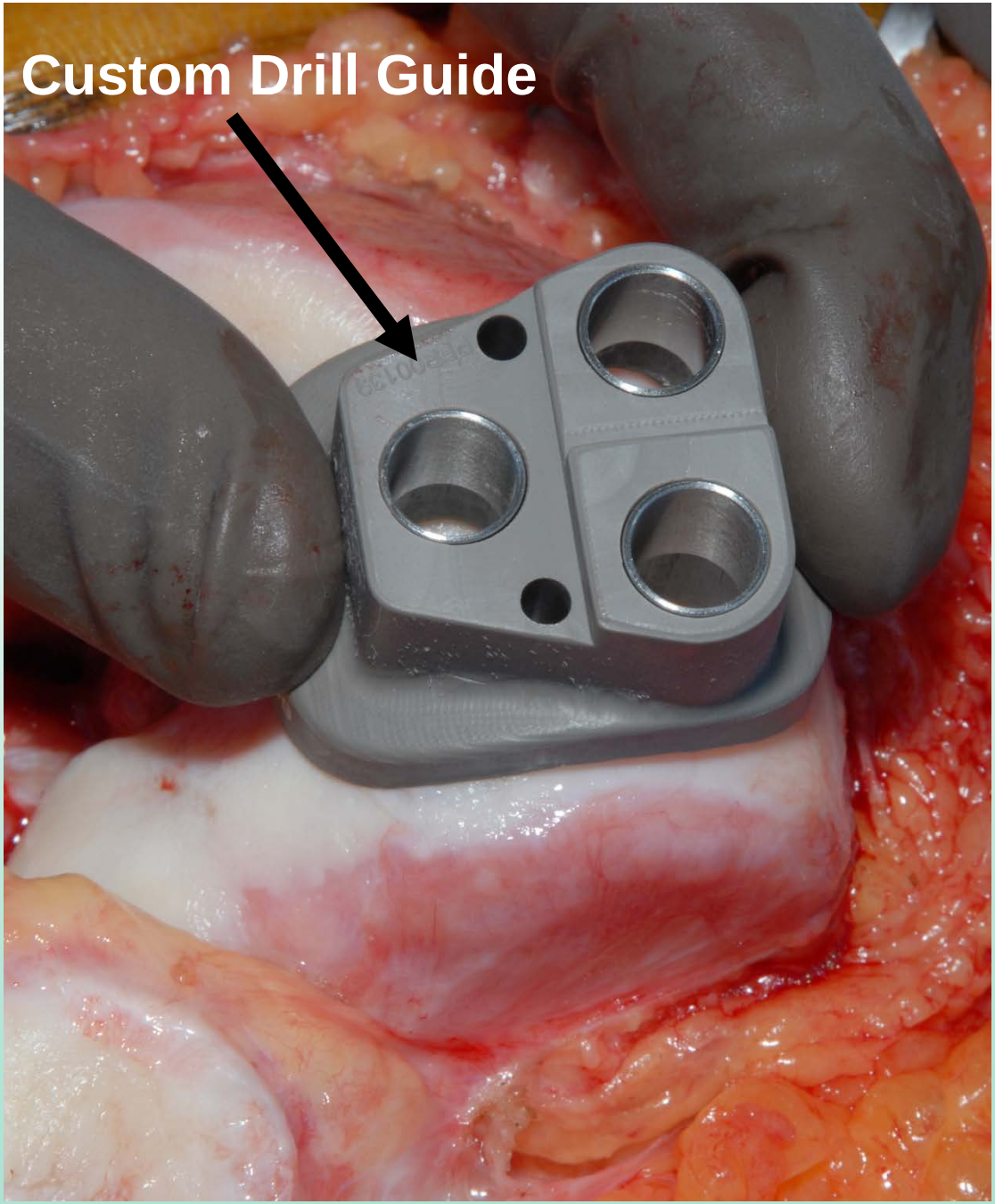
- Bring the patient’s femur model with you to the O.R.

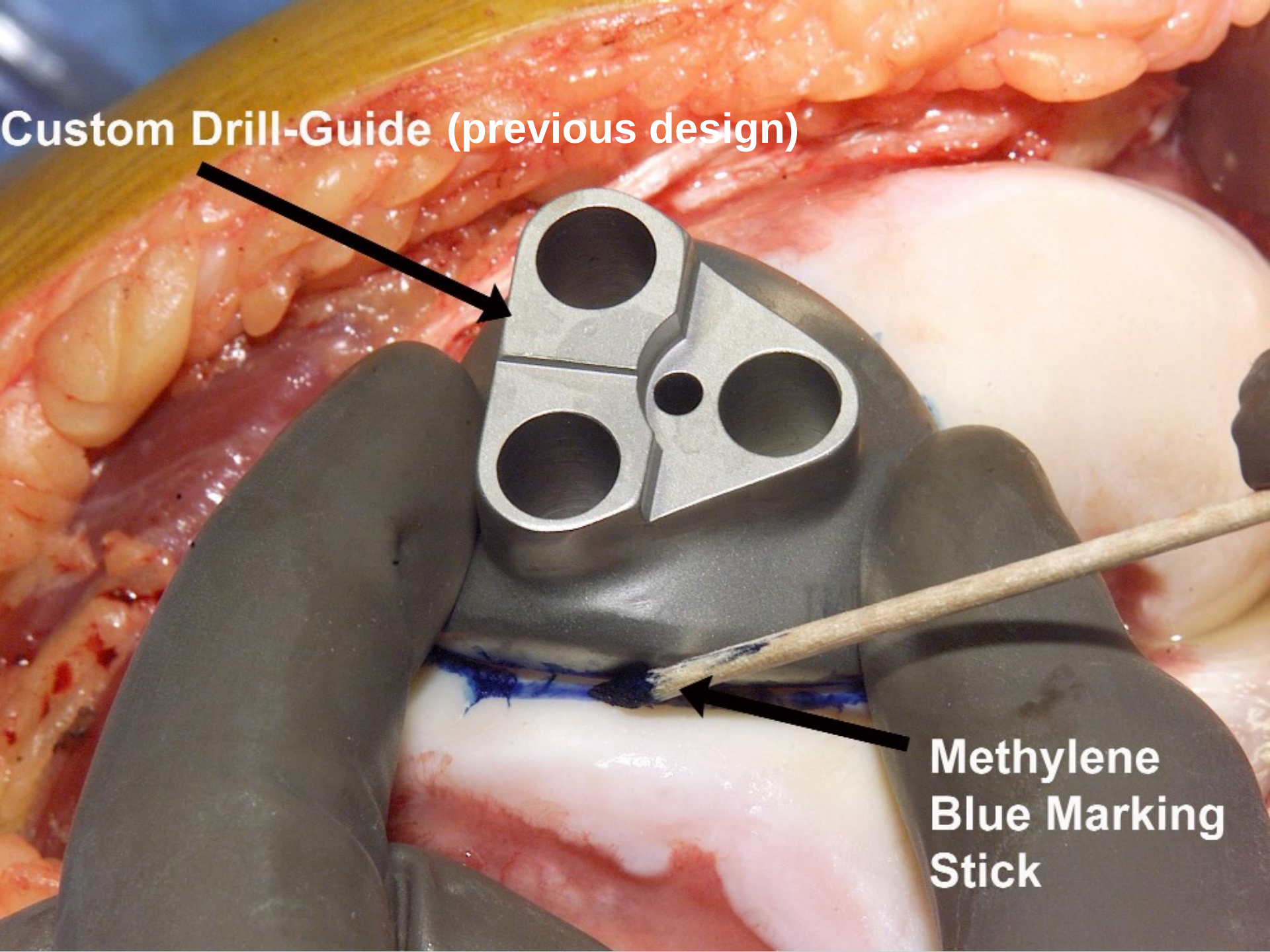
Surgical Case Photos

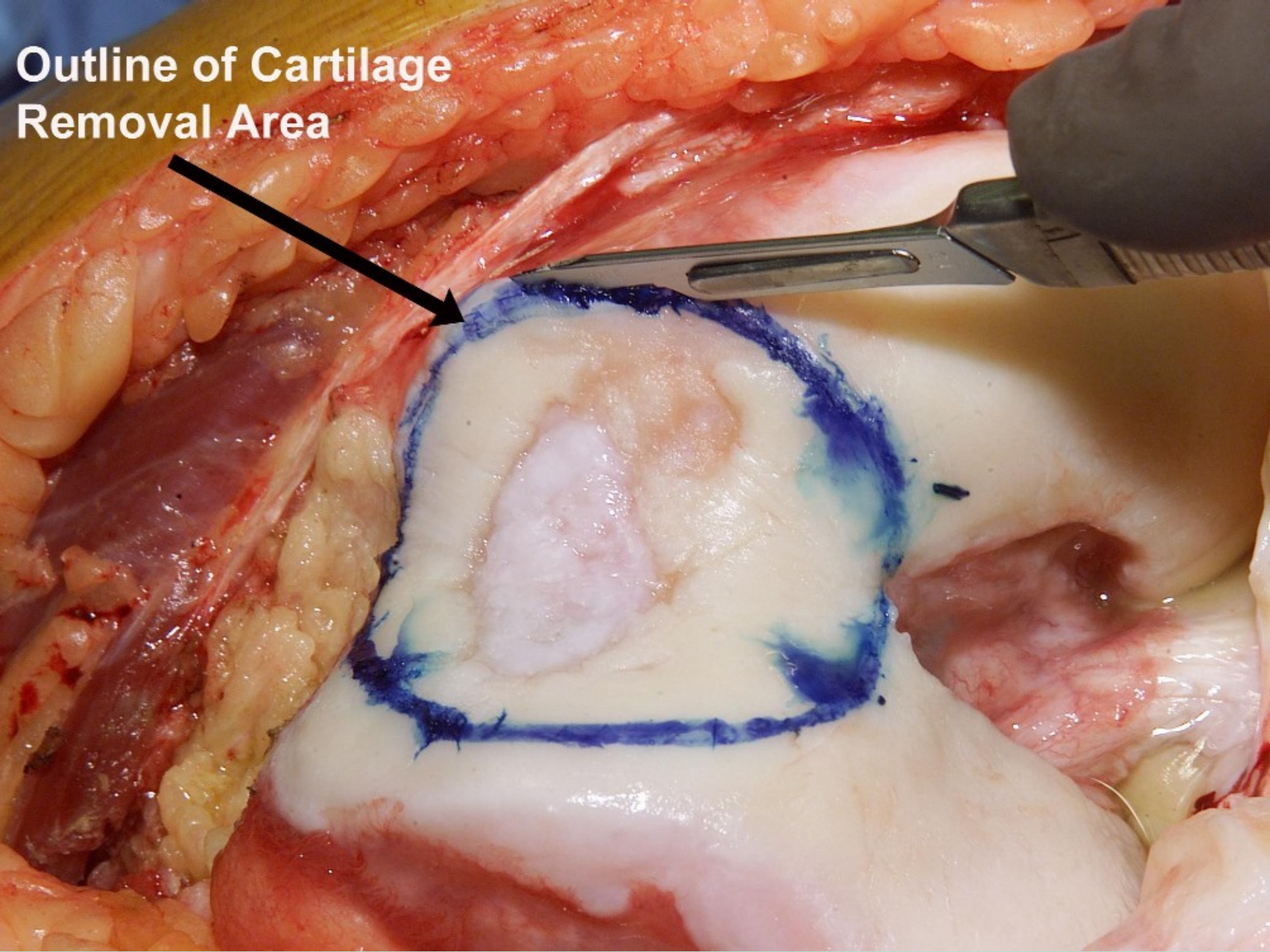
The following slides are from the KineMatch PFR Surgical Technique and the **Journal of Bone And Joint Surgery "Surgical Techniques Supplement"** published with the September 2007 issue. A DVD surgical video of our device was also included with the Supplement.

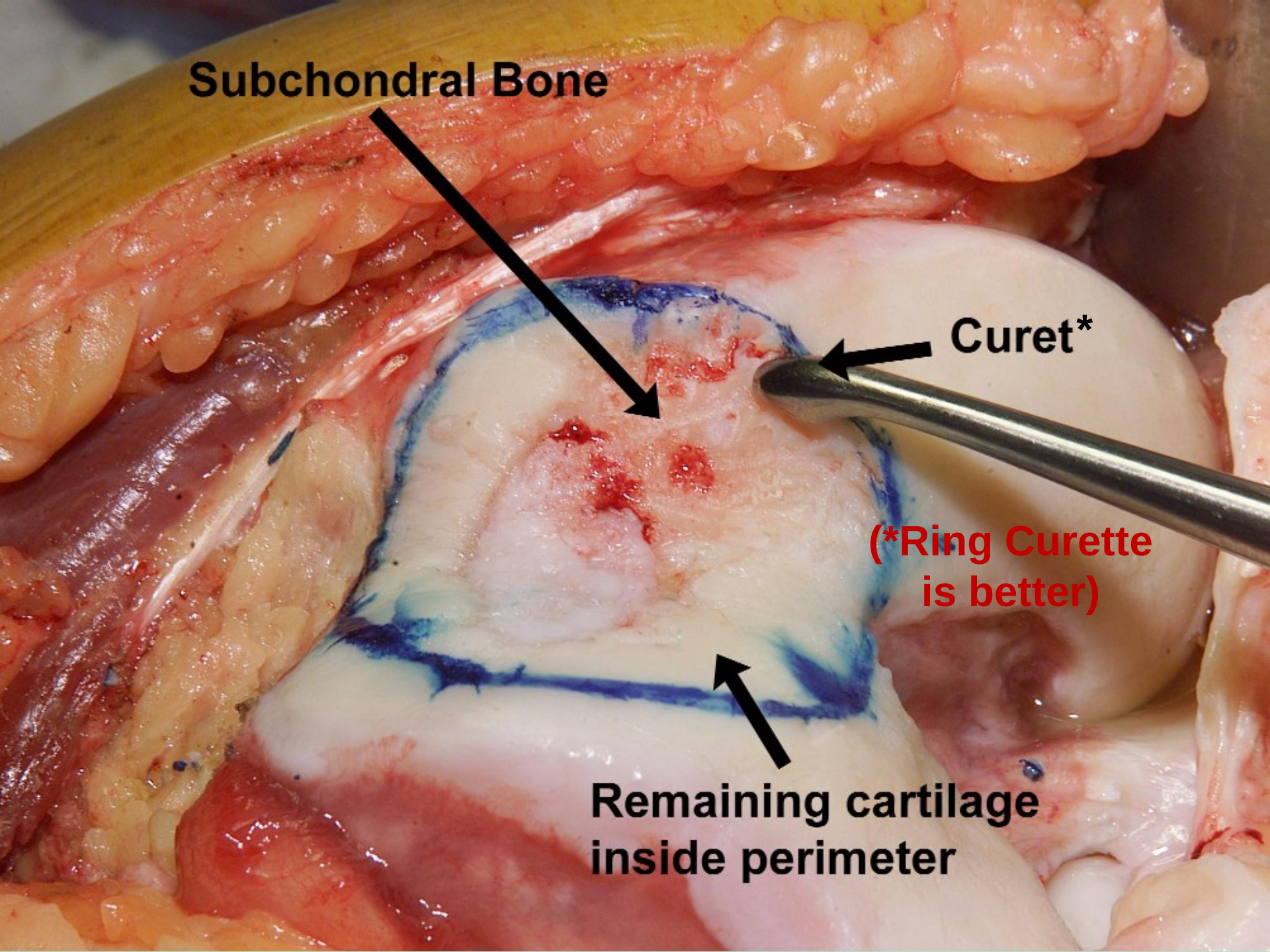


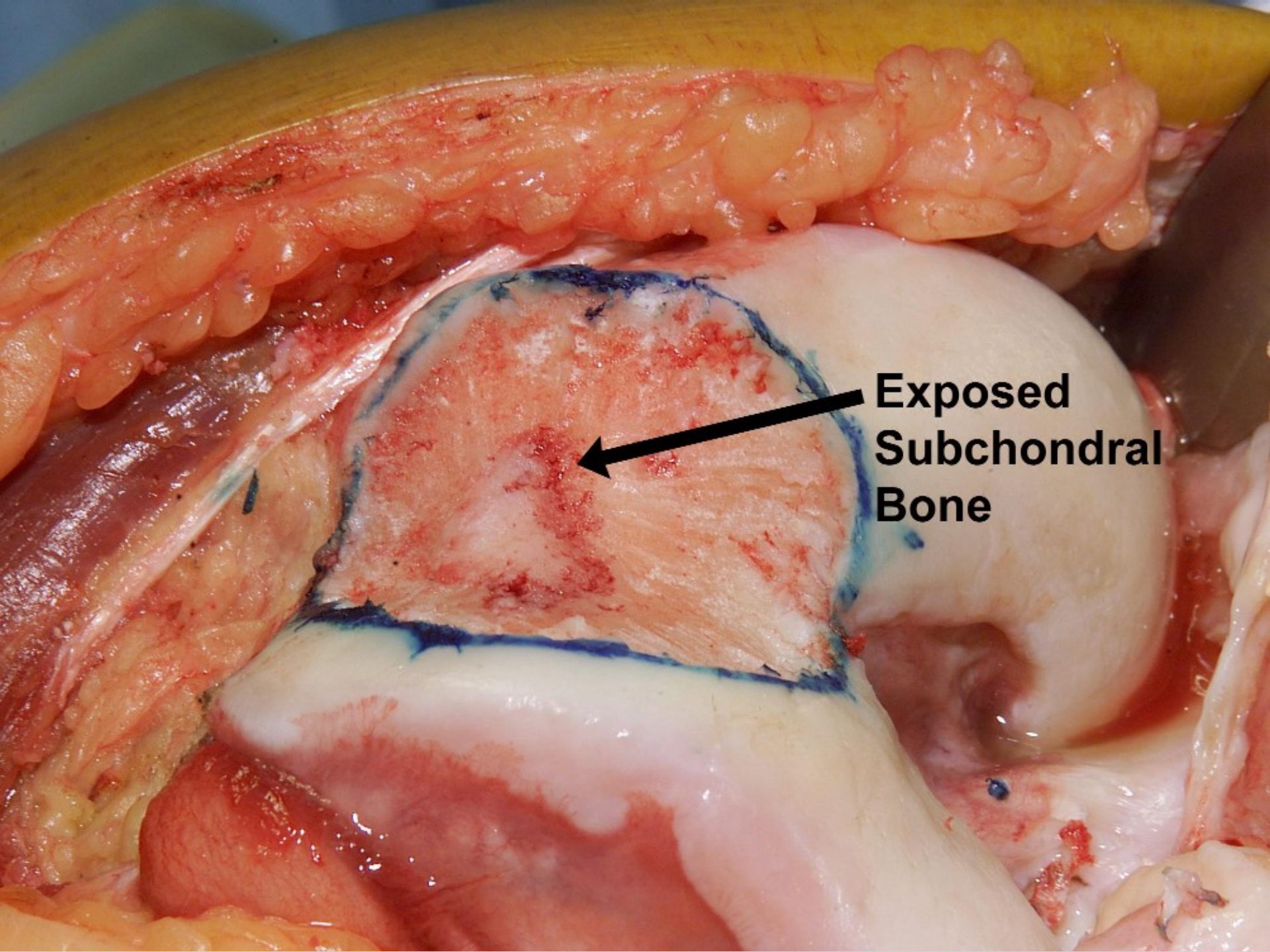

Degenerated Trochlea
Medial Femoral Condyle
Degenerated Patella
Lateral Femoral Condyle


Custom Drill Guide


Custom Drill-Guide (previous design)
Methylene
Blue Marking
Stick

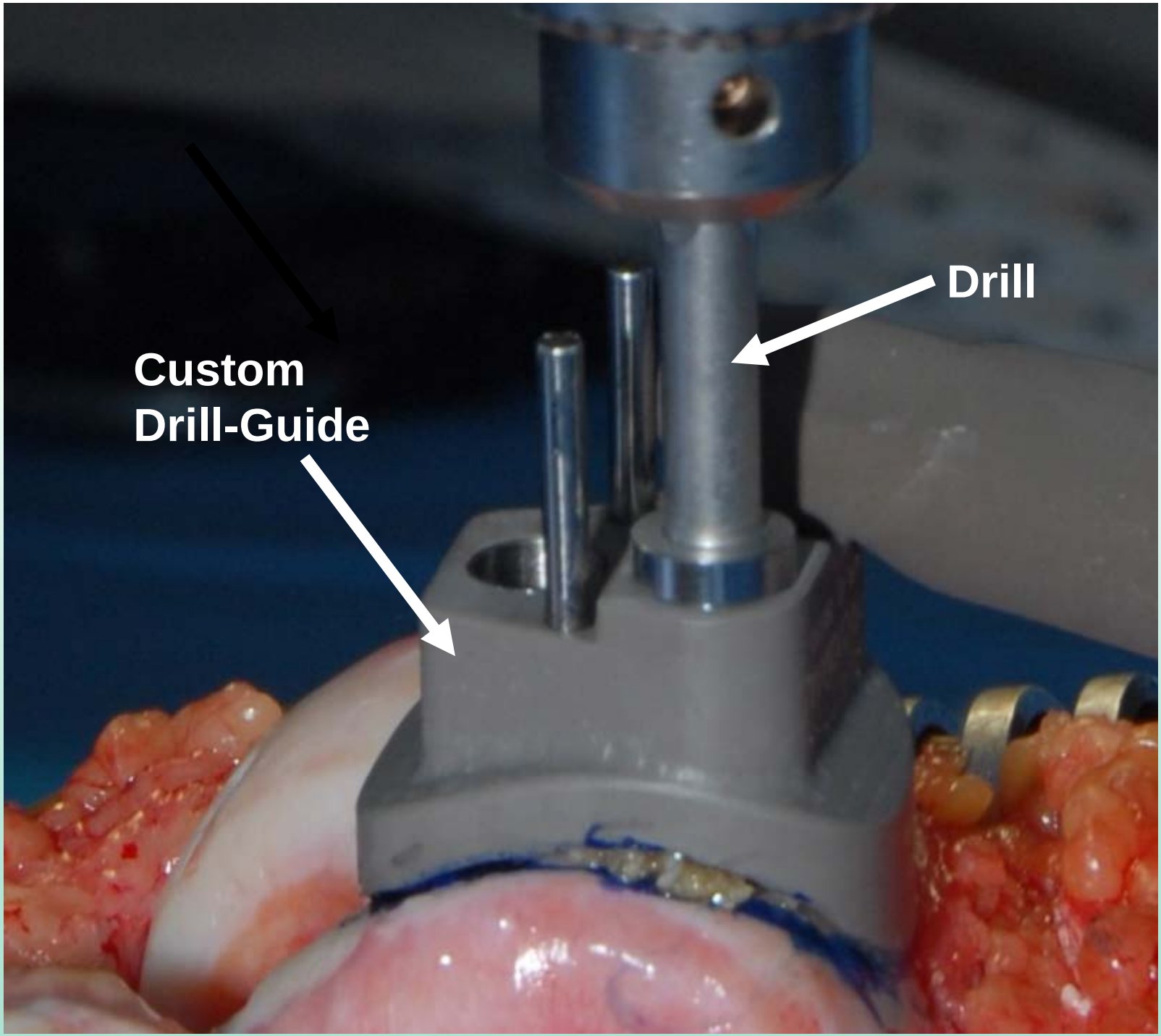

Outline of Cartilage
Removal Area

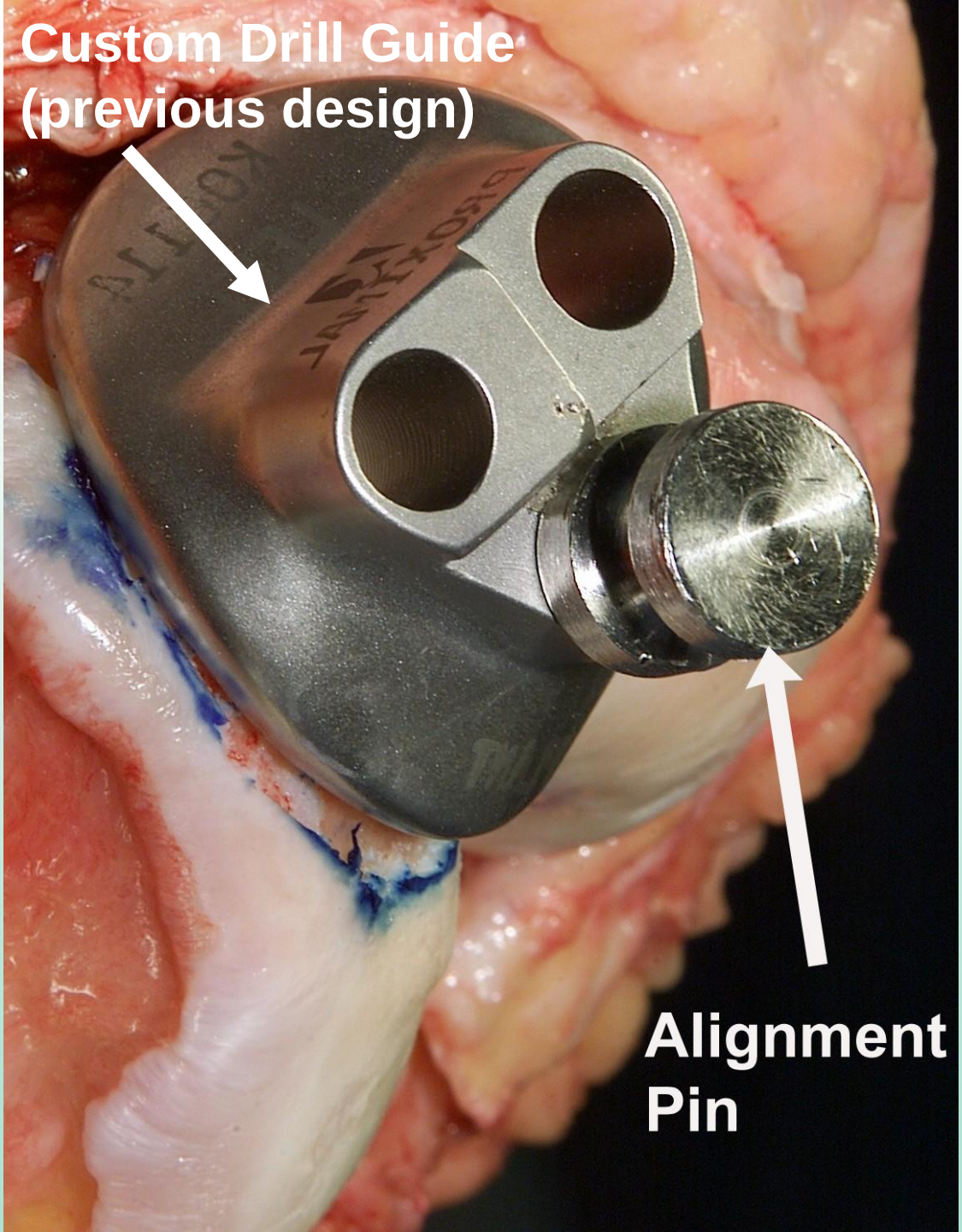

Subchondral Bone
Curet*
(*Ring Curette is better)
Remaining cartilage inside perimeter

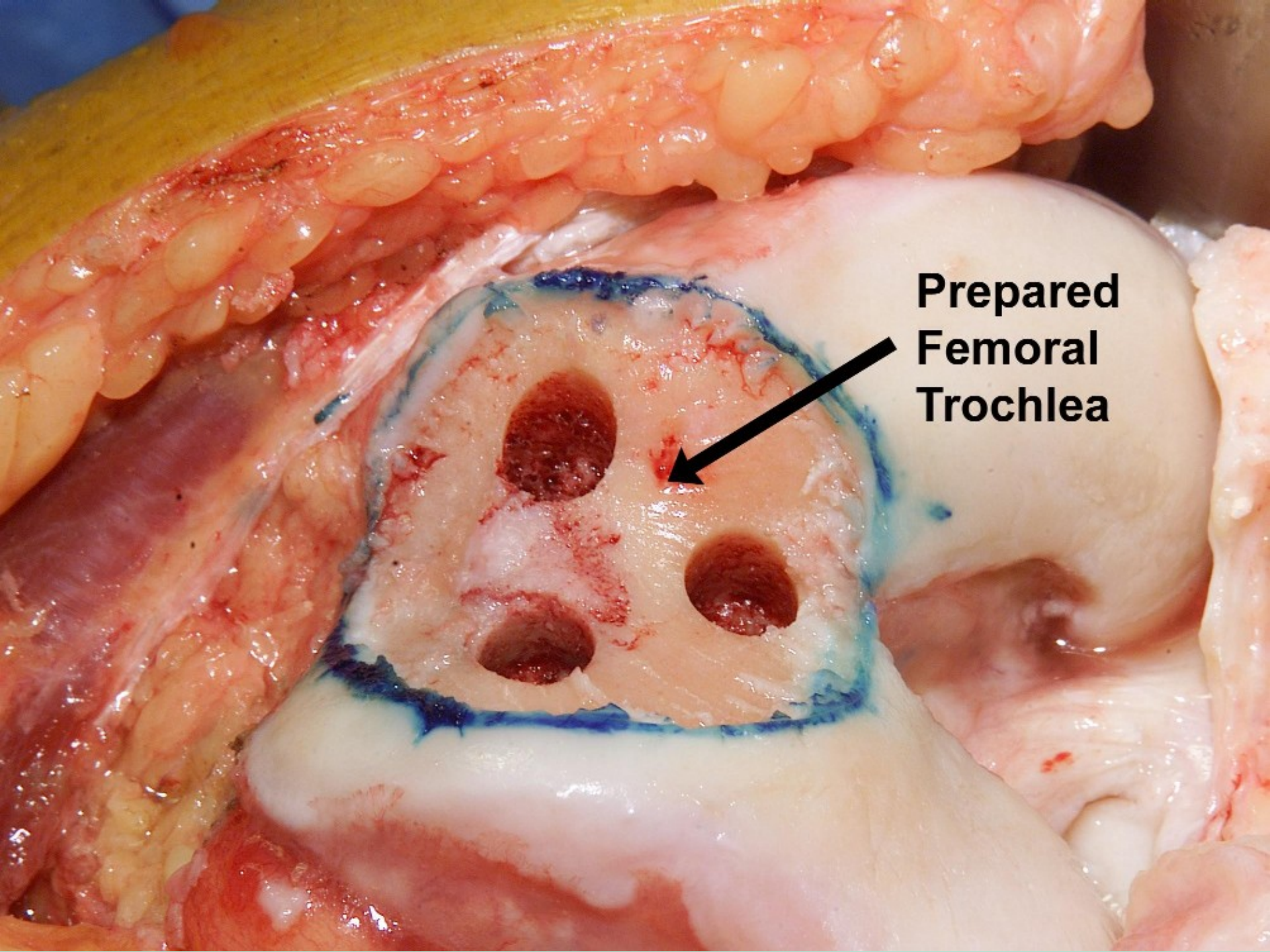

Exposed
Subchondral
Bone

Next step

- 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.

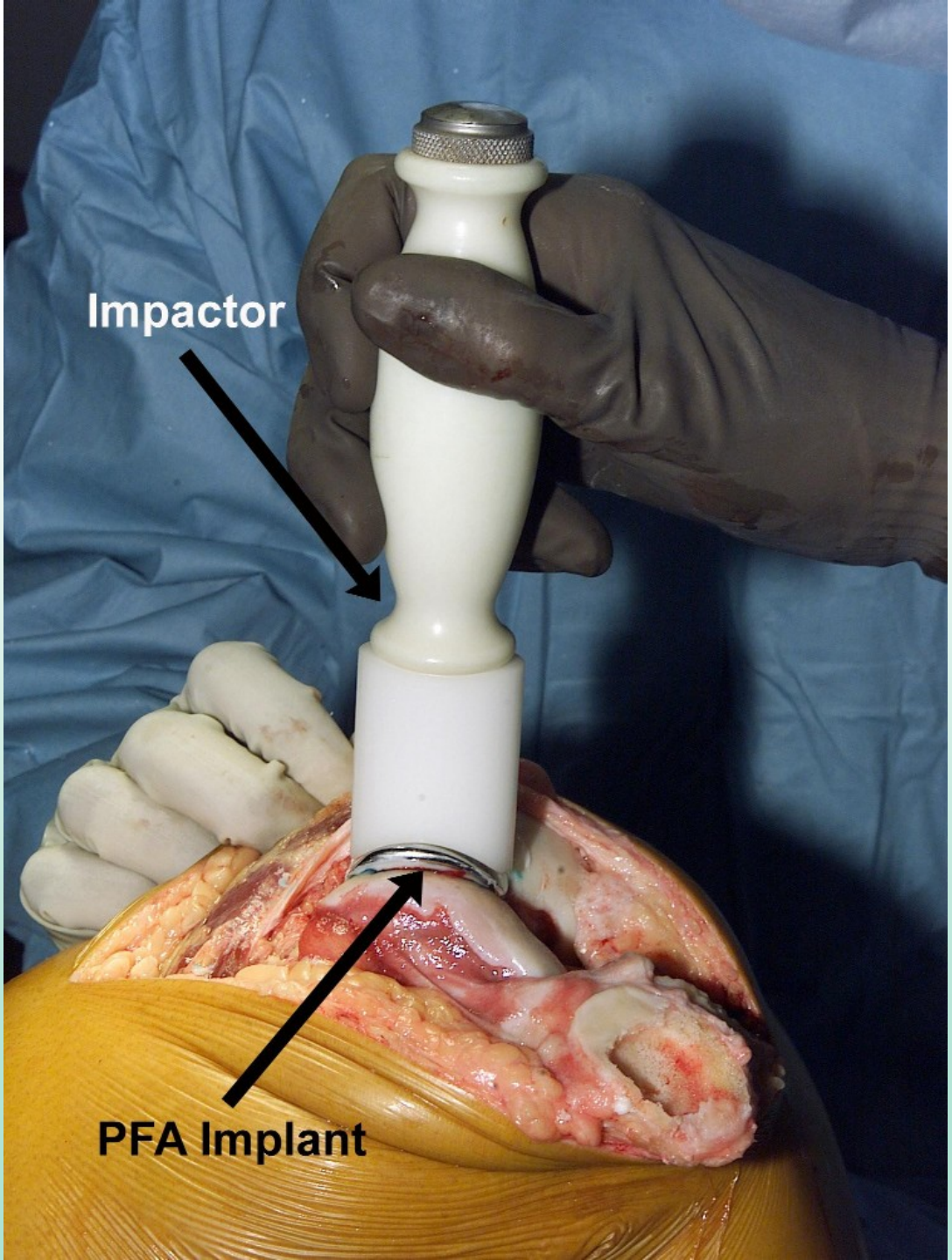

Drill
Custom
Drill-Guide

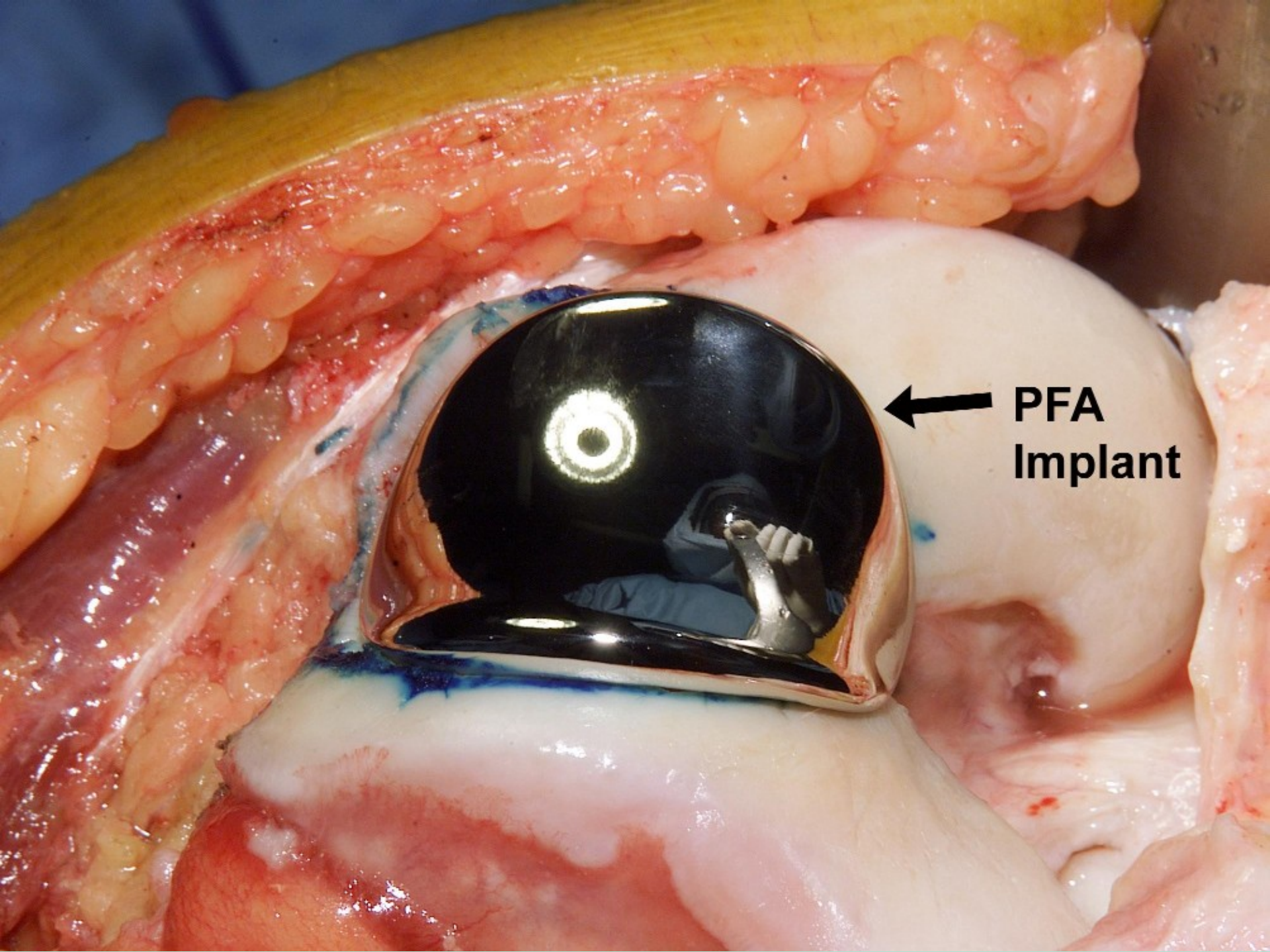

Custom Drill Guide
(previous design)
Alignment
Pin


Prepared
Femoral
Trochlea

Next step

- USE CARBOJET – Nothing is properly prepared for cementing without it!

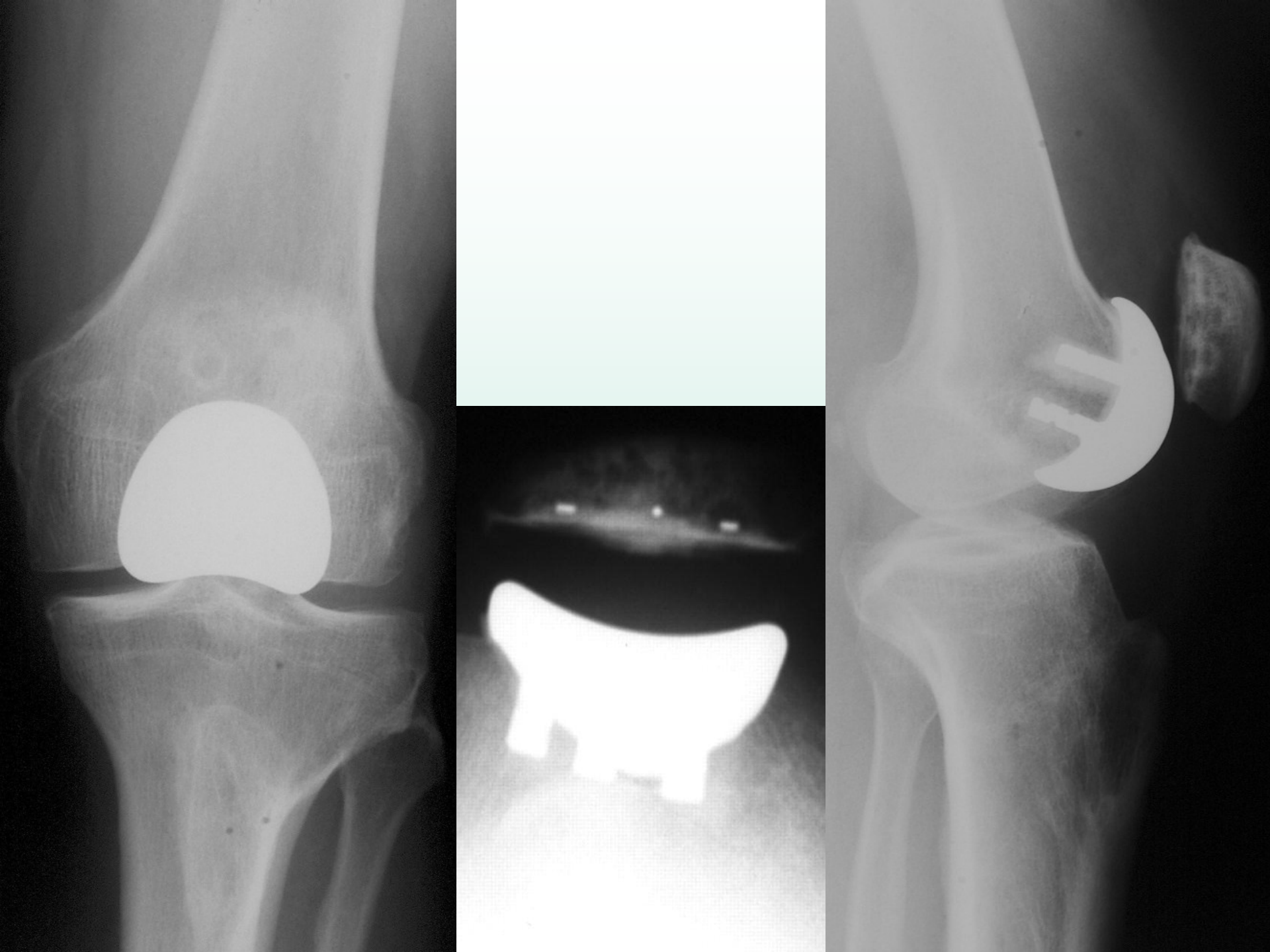

Impactor
PFA Implant


PFA
Implant

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



Thank You

Questions?