ACL Injuries in the Child Athlete

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The ACL Story

1. “The Unholy Triad”, O’Donohue 1955
2. Often does not require repair, Turek 1959
3. Non-contact, cutting injury, Hughston JC 1976
4. Direct repair unsuccessful, Feagin JA 1976
5. Extra articular reconstruction, 1970s, early ’80s
6. “Anatomic” repair, Eriksson, Fu
7. Pediatric ACL, extremely rare; no mid substance

“Instability of the knee is a very unusual symptom in children. Torn menisci and anterior cruciate avulsion are seen very rarely…”

Lloyd-Roberts GC. Orthopaedics in Infancy and Childhood. New York: Appleton-Century-Crofts, 1971.

“In youth, the anterior cruciate is strong and, instead of rupturing at the anterior insertion, the bone is avulsed.”

Turek SL. Orthopaedics: Principles and Their Application. Philadelphia: Lippincott Williams & Wilkins, 1976.

Boston Children's Hospital 2013

Pre-pubescent ACL: Extraphyseal ITB (1976)
Pubescent ACL: Transphyseal hamstring

993 knees; 1995-2008
Presently ~ 150/year

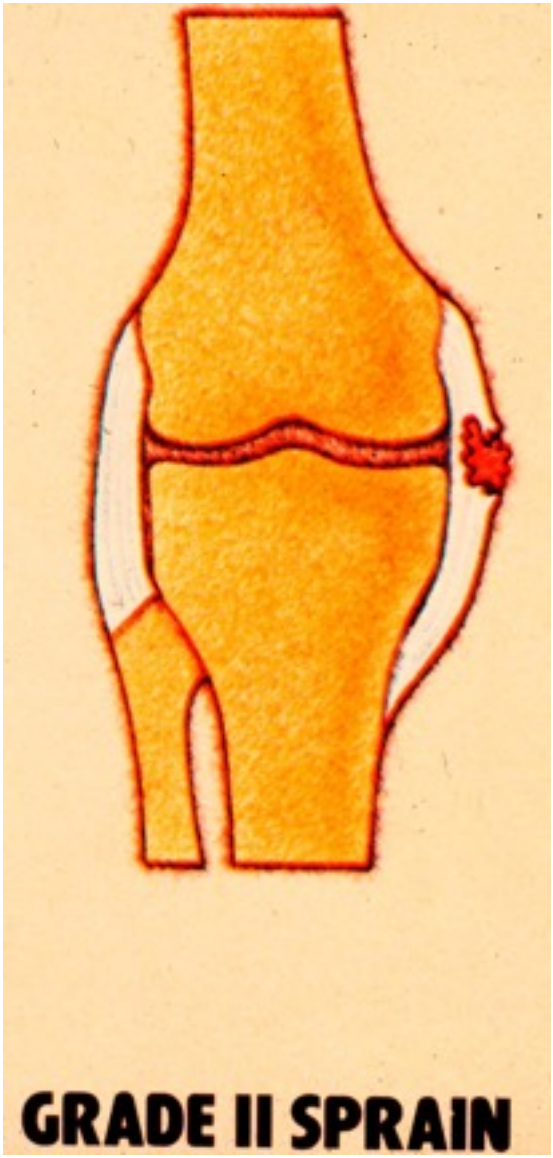
Knee: Young Athlete

1. **Ligament**
2. Internal derangement
3. Extensor mechanism
4. Physis
5. Other



Child: Knee Ligament

1. **Collateral**
2. Cruciate


GRADE II SPRAIN



Child: Knee Ligament

1. Collateral
2. **Cruciate**

Recent Observations

- The incidence of intrasubstance tears seems to be increasing
- They do not do well untreated
- Adolescents (B.A 14 y/o boys, 13 y/o girls) not problem
- Pre-pubescent (“wide open growth plates”) the issue

Gender (2001 – 2006)

1068 patients: 584 females, 484 males
14 and under = 179 patients
83 males: (83/179) = 46.4%
96 females: (96/179) = 53.6%
ages 13-19 = 541 patients
204 males: (204/541) = 37.7%
337 females: (337/541) = 62.3%
477 patients ages 20 and over

hypothesis works!

Micheli/Metzel article, 1992-1997; ages 13-19; soccer: 49 females, 20 males; basketball: 29 females, 11 males

Total:	Micheli / Metzl	Current Data	Change
78 females	71.6%	62.3%	9.3% decrease
31 males	28.4%	37.70%	9.3%
	100.0%		

Pearls:

1) **Fairly even gender distribution of ACL surgery in patients aged 14 and underconsistent with hypothesis (46.4% males, 53.6% in females)variance=13 patients, 7.2% higher in females**
2) **Females have a higher incidence of ACL reconstructive surgery than males, particularly in adolescents Per current data, 24.6% variance in female adolescents compared to males (13-19 years of age)**
3) **Frequency of ACL surgery over the past few years at BCH has increased consistently with increased sports participation in pediatric athletes**

ACL Injury: Child and Adolescent

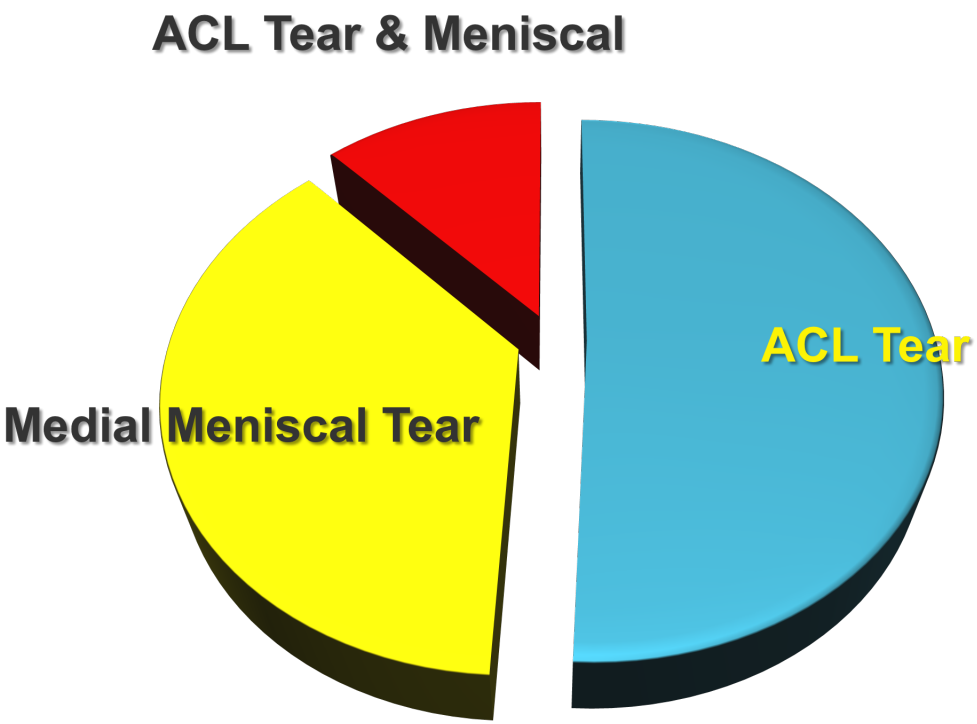
1. Diagnosis
2. Treatment
3. Rehabilitation

ACL Injury: Child and Adolescent

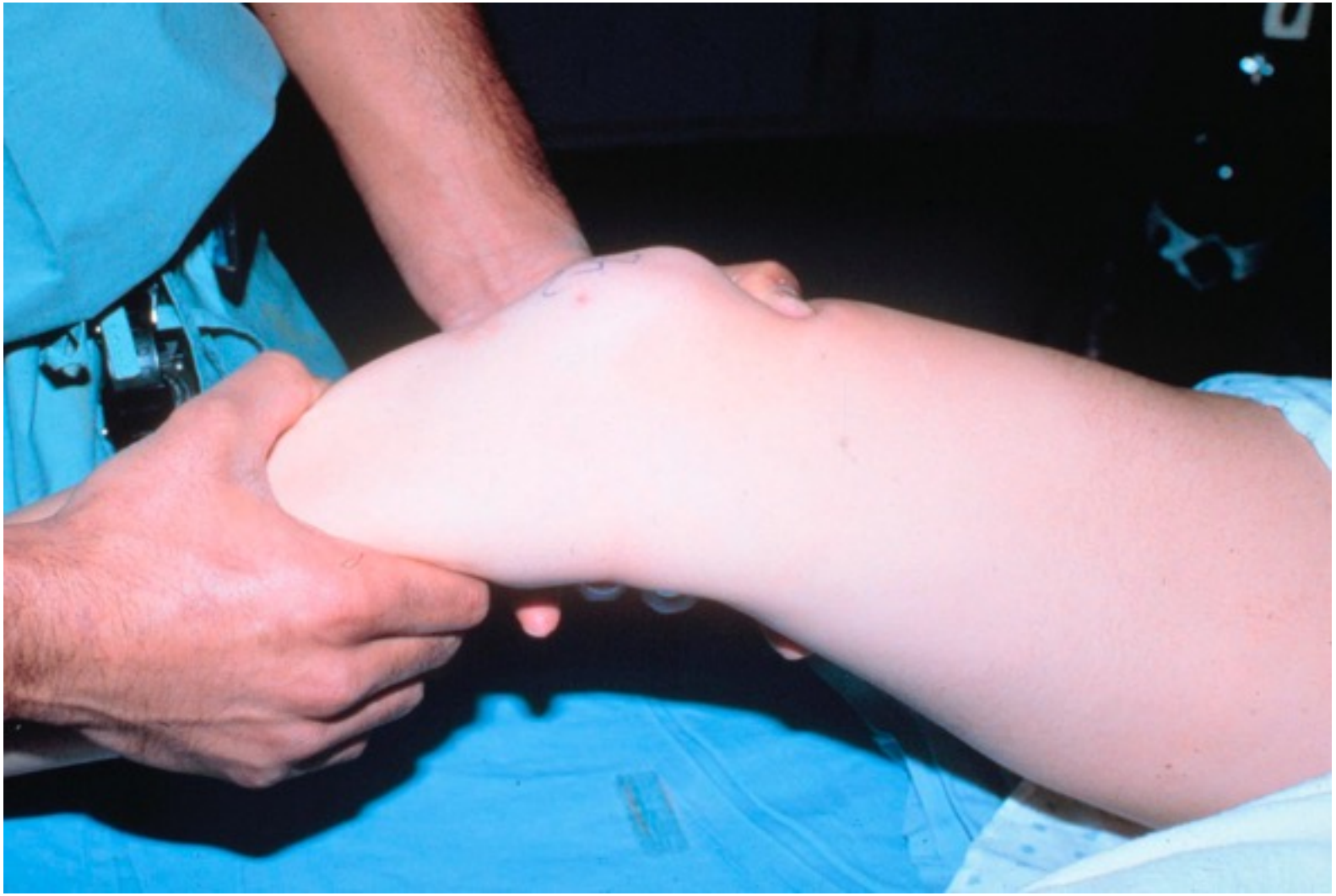
1. **Diagnosis**
2. Treatment
3. Rehabilitation

Hemarthrosis

Total Group



Lachman Test



MRI

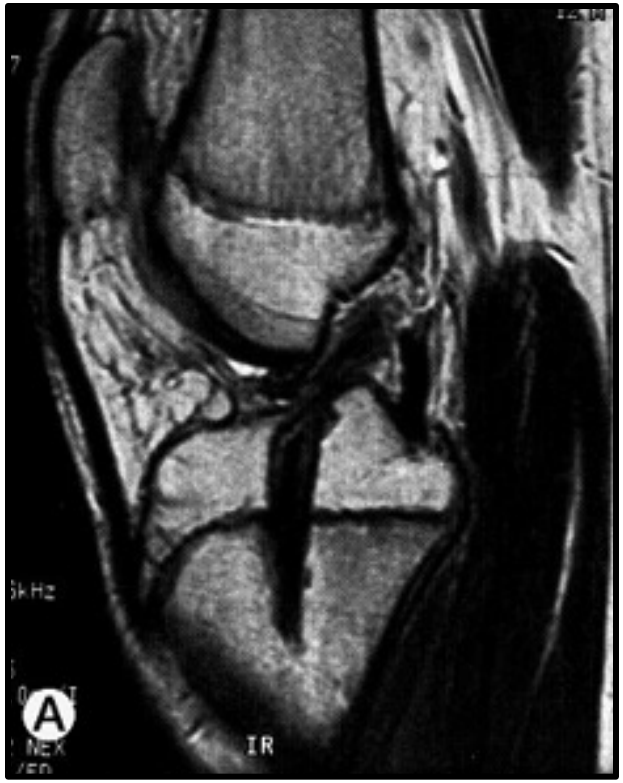

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ACL Injury: Child and Adolescent

1. Diagnosis
2. **Treatment**
3. Rehabilitation

Controversy: Pediatric ACL Injuries

- **Initial Management**
  - Nonoperative vs. operative
- **Operative Management**
  - Technique
    - Nontransphyseal
    - Partial transphyseal
    - Transphyseal
  - Graft choice/fixation
  - Age/skeletal maturity
- **Complications**
  - Growth disturbance



Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

Treatment: Factors

1. Biologic age

2. Injury type

3. Severity of injury

Tanner Staging of Biological Age

I. Establishing biological age

	Tanner Stage	Chronologic Age
Group A	I	< 10
Pre-pubescent	II	10-13
Group B	III	13-14
(Pubescent)	IV	> 14

Left Wrist: Bone Age



Please get bone age!

Treatment Factors

- Biologic age
- **Injury type**
- Severity of injury

ACL Injury Type

II. ACL Injury Classification

Type I Bone avulsion
Type II Interstitial tear
Type III Both (avulsion & interstitial tear)

ACL Injury: Young Athlete

1. Partial
2. **Complete: pre-pubescent**
3. Complete: adolescent



Controversies: Child ACL

- **Operative vs. non-operative?**
- Which operation?
- Complications?
- Long term outcome?

Complete ACL
Pre-Pubescent

1. Brace and exercise until grown

2. Operative treatment

3. Associated meniscal repair ?


CONCORD

Pediatric Knee Injuries
ACL Injuries

Prognosis of Nonoperative Management (complete tears)

Angel & Hall (*Arthroscopy 1989*)
- 5/7 failure (ACL reconstruction)

Graf et al (*Arthroscopy 1992*)
- 7/8 failure (ACL reconstruction, meniscal tears)

Janary et al (*J Pediatr Orthop 1996*)
- 16/23 failure (ACL reconstruction)

Mizuta et al (*JBJS-B 1985*)
- 1/18 return to preinjury sport level, 6/18 meniscal tears

McCarrol et al (*AJSM 1988*)
- 3/16 return to preinjury sport, 4/16 meniscal tears

Associated Injuries in Pediatric and Adolescent Anterior Cruciate Ligament Tears: Does a Delay in Treatment Increase the Risk of Meniscus Tears?

Millett, Willis, Warren
Arthroscopy; 18:955-9, 2002

39 patients, 26 assoc. injury

Delay > 6 wk ↑ MM risk

Meniscal and chondral injuries associated with pediatric anterior cruciate ligament tears: relationship of treatment time and patient-specific factors.

Dumont GD, Hogue GD, Padalecki JR, Okoro N, Wilson PL.
Am J Sports Med. 2012 Sep;40(9):2128-33.

Pediatric ACL treated > 150 days after injury had increased mm tear

(↑ age, wt.)

Controversies: Child ACL

- Operative vs. non-operative?
- **Which operation?**
- Complications?
- Long term outcome?

Pediatric Knee Injuries

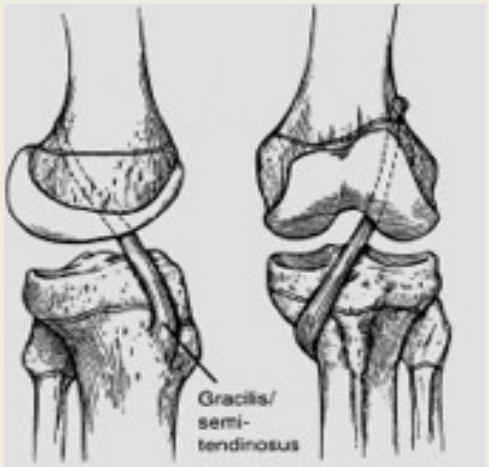
ACL Reconstruction

Extra-Articular



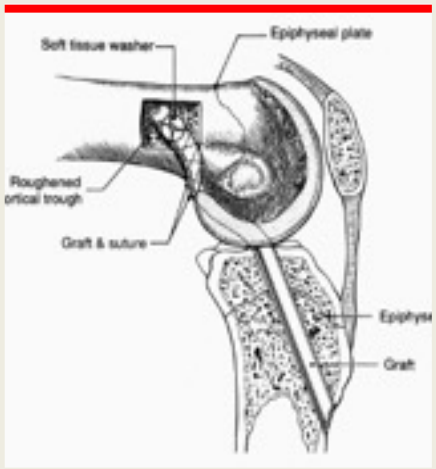
-Dahlstedt 1988
-McCarroll 1988
-Lazzarone 1990
-Graf 1992
-Nakhostine 1995

Physeal Sparing



-DeLee 1983
-Brief 1991
-Janarv 1996
-Micheli 1999
-Anderson 2004
-Guzzanti 2004

Partial Transphyseal



-Lipscomb 1986
-Andrews 1994
-Lo 1997
-Bisson 1998

Complete Transphyseal



-Lipscomb 1986
-McCarroll 1994
-Matavan 1997
-Aronowitz 2000

Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

CASE STUDY: 1978

- 3 y/o boy; congenitally absent ACL
- Bracing unsuccessful
- Modified McIntosh procedure
- Stable knee
- Dartmouth lacrosse
- NY stockbroker
- Helicopter skiing



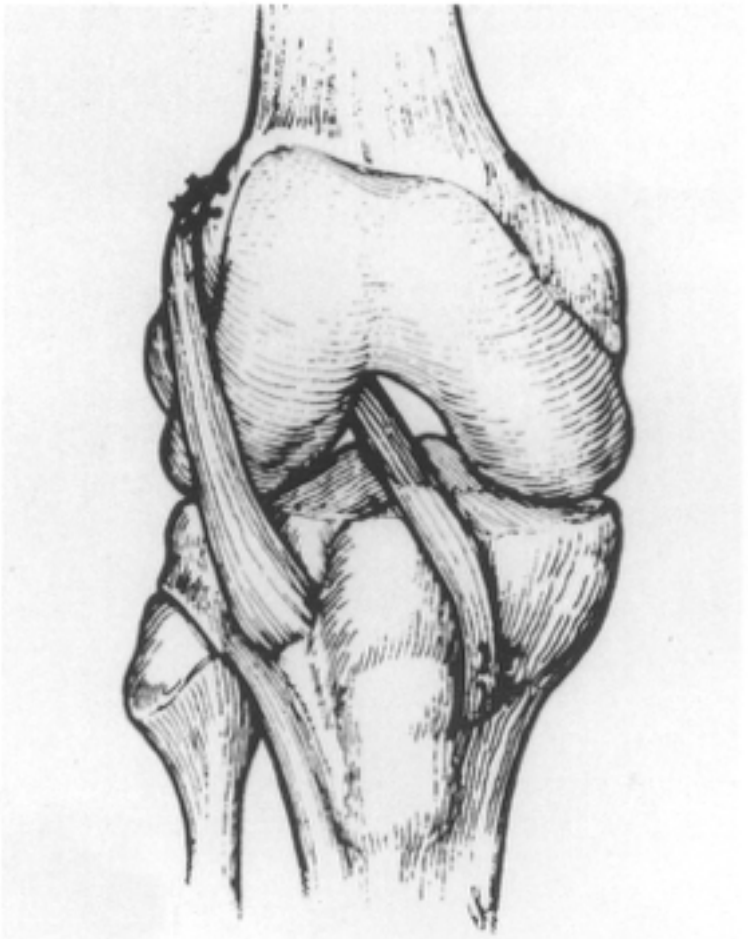


Figure 24–10 Micheli variation of MacIntosh/Darby combined intra/extraarticular physeal-sparing reconstruction. (Reprinted with permission from: Rask BP, Micheli JL: The pediatric knee. In Scott WN (ed): The knee, vol. 1, St. Louis: Mosby-year Book, 1994. Copyright Elizabeth Roselius).

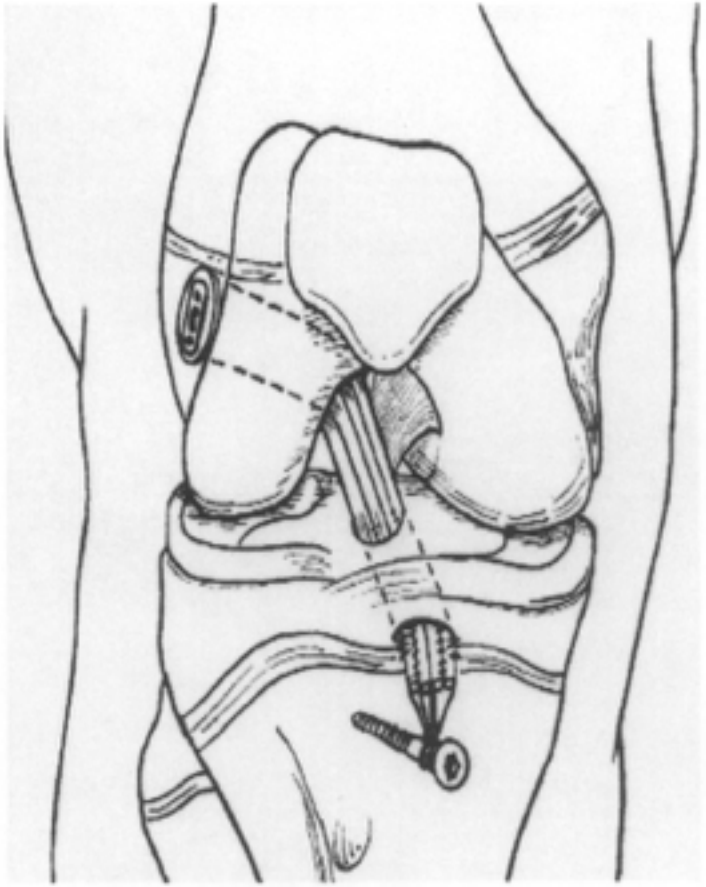
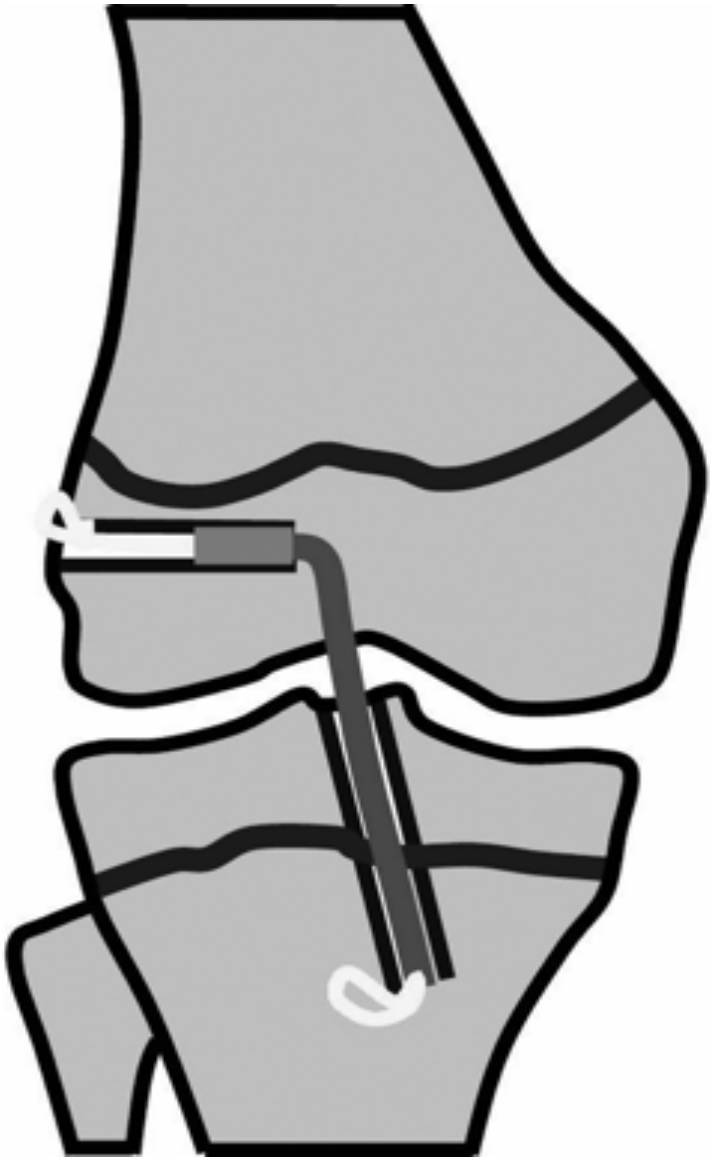
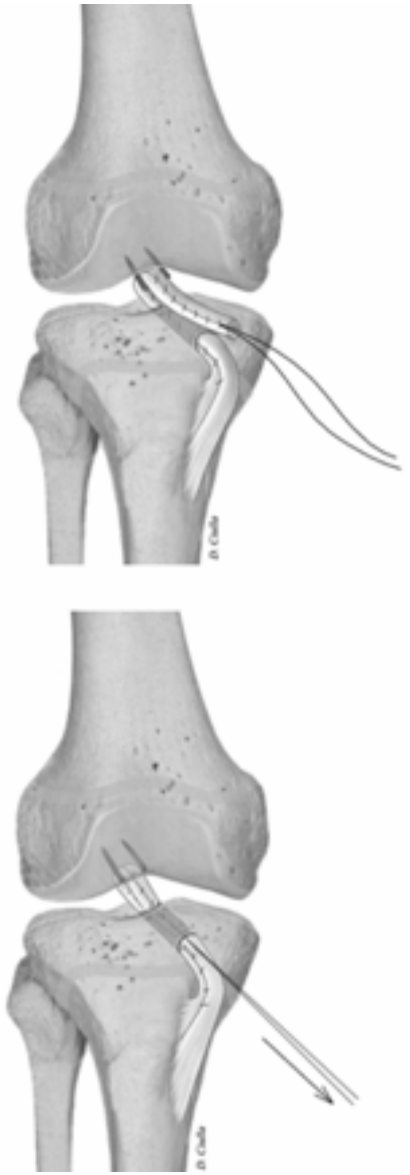


Figure 24–17 All-epiphyseal tunneling technique as reported by Anderson.







Which Operation?

Decision Parameters

1. Safety
2. Efficacy
3. Biomechanics
4. Long term outcome (child)

Decision Parameters

1. **Safety**
2. Efficacy
3. Biomechanics
4. Long term outcome (child)

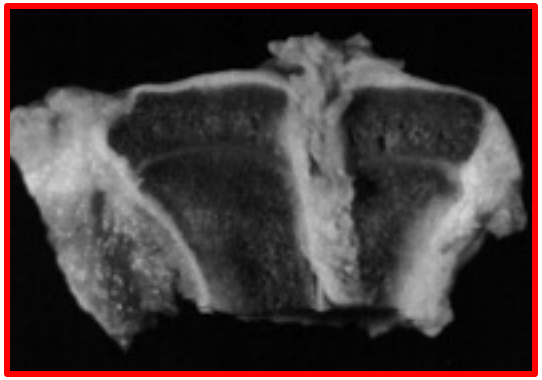
Operative Complications

Dramatically under-reported in the medical literature!

Pediatric Knee Injuries

Growth Disturbance

- **Growth Disturbance**
  - **Animal Models**
    - **Guzzanti (JBJS 1994)**
      - Rabbit, 2mm tunnels, 3/21 disturbance
    - **Stadelmeier (AJSM 1995)**
      - Canine, 5/32” tunnels, no disturbance
    - **Edwards (JBJS 2001)**
      - Canine, 80N, femoral valgus
  - **Clinical Series**
    - **2 Cases**
      - Lipscomb (JBJS 1986)
      - Koman (JBJS 1999)





Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

The risk of growth changes during transphyseal drilling in sheep with open physes.

Seil R, Pape D, Kohn D.

Arthroscopy. 2008 Jul;24(7):824-33.

Sheep:
5mm drill holes
Tibia – no problem
Femur – empty
Achilles tendon graft no growth disturbance

Hindlimb growth after a transphyseal reconstruction of the anterior cruciate ligament: a study in skeletally immature sheep with wide-open physes.

Meller R, Kendoff D, Hankemeier S, Jagodzinski M, Grotz M, Knobloch K, Krettek C.

Am J Sports Med. 2008 Dec;36(12):2437-43.

Sheep
Central drill holes
Small soft tissue graft
No physeal arrests

The influence of femoral technique for graft placement on anterior cruciate ligament reconstruction using a skeletally immature canine model with a rapidly growing physis.

Chudik S, Beasley L, Potter H, Wickiewicz T, Warren R, Rodeo S. Arthroscopy. 2007 Dec;23(12):1309-1319.

Concise model, 3 femoral techniques

Conclusion: "ACL reconstruction in the skeletally immature individual is complicated by the presence of physeal and epiphyseal cartilage…
Animal models can provide insight and direction as we develop and evaluate our treatment methods for this clinical problem, but these animal models have anatomic and physiologic differences that limit direct comparison to humans."

Computer Analog Studies

Anterior cruciate ligament reconstruction in the skeletally immature: an anatomical study utilizing 3-dimensional magnetic resonance imaging reconstructions.

Kercher J, Xerogeanes J, Tannenbaum A, Al-Hakim R, Black JC, Zhao J.
J Pediatr Orthop. 2009 Mar;29(2):124-9.

31 physeal sets
6mm-11mm: 2.3% - 7.8% average
MAARS software package
Raised concerns about femoral physis

Volumetric injury of the physis during single-bundle anterior cruciate ligament reconstruction in children: a 3-dimensional study using magnetic resonance imaging.

Shea KG, Belzer J, Apel PJ, Nilsson K, Grimm NL, Pfeiffer RP.
Arthroscopy. 2009 Dec;25(12):1415-22.

MRI 3D modeling; 10 pediatric knees

Drill hole	Femur %	Tibia %
6mm	2.4	1.6
7mm	3.2	2.2
8mm	4.2	2.9
9mm	5.4	3.8

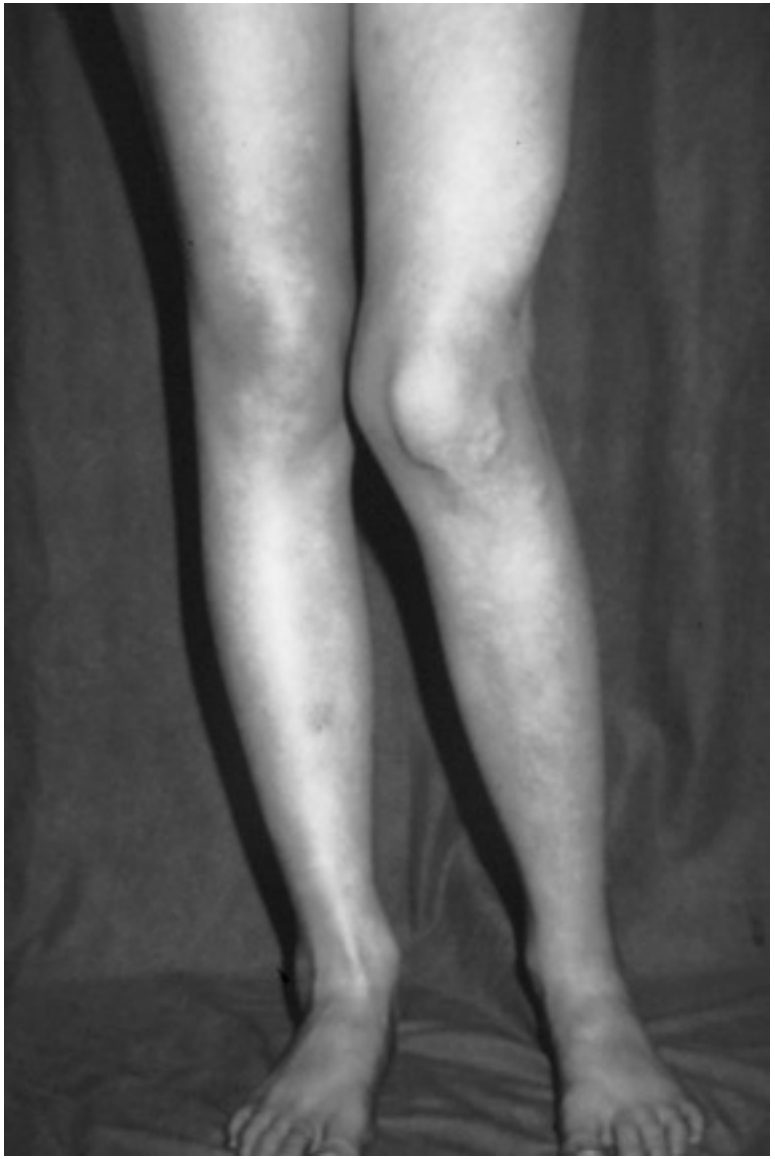
Volumetric injury of the distal femoral physis during double-bundle ACL reconstruction in children: a three-dimensional study with use of magnetic resonance imaging.

Shea KG, Grimm NL, Belzer JS.
J Bone Joint Surg Am. 2011 Jun 1;93(11):1033-8.

"Double-bundle techniques substantially increase the volume of injury to the physis, which appears to increase the risk of abnormal growth in the distal femoral physis following this surgical procedure."

Femoral Physeal Injury

- Angular deformity
- Leg length



The effect of percutaneous pin fixation in the treatment of distal femoral physeal fractures.

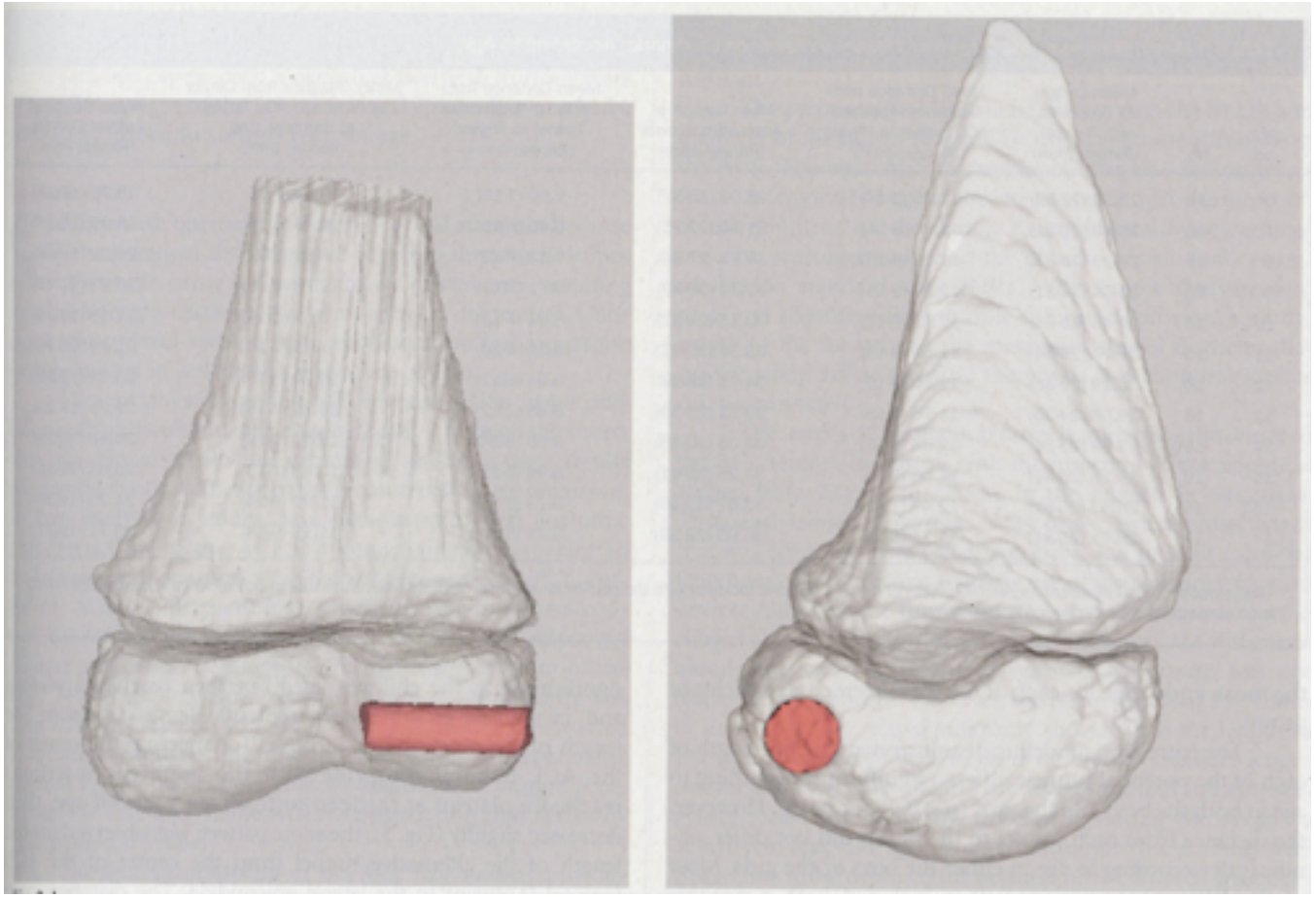
Garrett BR, Hoffman EB, Carrara H.
J Bone Joint Surg Br. 2011 May;93(5):689-94.

21% significant physeal injury

Anatomic landmarks utilized for physeal-sparing, anatomic anterior cruciate ligament reconstruction: an MRI-based study.

Xerogeanes JW, Hammond KE, Todd DC.
J Bone Joint Surg Am. 2012 Feb 1;94(3):268-76.

Femoral intra epiphyseal tunnel



Have you ever seen a growth disturbance from ACL reconstruction in a skeletally immature patient?



Kocher el at (JPO 2002)

- 8 cases: Distal femoral valgus with bony bar
  - 3: Implants (interference screws) across physis
  - 3: Patellar tendon graft bone block across physis
  - 1: Large (12mm) tunnel with patellar tendon graft
  - 1: Over-the-top graft placement
- 2 cases: Genu valgum without bony bar
  - Lateral extra-articular tenodesis
- 2 cases: Leg-length discrepancy
  - 2.5cm shortening (PT bone block across physis)
  - 3.0cm overgrowth (6mm hamstrings graft)
- 3 cases: Recurvatum with apophyseal bar
  - Hardware across tibial tubercle apophysis

Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

Growth Plate Disturbance After Transphyseal Reconstruction of the Anterior Cruciate Ligament in Skeletally Immature Adolescent Patients: An MR Imaging Study.

Yoo WJ, Kocher MS, Micheli LJ. J Pediatr Orthop. 2011 Sep; 31(6):691-6.

43 patients (12.4-16.5 years)
16 month new follow-up
2.6% of physeal area (mean)
5/43 focal physeal disturbance

Decision Parameters

1. Safety
2. **Efficacy**
3. Biomechanics
4. Long term outcome (child)

Decision Parameters

1. Safety
2. Efficacy
3. **Biomechanics**
4. Long term outcome (child)

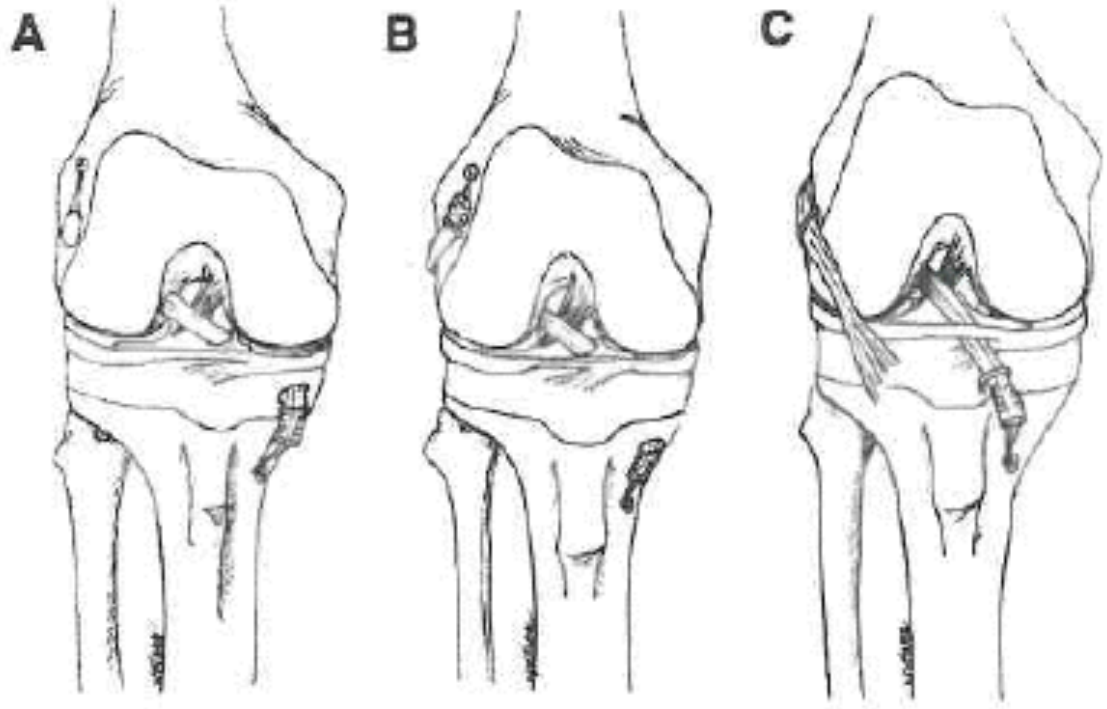
Biomechanical Evaluation of Pediatric Anterior Cruciate Ligament Reconstruction Techniques

Kennedy A, Coughlin DG, Metzger MF, Tang R, Pearle AD, Lotz JC, Feeley BT. Am J Sports Med. 2011 May;39(5):964-71.

Reconstructions Tested

1. Epiphyseal
2. Trans tibial / over the top
3. ITB extra / intra ★

“The ITB best restored A-P stability and rotational control.”



The 3 reconstruction techniques used in the study: A, all-epiphyseal reconstruction. The tunnels were placed in the femoral and tibial ACL attachments and drilled to stay within the epiphysis. The graft was secured on the femur with an EndoButton and post and on the tibial side with a staple and post. B, transtibial over-the-top ACL reconstruction. The graft was secured on the femoral and tibial side with a staple and post. C, iliotibial band ACL reconstruction. The graft was secured first on the femur with a staple, then tensioned appropriately and secured to the tibia with a staple and post.

Figures drawn by Rosanna Wustrack, MD.

Drill Holes Through Physis

1. Size of physis
2. Size of drill hole
3. Location of drill hole
4. Technique
5. Maturation level

Complete ACL Pre-Pubescent

1. Brace and exercise until grown
2. **Extra-articular / over the top ITB with hamstrings**
3. Associated meniscal repair ?

Modified McIntosh

ITB, INTRA, EXTRA over the top

Evolution of the ITB
Extra / Intra Repair

1972 – Macintosh, "Return lateral loop" for pivot shift

Galway RD, Beaupre A, Macintosh DL. Pivot shift: a clinical sign of symptomatic anterior cruciate insufficiency. J Bone Joint Surg Br. 1972;54:763-764.

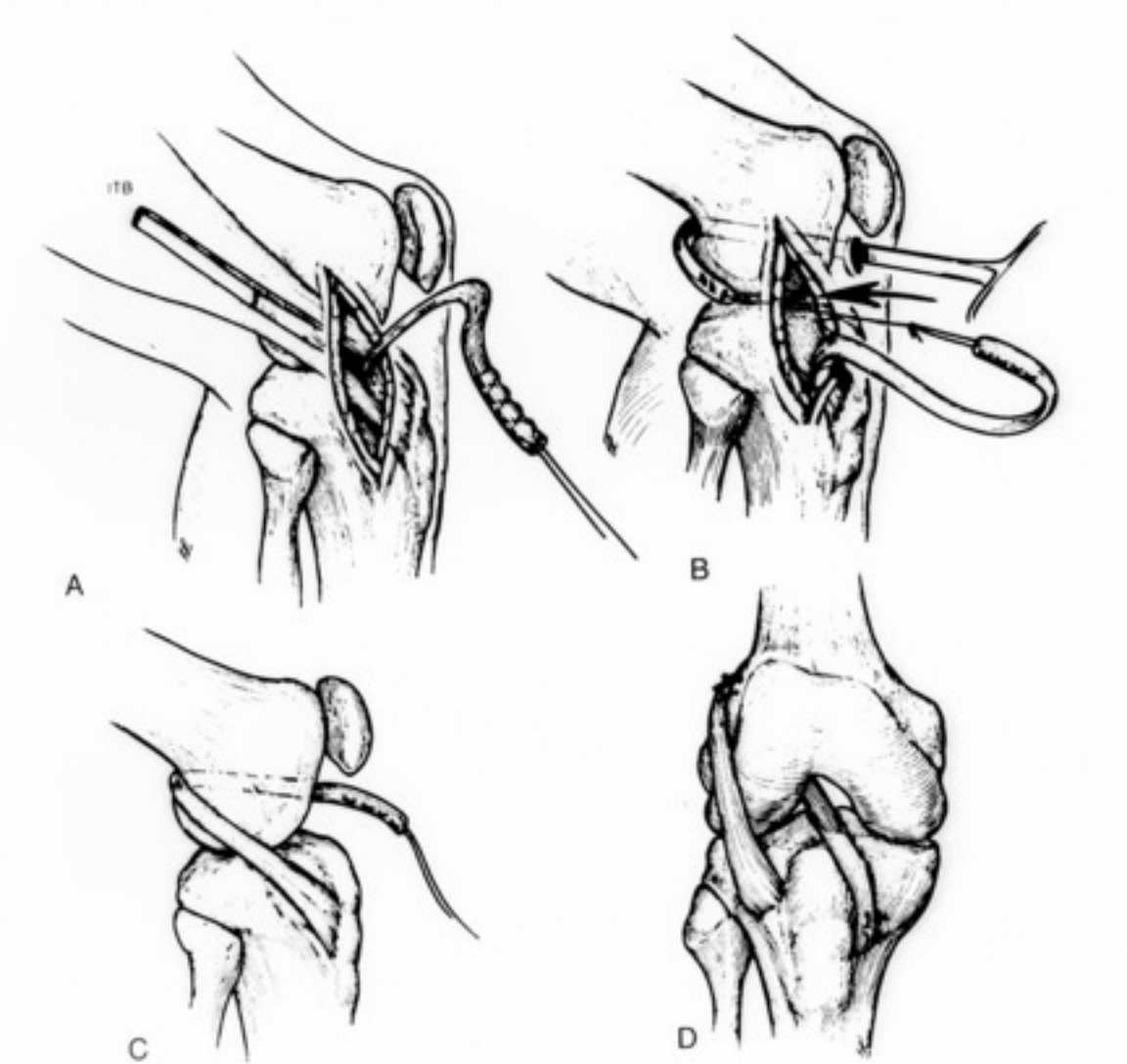
1976-1978 – Lyle J. Micheli, 3 cases, congenital absent ACL, "modified Macintosh", age 3-6 years

1978-1999 – ACL tear, meniscus tear

Micheli LJ, Rask B, Gerberg L. Anterior cruciate ligament reconstruction in patients who are prepubescent. Clin Orthop. 1999; (364):40-47.

1999-present – ACL instability

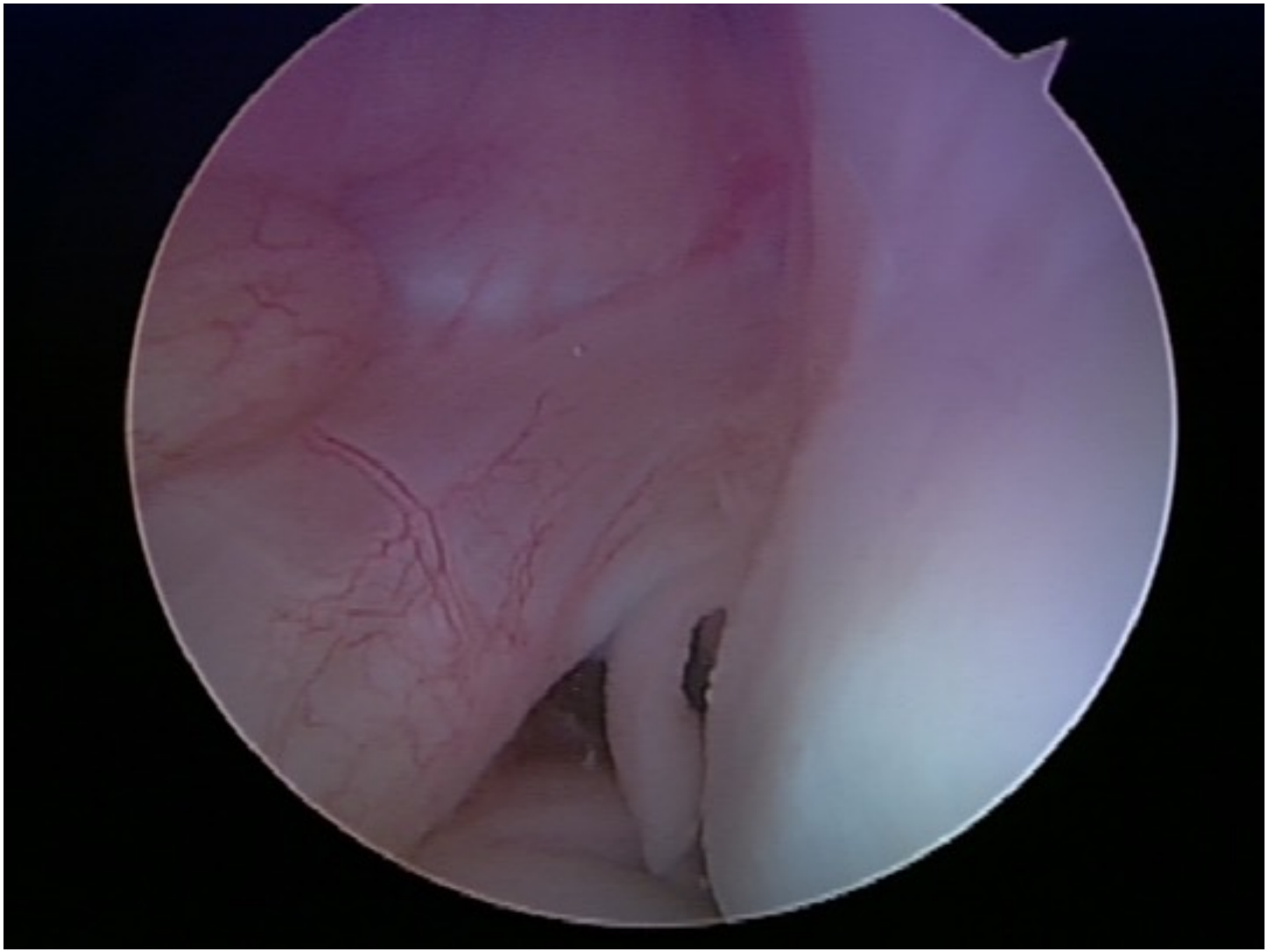
Kocher M, Garg S, Micheli L. Physeal Sparing Reconstruction of the Anterior Cruciate Ligament in Skeletally Immature Prepubescent Children and Adolescents. JBJS 2005, 87A:11, 2371-2379.


ITB
A
B
C
D









Micheli LJ, Rask B, Gerberg L

Anterior Cruciate Ligament Reconstruction in Patients Who Are Prepubescent

Clin Orthop. 1999; (364): 40-47

9 patients, satisfactory

10 Children:
8 Males; 2 Females

- C.A. 2-14 years
- S.A. 2-12 6/12 years
- 3/10 meniscal repair

Follow-up Exam

- 9 of 10
- 2-15 years post-op
- Average 5.3 years

Kocher M, Garg S, Micheli L

Physeal Sparing Reconstruction of the ACL in Skeletally Immature Children and Adolescents

JBJS 87A: 2371-2379. 2005

Method

1980-2002: 50 Pre-pubescent ACL

44 Tanner 1, 2. (28 boys, 16 girls)
Mean Age: 10.3 yr (3.6 – 14.0 yr)

24 pts. Meniscal surgery
IKDC, Lysholm, exam: Radiograph

Results

Followup 2.0 – 15.1 yr: mean 5.3

42 Patients

- IKDC 96.7 + - 6.0 (88.5 – 100)
- Lysholm 95.7 + - 6.7 (74-100)
- Lachman 1/44

4 pts: Subsequent meniscus surgery

2 pts: Revision ACL (4.7, 8.3 yr w/ Op)

No growth disturbance

No perioperative complications

Decision Parameters

1. Safety
2. Efficacy
3. Biomechanics

4. Long term outcome (child)

Long-Term Outcome?

- **Aichroth, P.M et. Al. The Natural History and Treatment**….
  JBJS (Br): 84B.38-41, 2002
  Mean age 13 yr. 25% Unsatisfactory (3 yr)

- **Edwards P.H, Grana W.A. ACL Reconstruction in the Immature Athlete: Long term results of intra articular reconstruction**…*Am J. Knee Surg. 14, 232-237, 2004*
  Average age 13.7 yrs. 4/21 failures (36 months: Range- 5 yrs.)

- **Kocher M, Garg S, Micheli L. Physeal Sparing Reconstruction of the Anterior Cruciate Ligament in Skeletally Immature Prepubescent Children and Adolescents**. *JBJS 2005, 87A:11, 2371-2379.* 4 2/44 success.
  2-15.1 yr (5.3 yr mean)

Outcome of anatomic transphyseal anterior cruciate ligament reconstruction in Tanner stage 1 and 2 patients with open physes.

Hui C, Roe J, Ferguson D, Waller A, Salmon L, Pinczewski L. Am J Sports Med. 2012 May;40(5):1093-8.

16 patients; age 8-14 (12 year mean)
Follow-up 21-34 months (25 months mean)

Complete transphyseal reconstruction of the anterior cruciate ligament in the skeletally immature.

Paletta GA Jr.

Clin Sports Med. 2011 Oct;30(4):779-88.

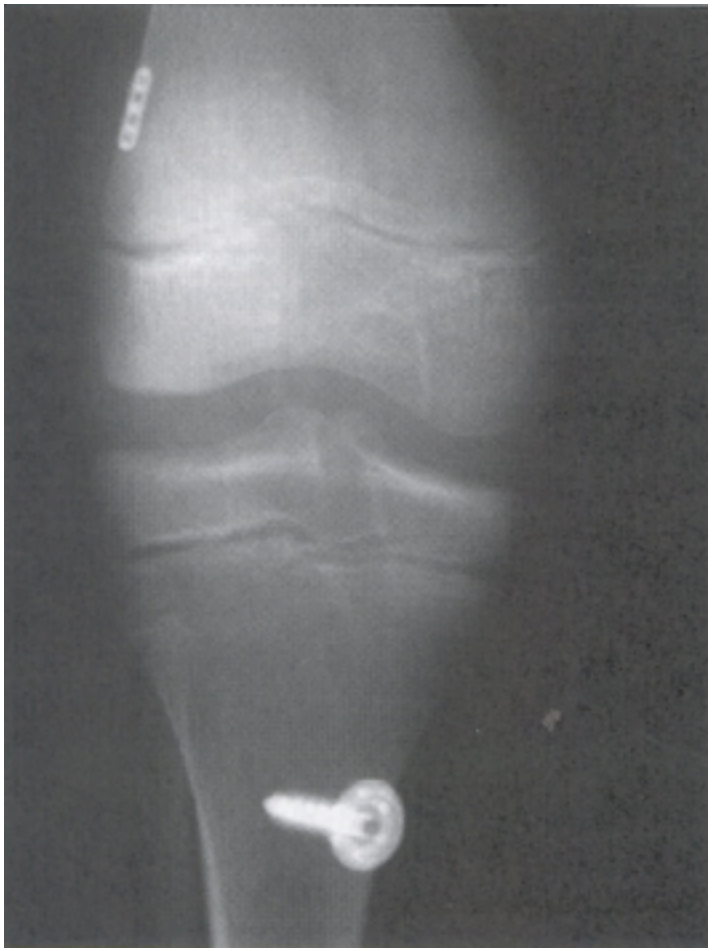
Surgical technique

- Vertical tibial tunnel
- 0.5cm reamers
- Avoid oblique femoral tunnel
- Metaphyseal fixation

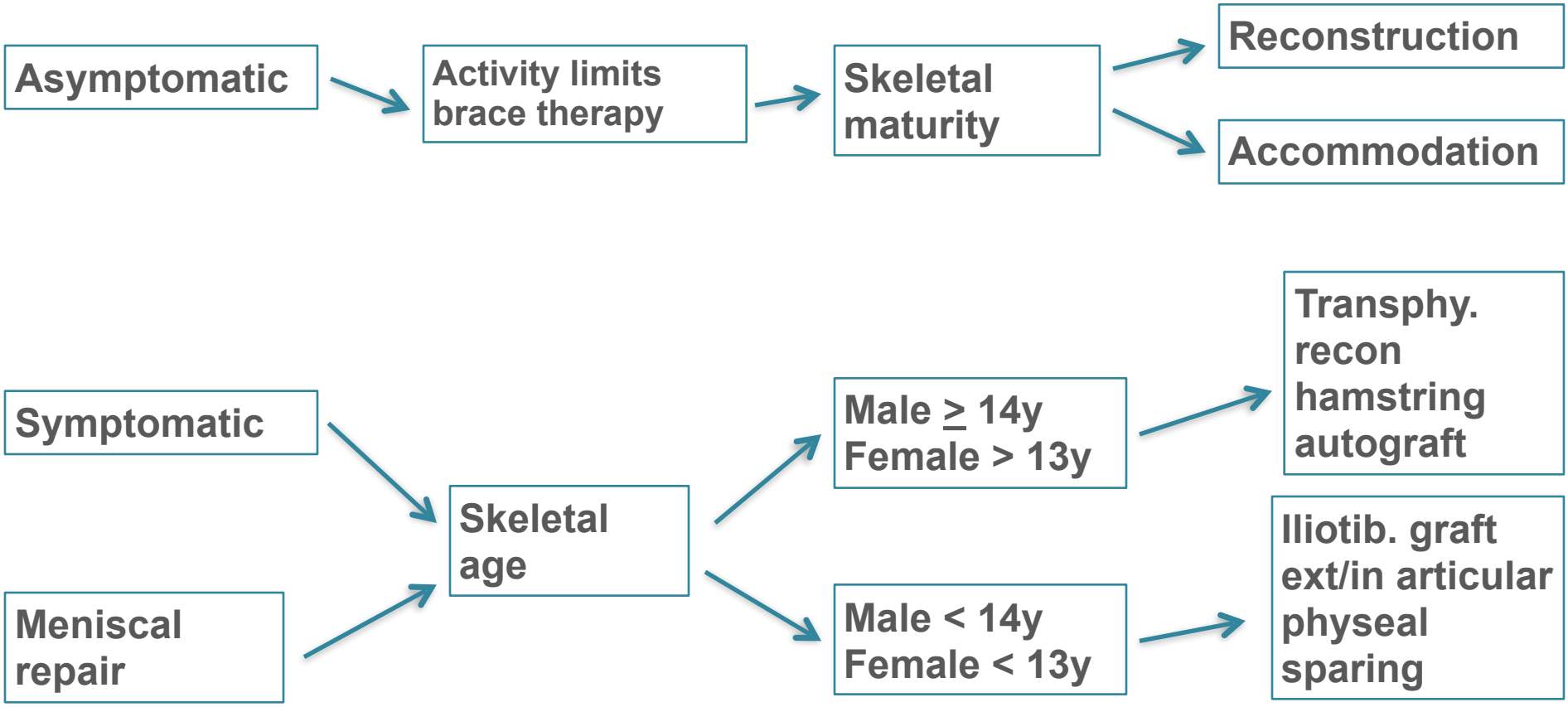
Presented 50 patients; 2009

3-10 years (4.5 years); chron 7-13 years

“Anatomic” reconstruction?

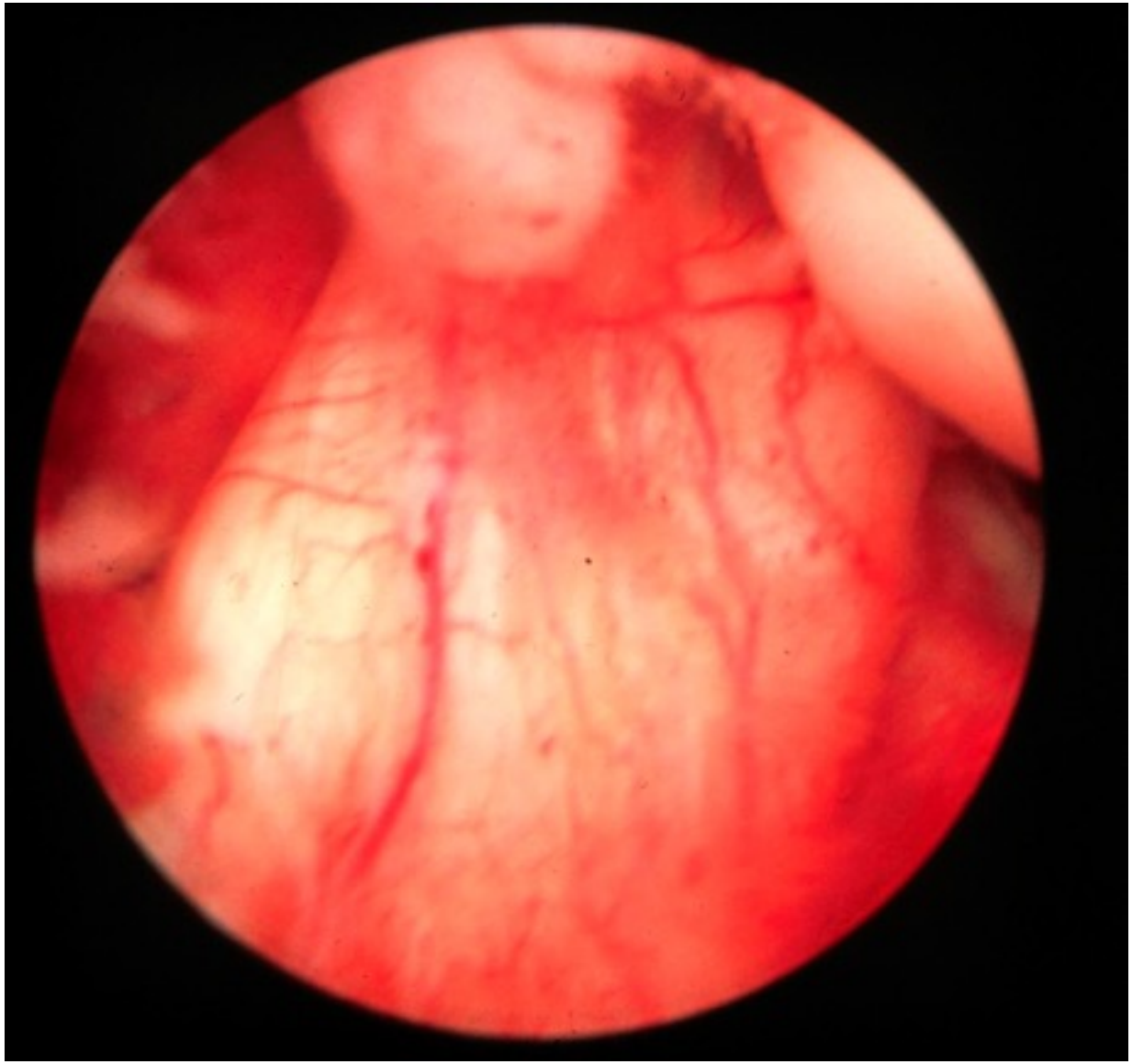


Complete ACL Tear: Child/Adolescent



ACL Injury: Young Athlete

1. **Partial**
2. Complete: pre-pubescent
3. Complete: adolescent



Adolescent ACL Tears

Complete: 39%

Partial: 61%

Adolescent ACL Tears

Complete: 42%

Partial: 58%

Partial ACL Tears

- **Kocher et al (*Am J Sports Med* 2002)**
  - **Patients**
    - Skeletally immature
    - Arthroscopically documented partial tear
      - 45 pts, 13.9 yrs old, 6.1 yr f/u
    - Exclusion criteria
      - Initial ACL reconstruction
        - » Repairable meniscal tear
        - » Grade C or D Lachman exam
        - » Grade C or D pivot-dhift exam
  - **Treatment**
  - **Outcome**
      - 31% (14/45) subsequent reconstruction



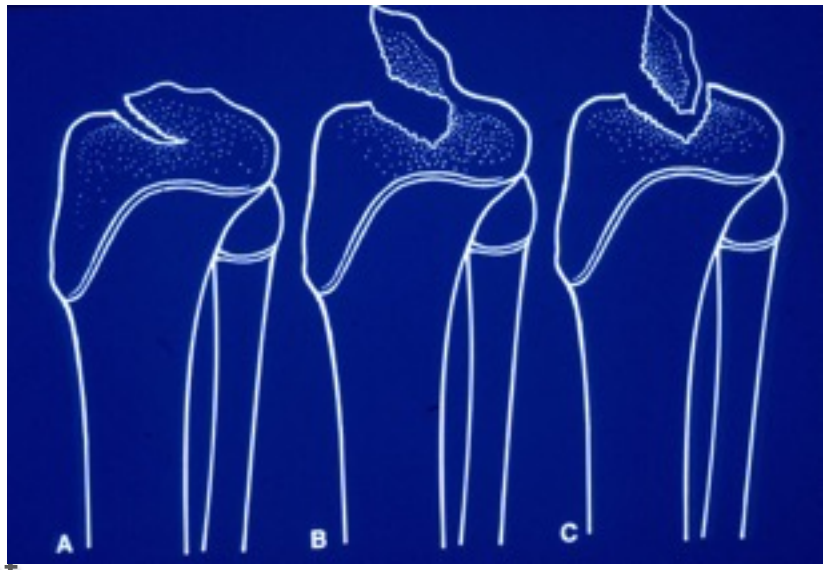


Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

Tibial Spine Fractures in Children

Tibial Spine Fx

- **Signs & Symptoms**
  - Hemarthrosis
  - Lack extension (bony block)
  - Anterior laxity
- **Imaging**
  - Lateral knee x-ray
- **Classification**
  - Meyers & McKeever (JBJS 1959)
    - Type I Minimal displacement
    - Type II Hinged
    - Type III Completely displaced



Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

Tibial Spine Fx Classification: Micheli

1. Stable – negative Lachman
2. Unstable – positive Lachman

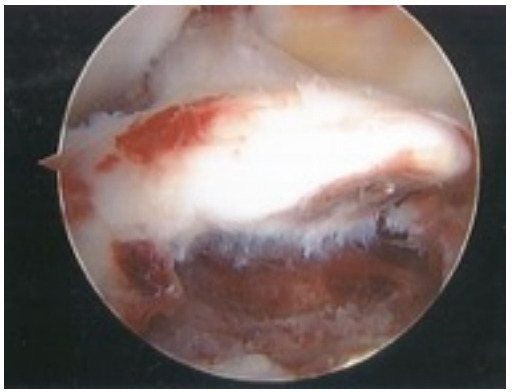
Tibial Spine Management

1. Stable
   - Cast or brace, 4-6 wk @ 30º flexion
2. Unstable
   - Arthroscopy, reduction, fixation

Tibial Spine Fx

Prognosis

- **Gronkvist et al (*JPO* 1984)/ McLennan (*JPO* 1995)**
  - Recommended ORIF for all displaced fractures
  - More laxity in closed treatment vs fixation
- **Baxter & Wiley (*JBJS* 1988)**
  - Mild-moderate knee laxity in 45% pts
  - Functionally not significant
- **Janarv et al (*JPO* 1995)**
  - Laxity 3-9 mm in 38% (functionally not significant)
- **Willis et al (*JPO* 1993)**
  - Anterior laxity in 64% (50 pts) @ 4 yrs
  - No complaints of instability
- **Kocher et al (Arthroscopy-in press)**
  - Laxity: 6.1 mm KT-1000 MMD
  - Function: 99.5 Lysholm score





Slide from: Pediatric Knee, Mininder S. Kocher, MD, MPH

Kocher M, Foreman E, Micheli L

Laxity and Functional Outcome of Arthroscopic Reduction and Internal Fixation of Tibial Spine Fractures in Children

J. Arthroscopy 19:1085, 2003



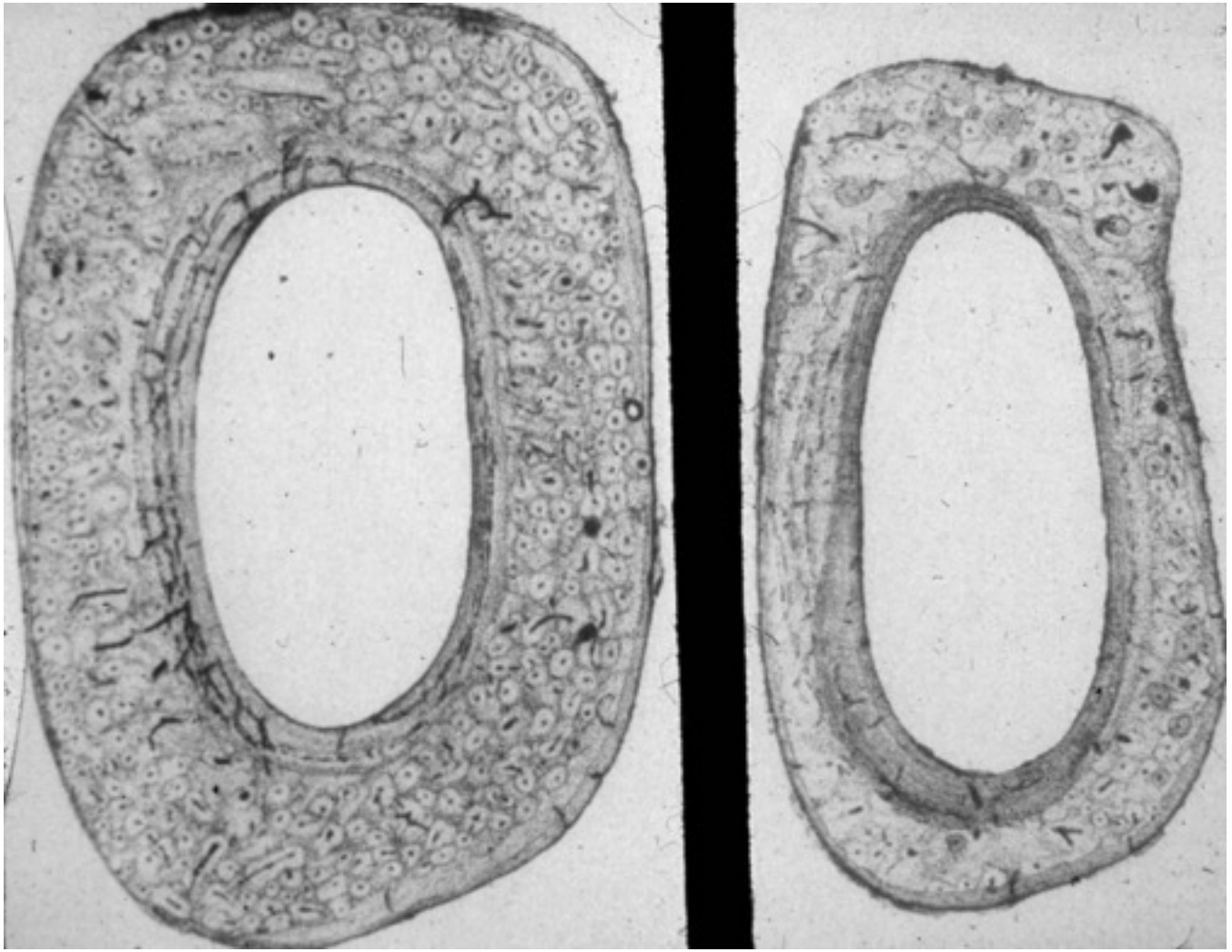






Prevention of ACL Injuries: Young Athlete

- **Strength training**
- Neuromuscular training
- Plyometrics
- Technique: cutting, landing, agility
- Bracing ?




YHL
25

Prevention of ACL Injuries: Young Athlete

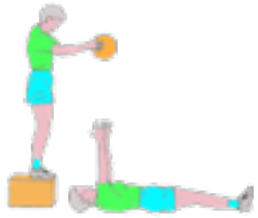
- Strength training
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- Bracing ?

Prevention of ACL Injuries: Young Athlete

- Strength training
- Neuromuscular training
- **Plyometrics**
- Technique: cutting, landing, agility
- Bracing ?







Lateral cone/line hop











Prevention of ACL Injuries: Young Athlete

- Strength training
- Neuromuscular training
- Plyometrics
- **Technique: cutting, landing, agility**
- Bracing ?


INDIANA
INDIANA







Prevention of ACL Injuries: Young Athlete

- Strength training
- Neuromuscular training
- Plyometrics
- Technique: cutting, landing, agility
- **Bracing ?**

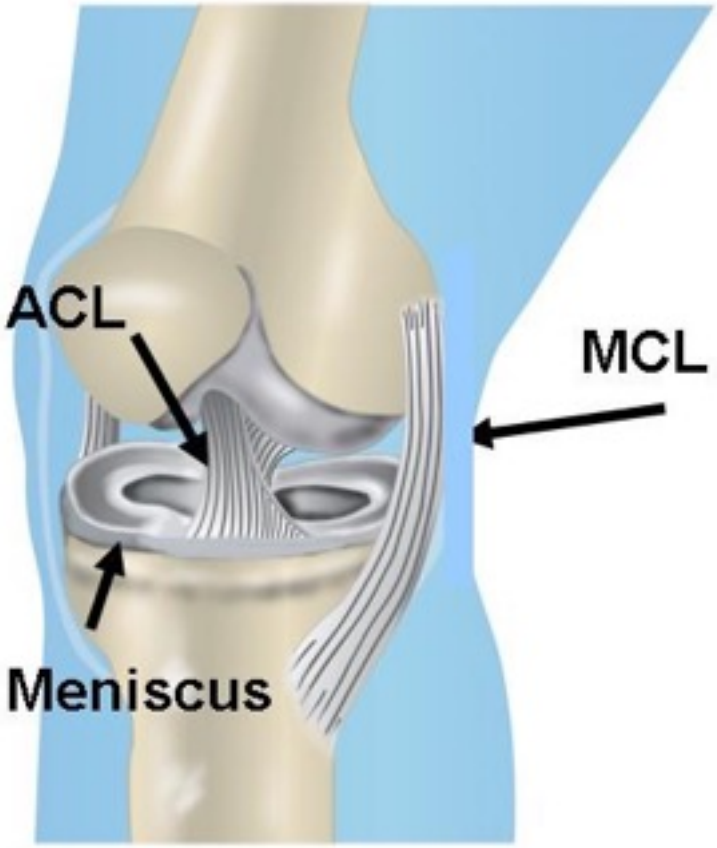
The Future
Biologic ACL Repair?

Martha Murray, MD

Bridge Enhanced ACL Repair: Early Results

Clinical Importance of ACL Injuries

- ACL: 550,000/year[1]
- Failure rate with suture repair > 90%[2]
- ACL reconstruction current gold standard of treatment



1. *Source: U.S. Bancorp Piper Jaffray Equity Research, Orthopedic Overview, 1999.*
2. *Feagin, 1976*

Adolescent ACL Injuries

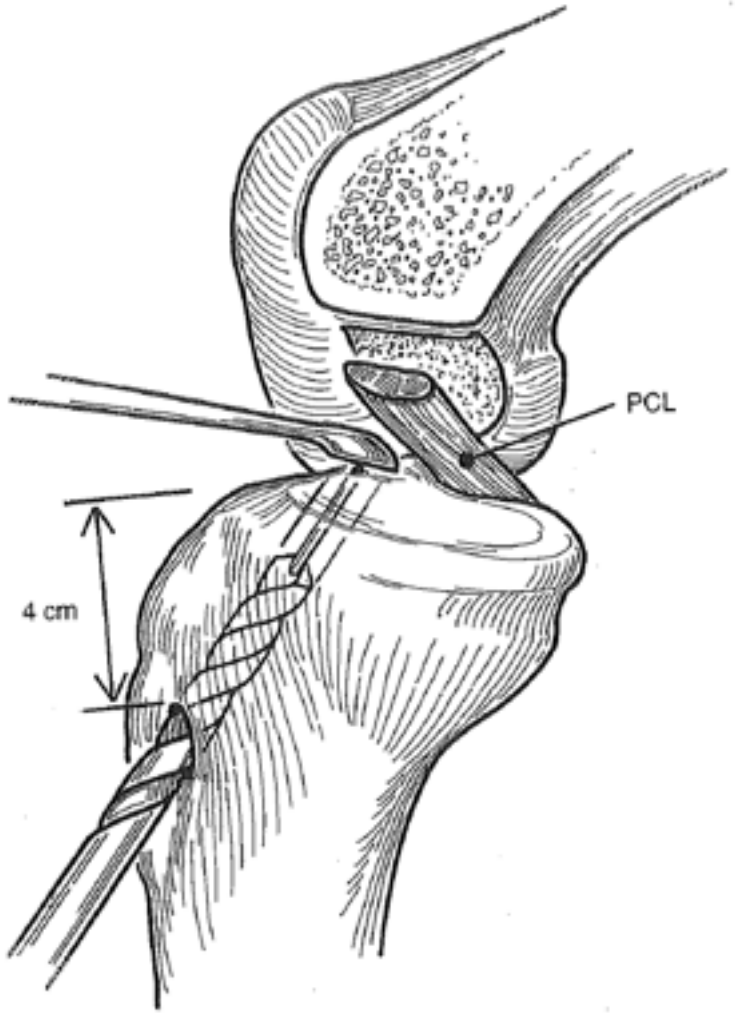
- High rate of early graft failure
  - Up to 20% in the first 2 years
- High rate of late graft failure
  - At 10 years, graft failure rates 50%[2]
- High risk of post-traumatic OA
  - 78% OA at 14 years after ACL injury with or without reconstruction[3]
  - 15YO +14 years =29YO with OA

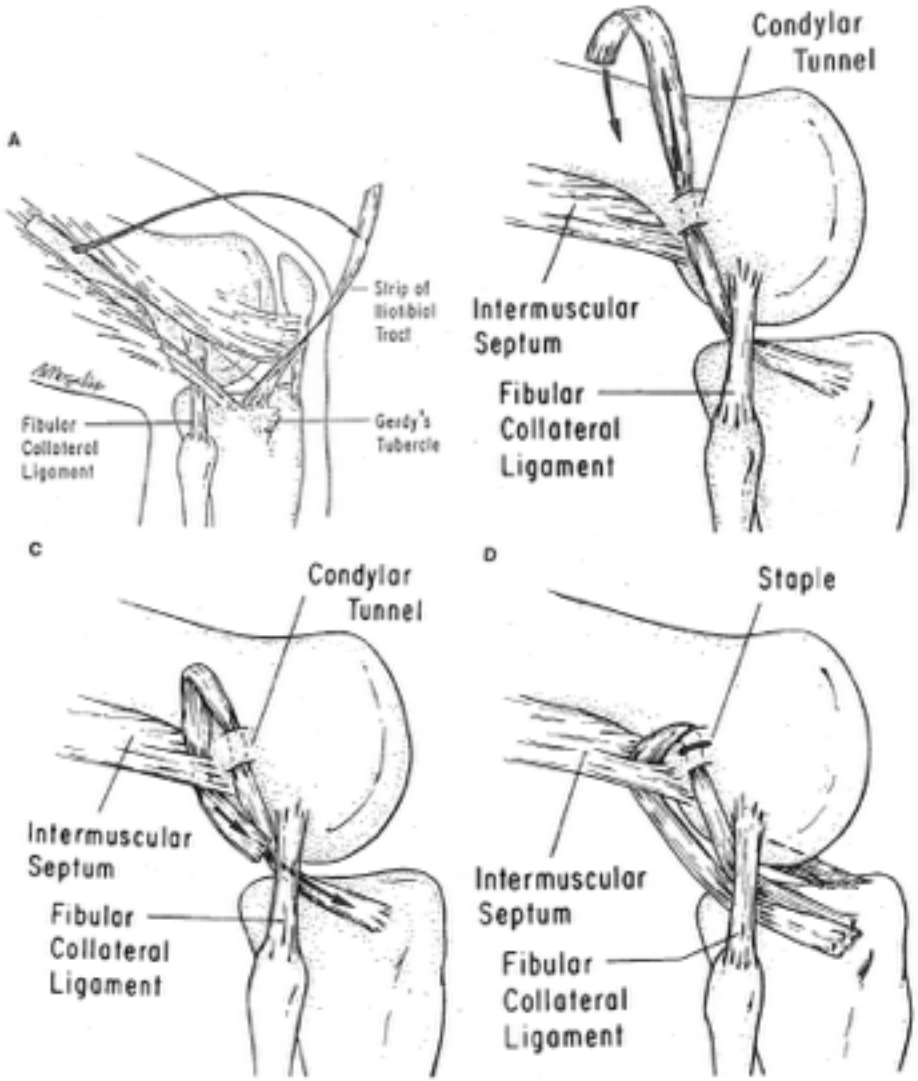


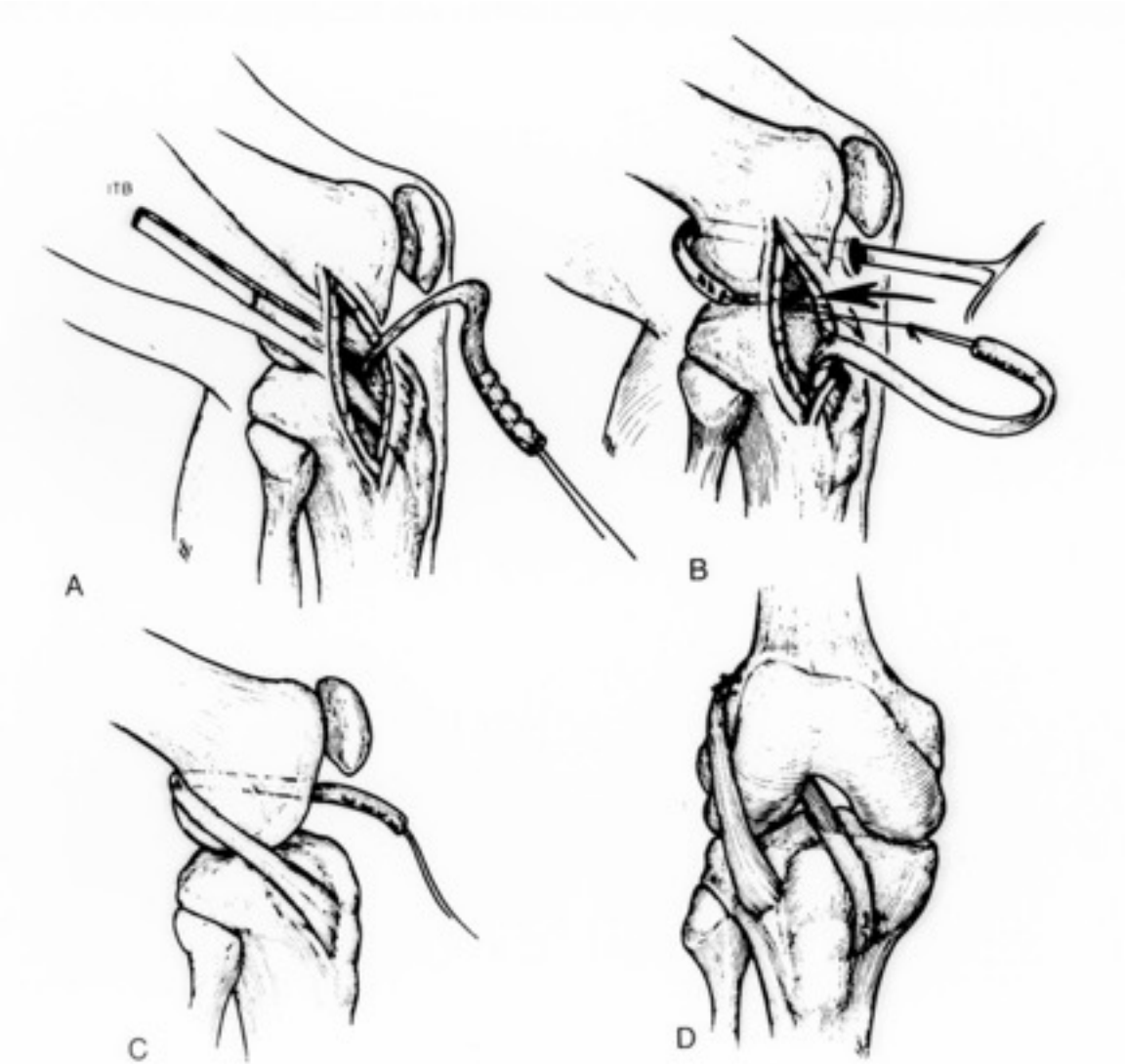
1. Kaeding et al, 2010; 2. Hanypsiak et al, 2011; 3. Von Porat et al, 2004

ACL Injury

1. Reconstruction: Intra articular
2. Reconstruction: Extra articular
3. Reconstruction: Combined
4. Repair?


PCL
4 cm


A
Strip of Iliotibial Tract
Gerdy's Tubercle
Fibular Collateral Ligament
Condylar Tunnel
Intermuscular Septum
Fibular Collateral Ligament
C
Condylar Tunnel
Intermuscular Septum
Fibular Collateral Ligament
D
Staple
Intermuscular Septum
Fibular Collateral Ligament


A
B
C
D

ACL Injury

1. Reconstruction: Intra articular
2. Reconstruction: Extra articular
3. Reconstruction: Combined
4. **Repair?**

ACL Repair: John Feagin

- 2 year f/u: 83% good/excellent
- 5 year f/u: poor function → ½
  - 94% had unstable knees

Feagin JA, Abbott HG, Rokous JA. The isolated tear of the ACL. J Bone Joint Surg. 1972;54A:1340.

Feagin JA Jr, Curl WW. Isolated tear of the anterior cruciate ligament: 5-year follow-up study. Am J Sports Med. 1976 May-Jun;4(3):95-100.

Can We Avoid Reconstruction?



ACL Tear



ACL Reconstruction: Removal and Replacement

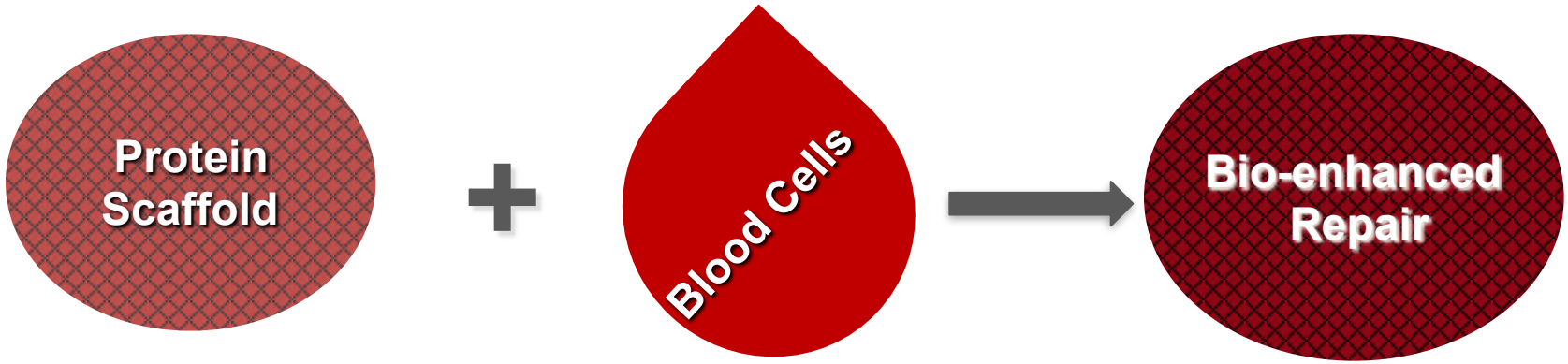


Repair and Regeneration

Suture repair + bio-active scaffold

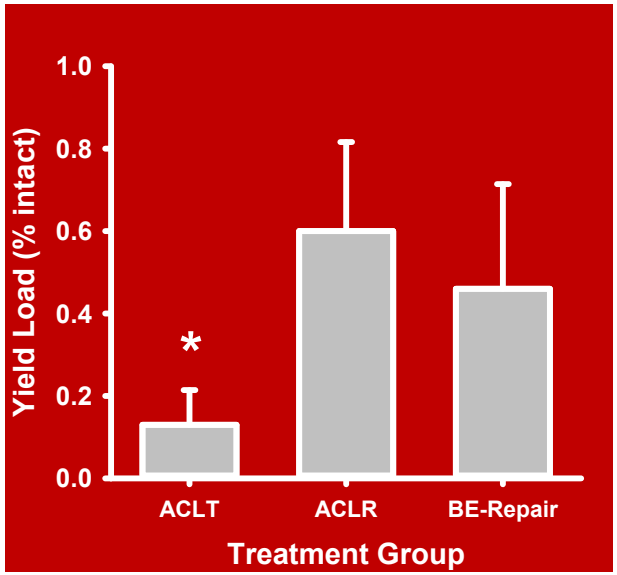
What if we add a bio-engineered scaffold to the gap of the torn ACL?

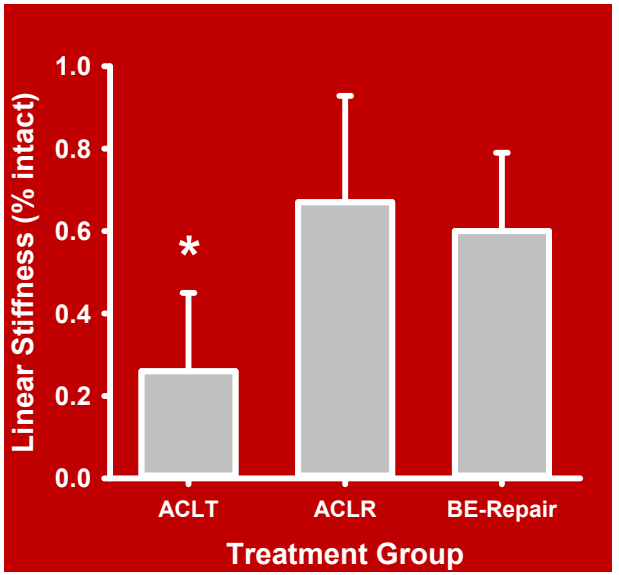
- Extracellular matrix scaffold used as a carrier for bioactive agent
- Biologic wound healing system (autologous blood)



Bridge-Enhanced ACL Repair (BEAR) Strength Equal to Reconstruction in Preclinical Trials

- Biomechanics equivalent to reconstruction at 3 months, 1 year after surgery in porcine model.
- No adverse reactions to the scaffold.





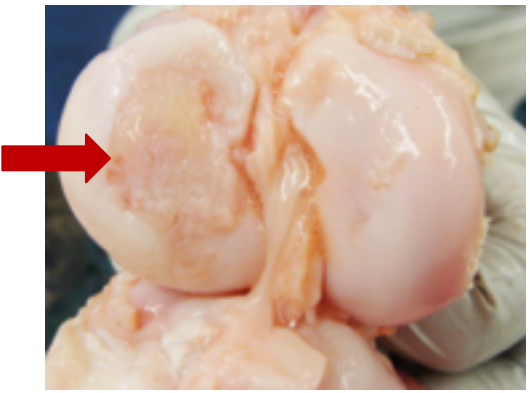
Murray & Fleming, AJSM 2013

Less cartilage damage seen with bio-enhanced repair at 1 year in porcine model

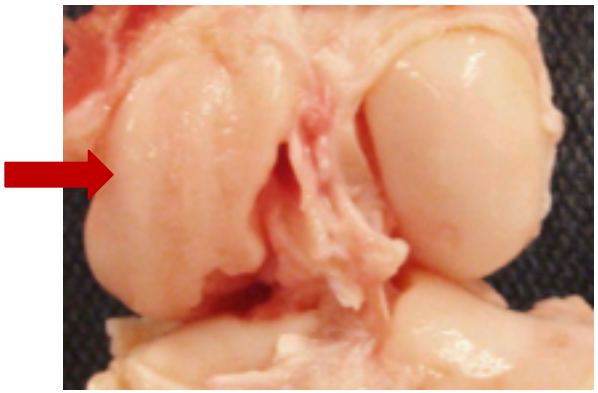




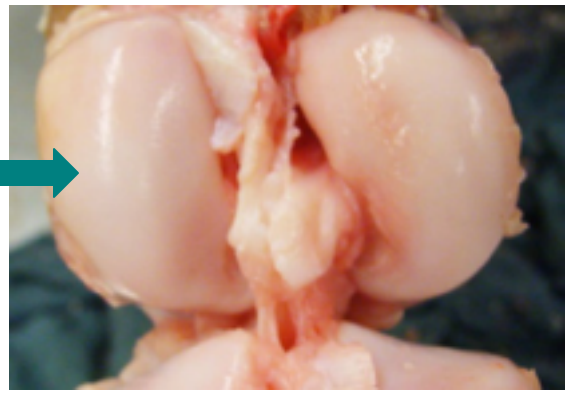




ACL transection



ACL reconstruction



Bridge-enhanced ACL repair (BEAR)

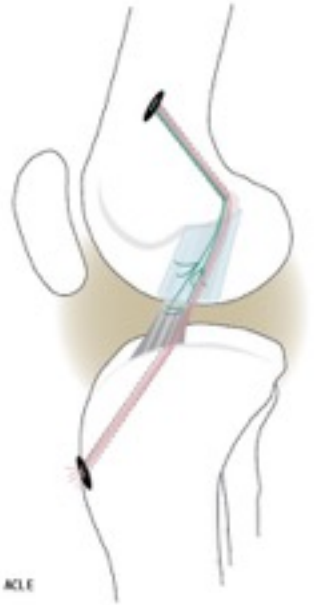
Murray & Fleming, AJSM 2013



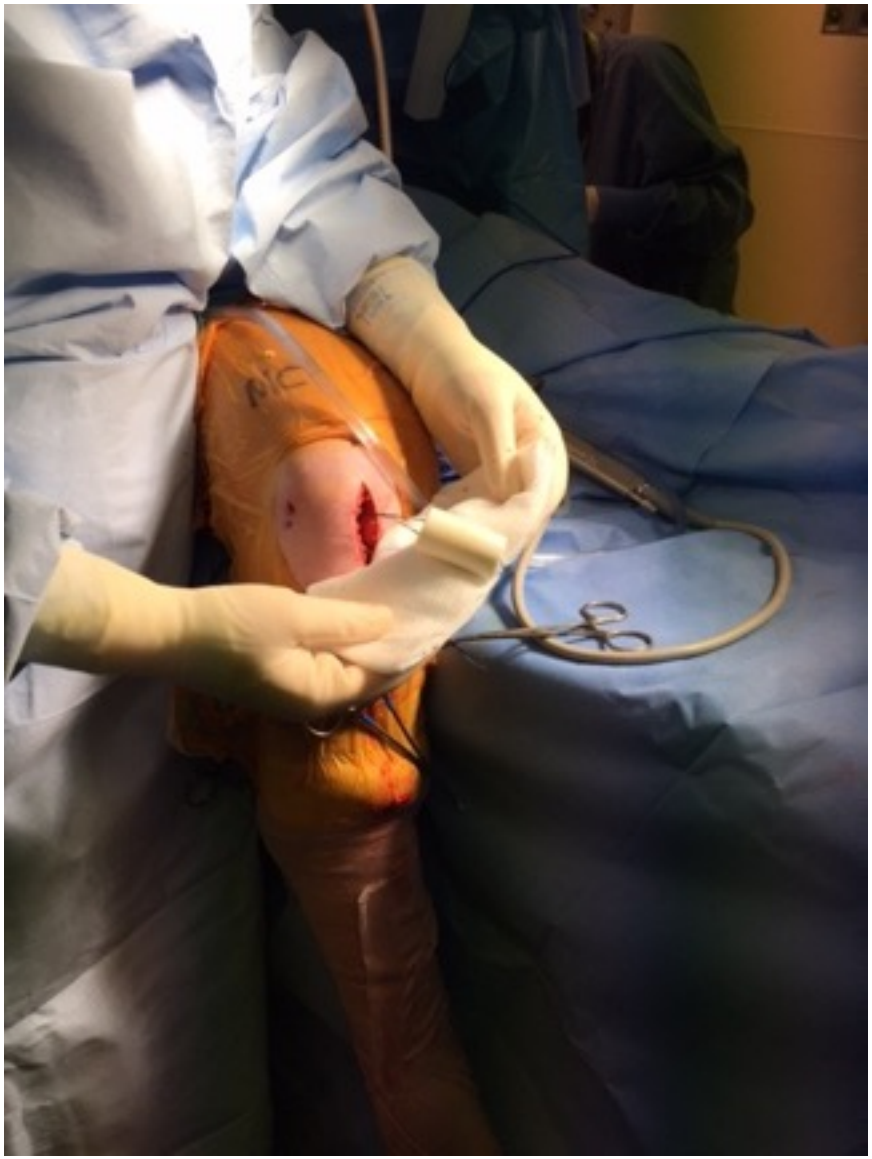


The BEAR Study

- 20 patient FDA-approved study
- 10 patients with Bridge-Enhanced-ACL-Repair (BEAR procedure)
- 10 patients with autologous hamstring graft
- Outcomes:
  - Safety (primary): Infection, inflammatory response, weakness, pain, implant failure
  - Efficacy (secondary): Knee laxity, pateint reported outcomes, muscle strength











BEAR Study: Early Results

- Enrollment completed
- All 10 BEAR patients past the 3 month point
  - No significant adverse events related to device
  - BEAR similar to ACL reconstruction at 6 months for
    - Patient reported knee function
    - Knee stability
  - BEAR significantly reduced time to recover hamstring strength
    - 75% strength: 3 mos for BEAR vs 6 mos for ACL reconstruction
    - 90+% strength: 6 mos for BEAR vs ACLR only at 68% at six months

Boston Children's Hospital
Orthopedic Center

BEAR PATIENT

Bridge-Enhanced ACL Repair **EXPERIMENTAL** patient

-NO NERVE BLOCKS

-PHYSICAL EXAM REQUIRED UNDER ANESTHESIA

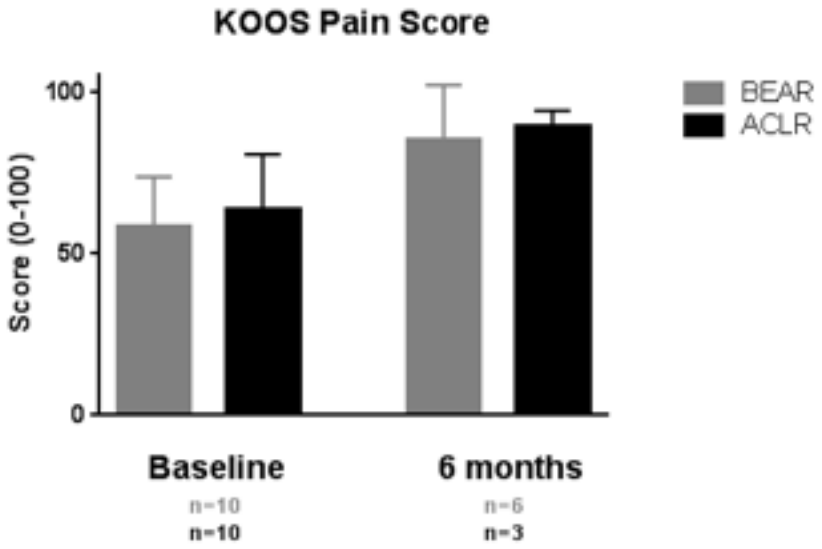
-NO CPM MACHINE

If you have any questions or concerns please contact Brett Flutie in the Operating Room, Patricia Connell at 617-355-4011 (ext: 54011), or Bethany Trainor at 617-355-2016 (ext: 52016).

Principal Investigator: Martha Murray, MD
Boston Children's Hospital
Division of Sports Medicine, Department of Orthopaedic Surgery
300 Longwood Ave, Boston, MA 02115
Phone: 617 355 7132
Email: martha.murray@childrens.harvard.edu

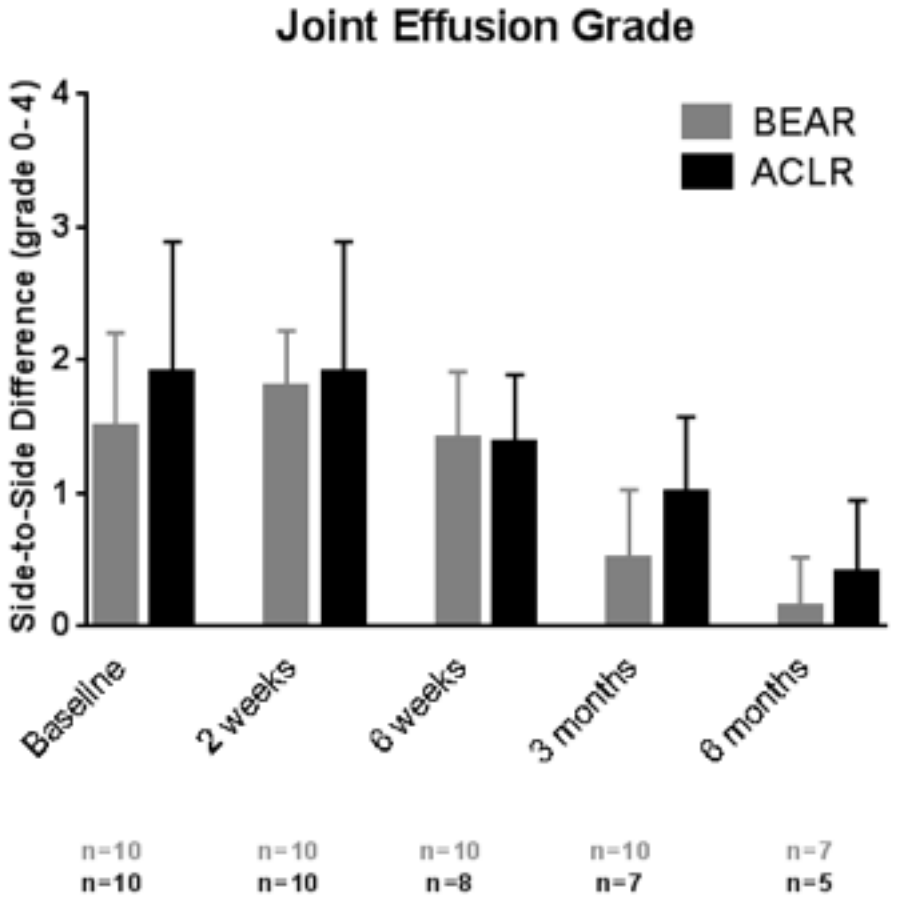
Pain: BEAR vs. ACL reconstruction

- No significant differences



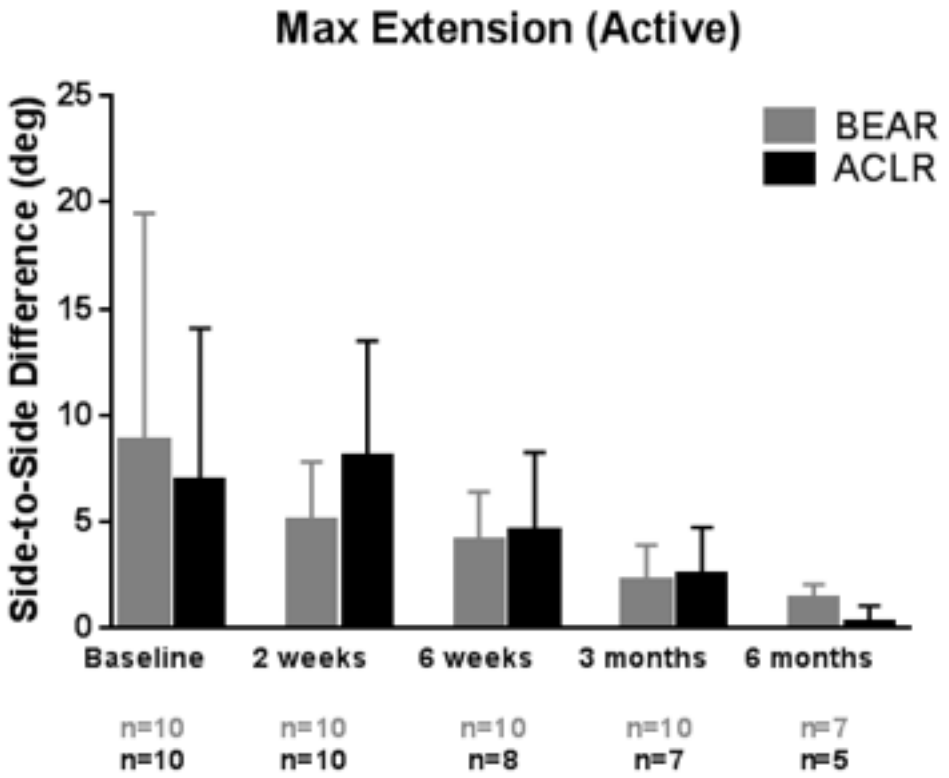
Effusion: BEAR vs. ACL reconstruction

- No significant differences at any time point



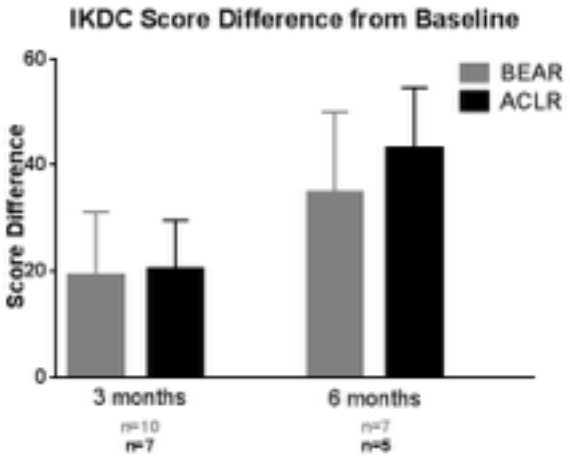
ROM: BEAR vs. ACL reconstruction

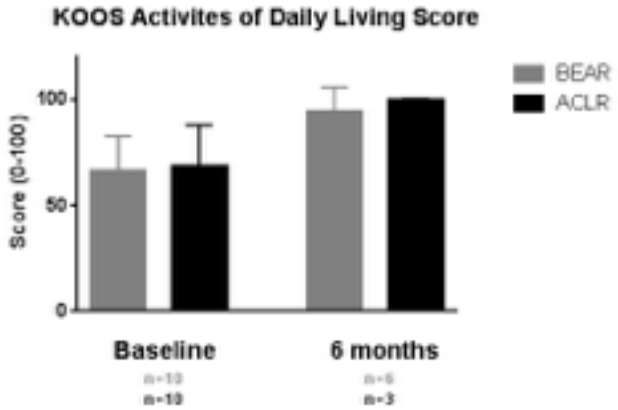
- No significant differences at any time point

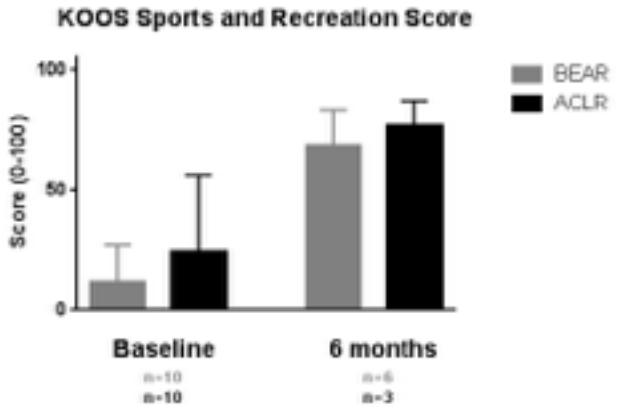


Patient Reported Outcomes: IKDC and KOOS

- No significant differences at any time point

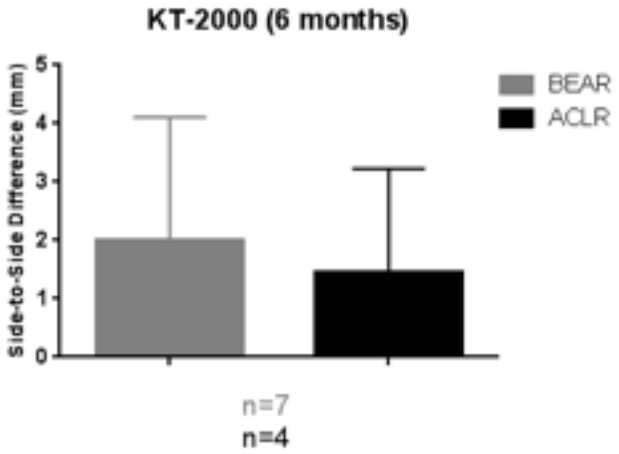


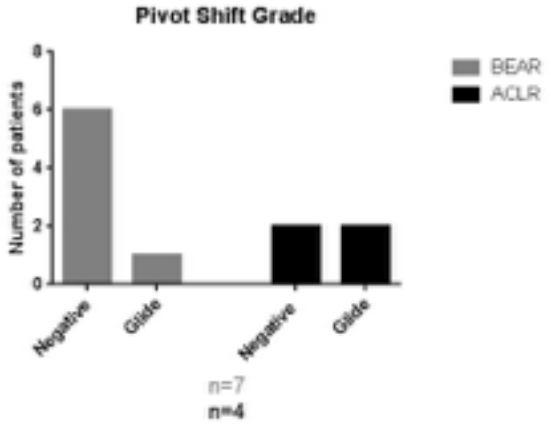




Knee Stability: 6 Months

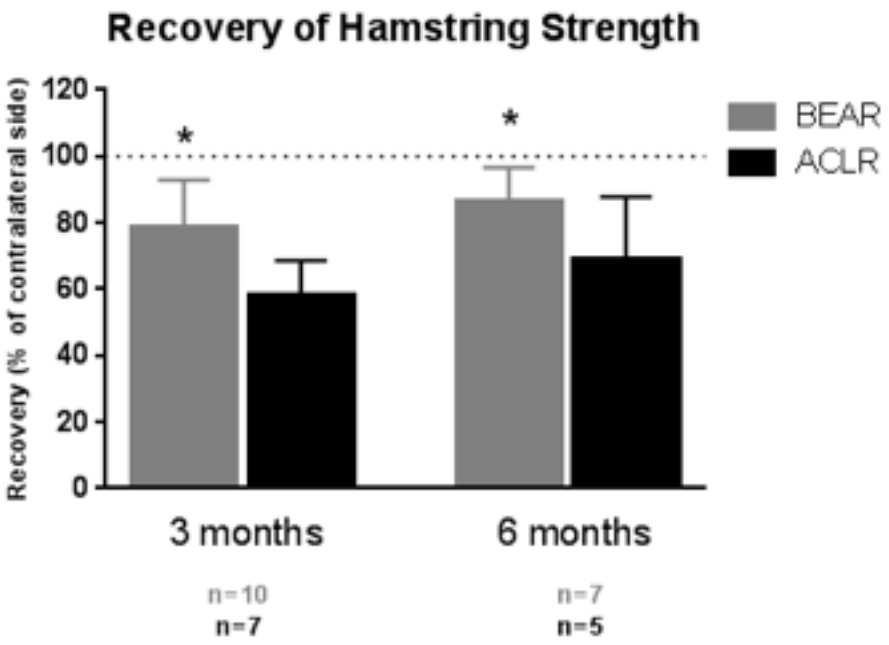
- No significant difference in KT-2000
- No significant difference in Pivot-Shift grade



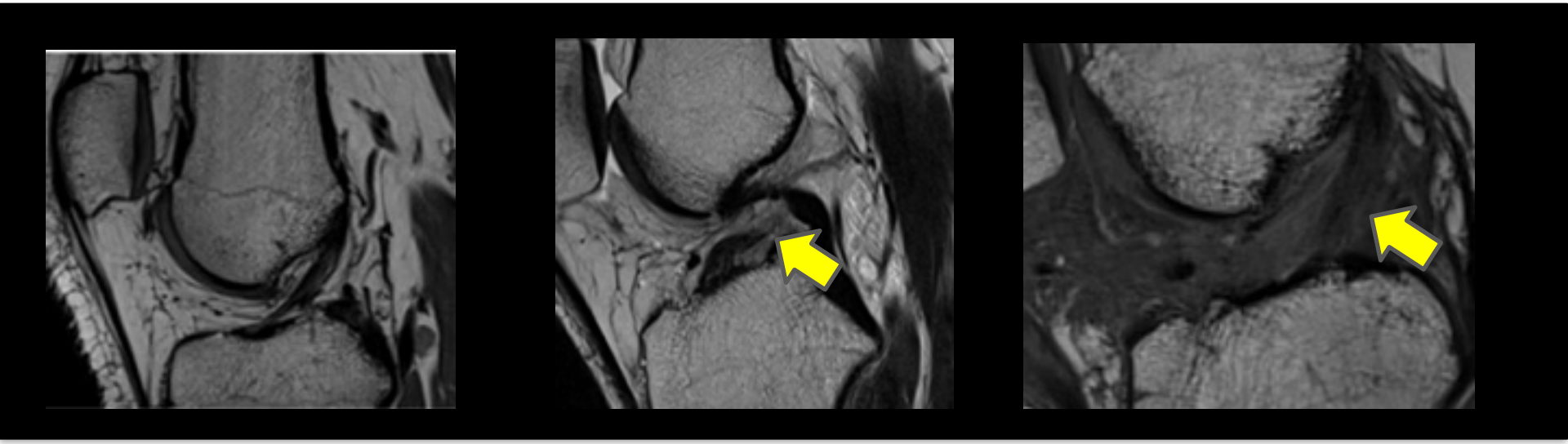


Hamstring Strength

- **Significantly greater recovery of hamstring strength with BEAR at 3 and 6 months (*p<0.001)**



First Bridge-Enhanced ACL Repair Patient

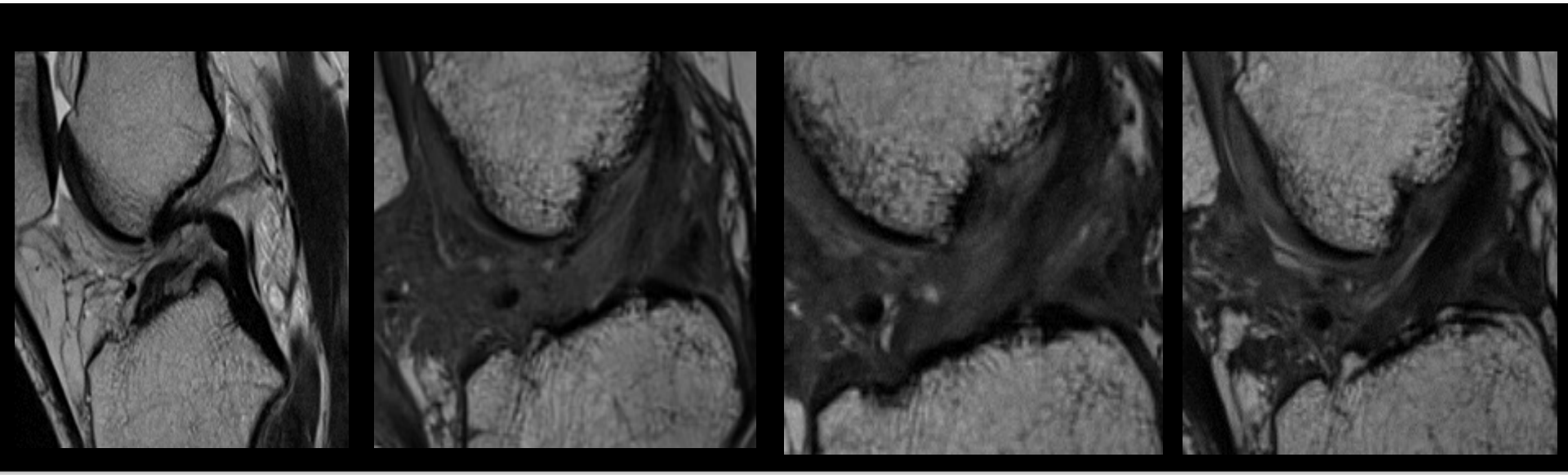


Normal ACL

Injury:
Arrow points to
torn ACL

Healing ACL at
3 months after
Bridge-Enhanced
ACL Repair

First Bridge-Enhanced ACL Repair Patient



Pre-op | 3 months post-op | 6 months post-op | 12 months post-op

KT 1 mm looser than contralateral normal side

Next Steps: BEAR II

- BEAR II: Single Center (BCH) RCT BEAR vs ACL recon
  - FDA IDE issued, IRB approvals pending
  - 100 patients
  - 14 to 35 y/o, surgery within 6 weeks of injury
  - Midsubstance tear
- MOON Multicenter RCT
  - Kaeding, Spindler, Wright
  - Trial planning in process

Conclusions

- Very early days yet, first patient only 1 year out
- Clearly needs further study
  - Who does it work for?
  - How can we improve the technique?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 7, 2016

Boston Children's Hospital
Martha M. Murray, M.D.
Associate Professor of Orthopaedic Surgery
300 Longwood Avenue, Hunnewell 2
Boston, Massachusetts 02115

Re: G150268
Trade/Device Name: BEAR™ ACL Scaffold
Dated: December 4, 2015
Received: December 9, 2015
CMS Category: A2 (For procedures to request re-evaluation of the categorization decision, please see the appropriate enclosure)
Annual Report Due: One Year from the Date of This Letter

Dear Dr. Murray:

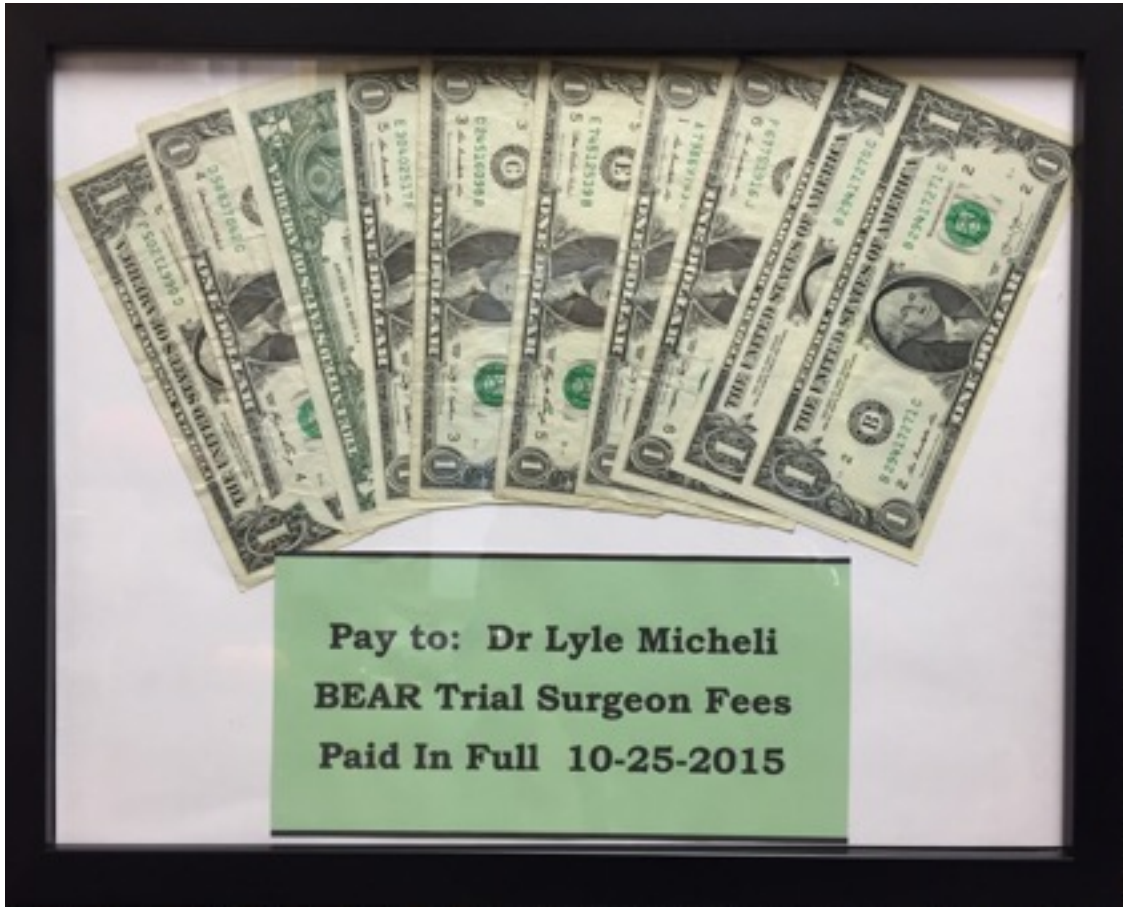
The Food and Drug Administration (FDA) has reviewed your Investigational Device Exemption (IDE) application regarding your pivotal study ("A Prospective, Randomized, Controlled, Clinical Trial Evaluating the Non-Inferiority of Bridge-Enhanced ACL Repair (BEAR) to ACL Reconstruction with an Autologous Tendon Graft (ACLR)") for a significant risk device. Your submission was amended via email dated January 5, 2016, to revise your protocol, case report forms, informed consent, and surgical technique to address our interactive request. FDA has determined you have provided sufficient data to support initiation of a human clinical study; this means that there are no subject protection concerns that preclude initiation of the investigation. Your application is therefore approved, and you may begin your investigation after you have obtained institutional review board (IRB) approval. Your investigation is limited to 1 US institution and 100 US subjects.

We would like to point out that approval of an IDE application does not ensure that the results of this investigation will provide a reasonable assurance of the safety and effectiveness of your device or assure a determination of clearance/approval for your premarket submission.

Your study may meet the definition of an applicable clinical trial, which requires mandatory registration and results reporting on http://www.clinicaltrials.gov. Please see "Guidance for Sponsors, Investigators, and Institutional Review Boards Questions and Answers on Informed Consent Elements, 21 CFR 50.25(c)" at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf for further information on this regulation.

FDA will waive those requirements regarding submission and prior FDA approval of a supplemental application and receipt of certification of institutional review board (IRB) approval

"Your investigation is limited to 1 US institution and 100 US subjects."


Pay to: Dr Lyle Micheli
BEAR Trial Surgeon Fees
Paid In Full 10-25-2015

CASE #1

13 YEAR OLD MALE

PATIENT HISTORY

- 13 year old male
- Twisting injury right knee
- 3 years previously
- MRI demonstrated torn ACL

- Advised to do no contact sports; allowed to play baseball with hinged brace

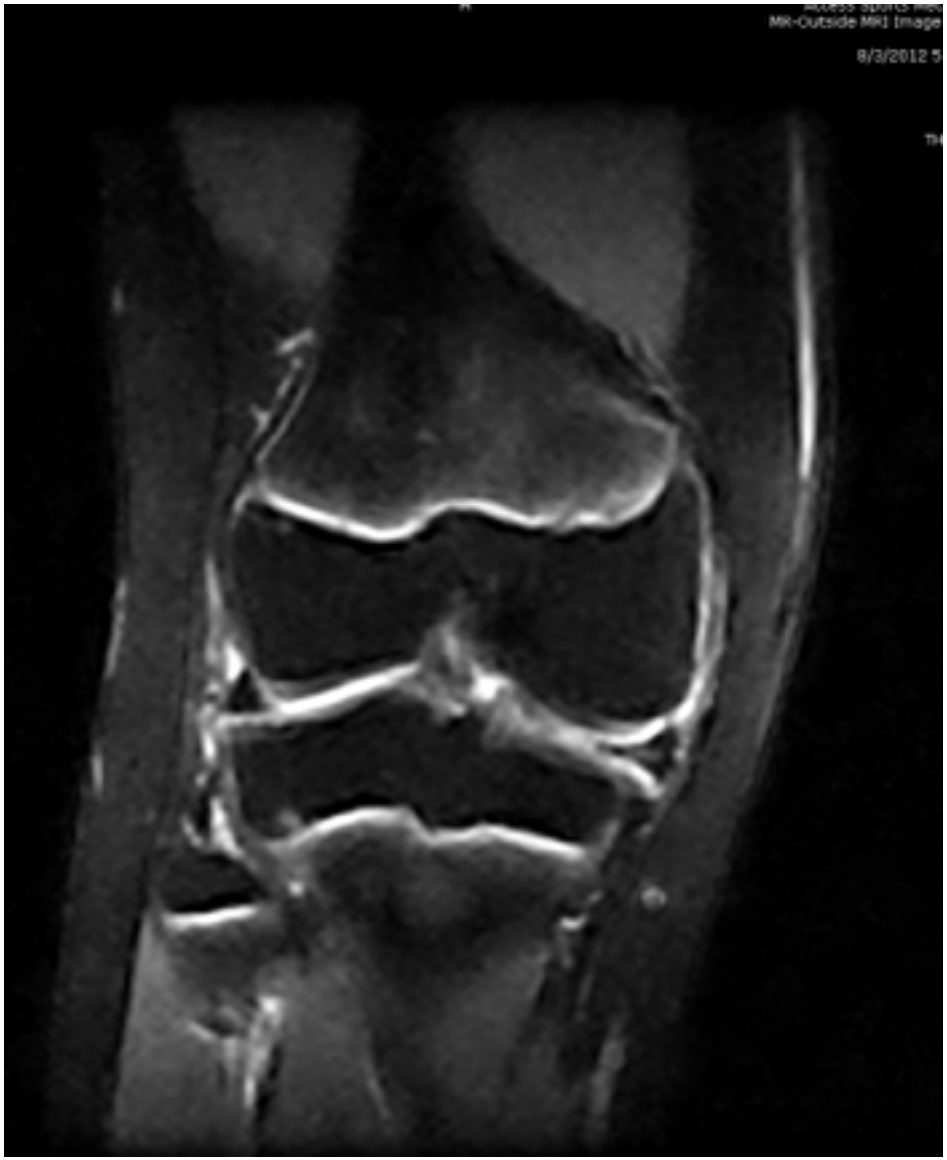
- 8/13/2012 – Persistent pain, MRI shows ACL, MM tear

- 8/15/2013 – Presents to our clinic with pain, locked knee; MRI showed MM tear, LM tear, chronic ACL

EXAM / IMAGING

- Thigh atrophy, anterior drawer
- 110° flexion, -15° extension
- Medial joint line tenderness




MR-Outside MRI Image
8/3/2012

WHAT WOULD YOU DO?

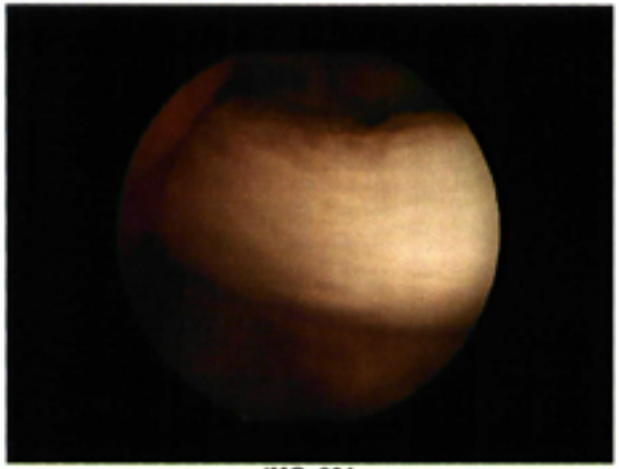
1. Arthroscopy
   ACL repair transphyseal
   Meniscal repair

2. ACL reconstruction extraphyseal
   Meniscus repair

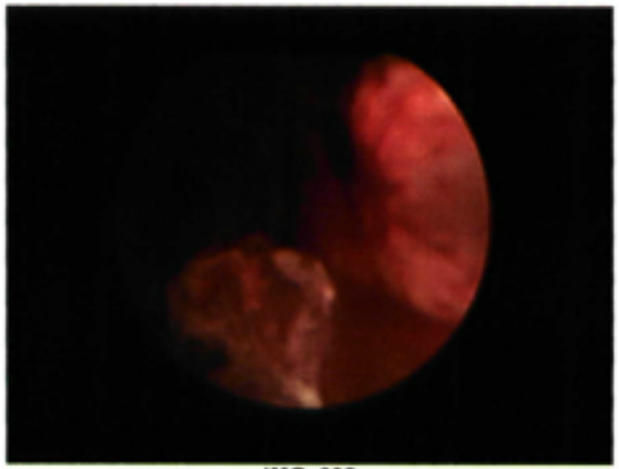
TREATMENT

- ACL reconstruction with ITB extraphyseal
- Repair bucket handle MM
- Repair anterior detachment LM

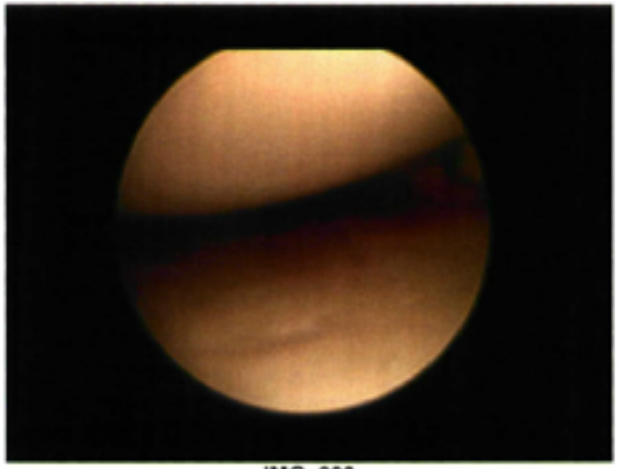

L
KK



IMG_001



IMG_002



IMG_003

POST OPERATIVE

- Brace, crutches
- ROM 0-30º x 4 weeks
- Then 60º
- Then 90º

Doing well at 1 year post op

CASE #2

10 YEAR OLD MALE

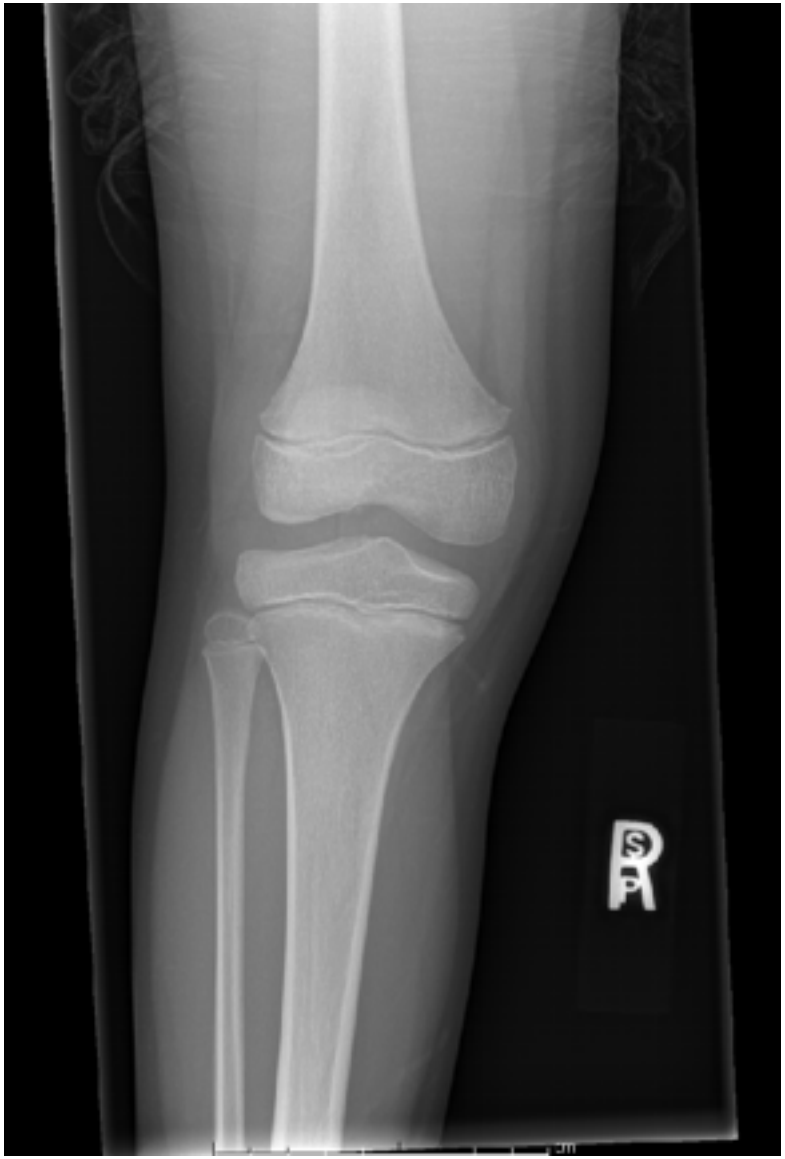
PATIENT HISTORY

- 10 year old male
- Fell off fence and twisted right knee
- 1 week later – pain, swelling while sliding into base
- Persistent knee pain, effusion

EXAM / IMAGING

- 1 month later
- Effusion, + Lachman, + pivot shift
- Baseball, football, golf
- Model, actor








H
F

WHAT WOULD YOU DO?

1. Brace, PT, activity modification

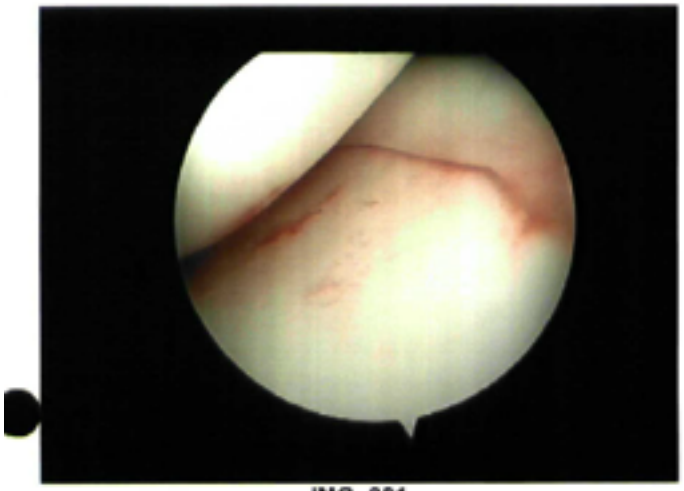
2. Surgery: extra physeal (without drill)

3. Surgery: extra physeal (with drill)

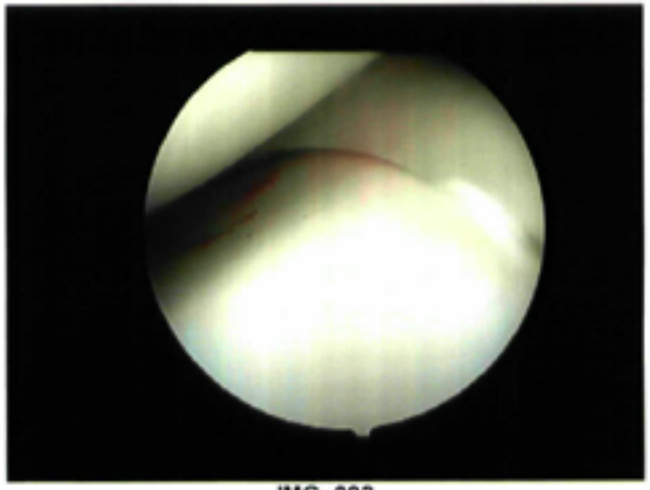
4. Surgery: transphyseal (with drill)
   - Small hole?
   - Vertical vs. oblique drill?

TREATMENT

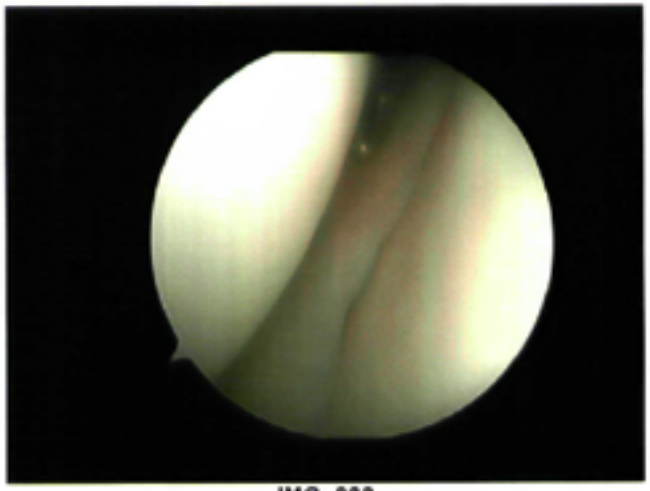
- 1 month pre-rehab PT
- Arthroscopy
- Iliotibial band: extra, intra articular
- Sutured at lateral intermuscular septum and anterior tibial periosteum



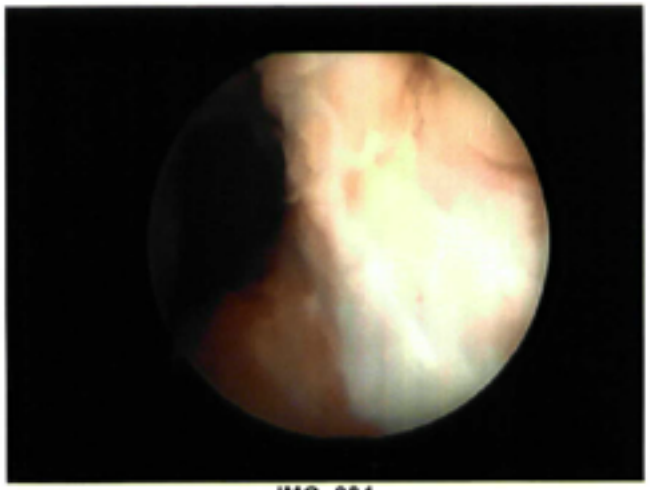
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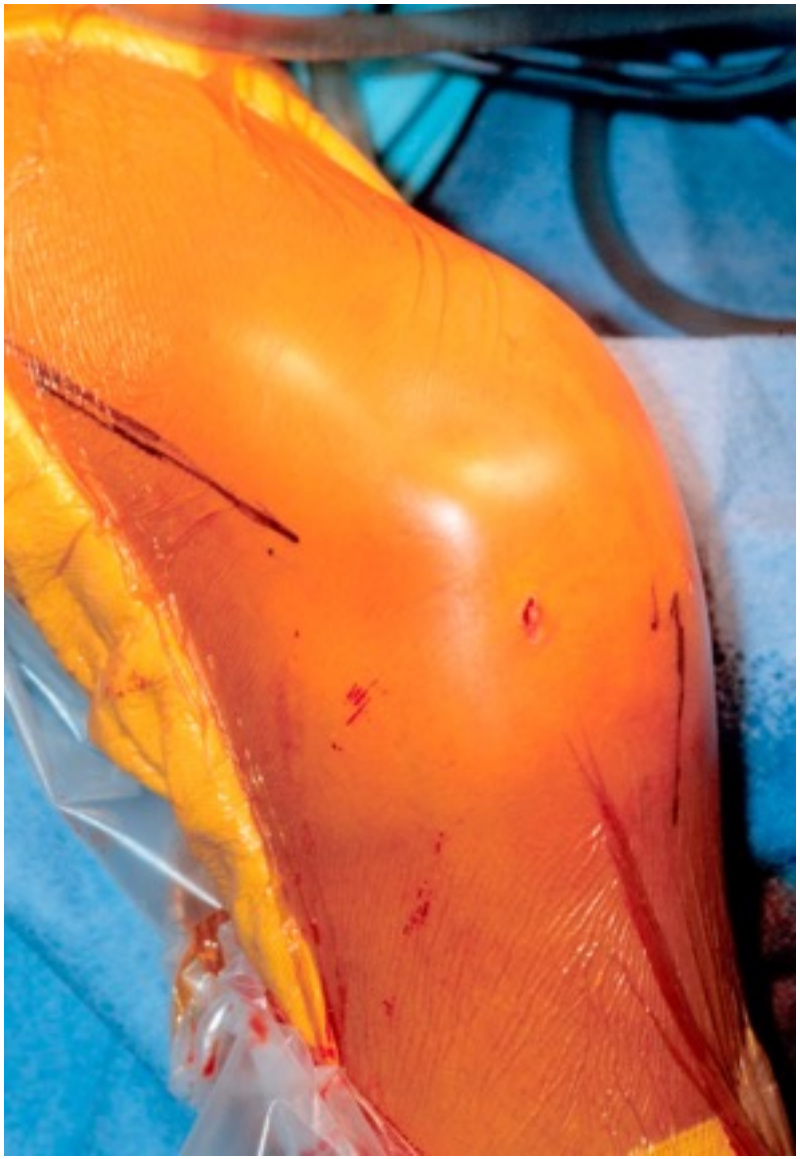
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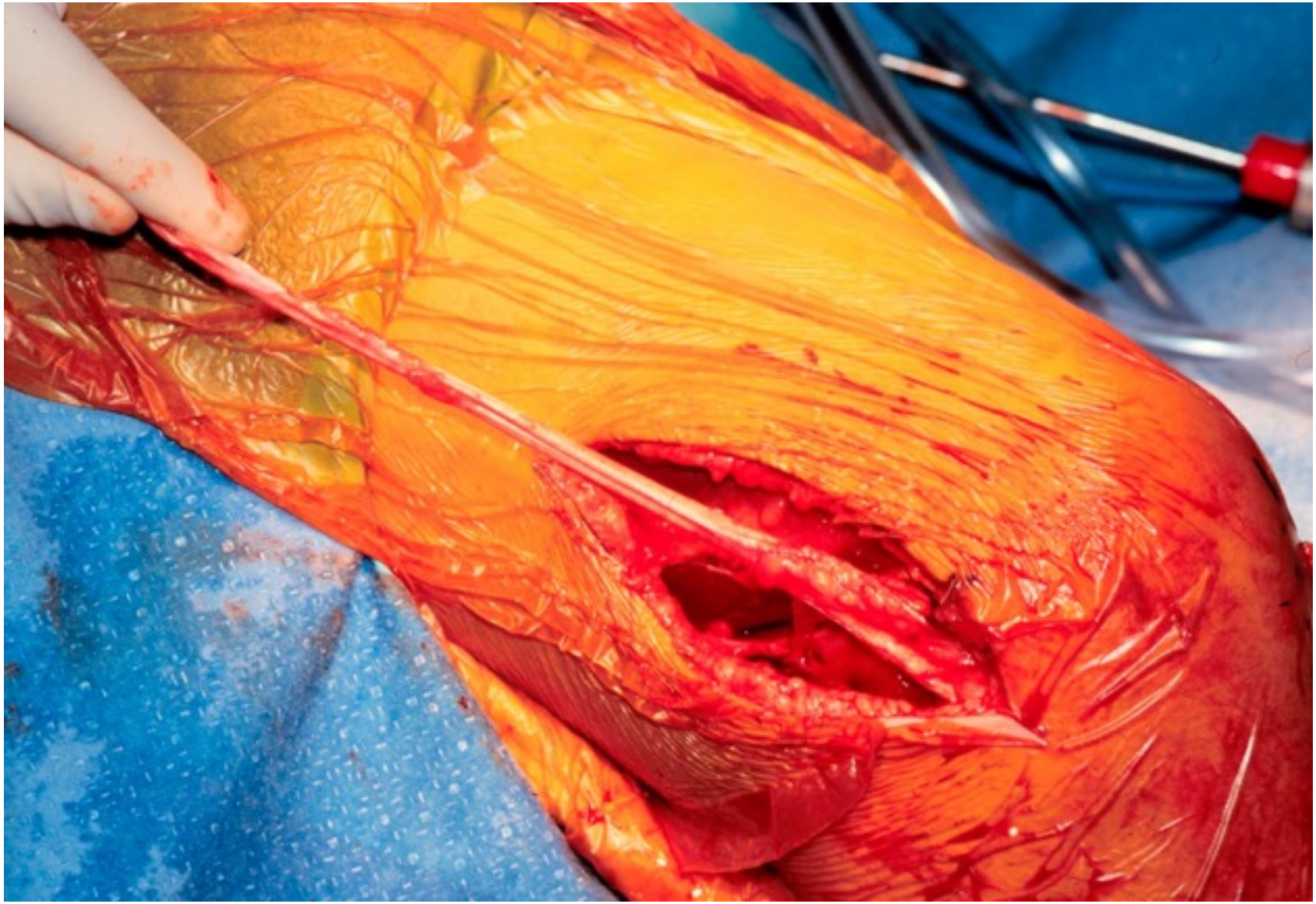


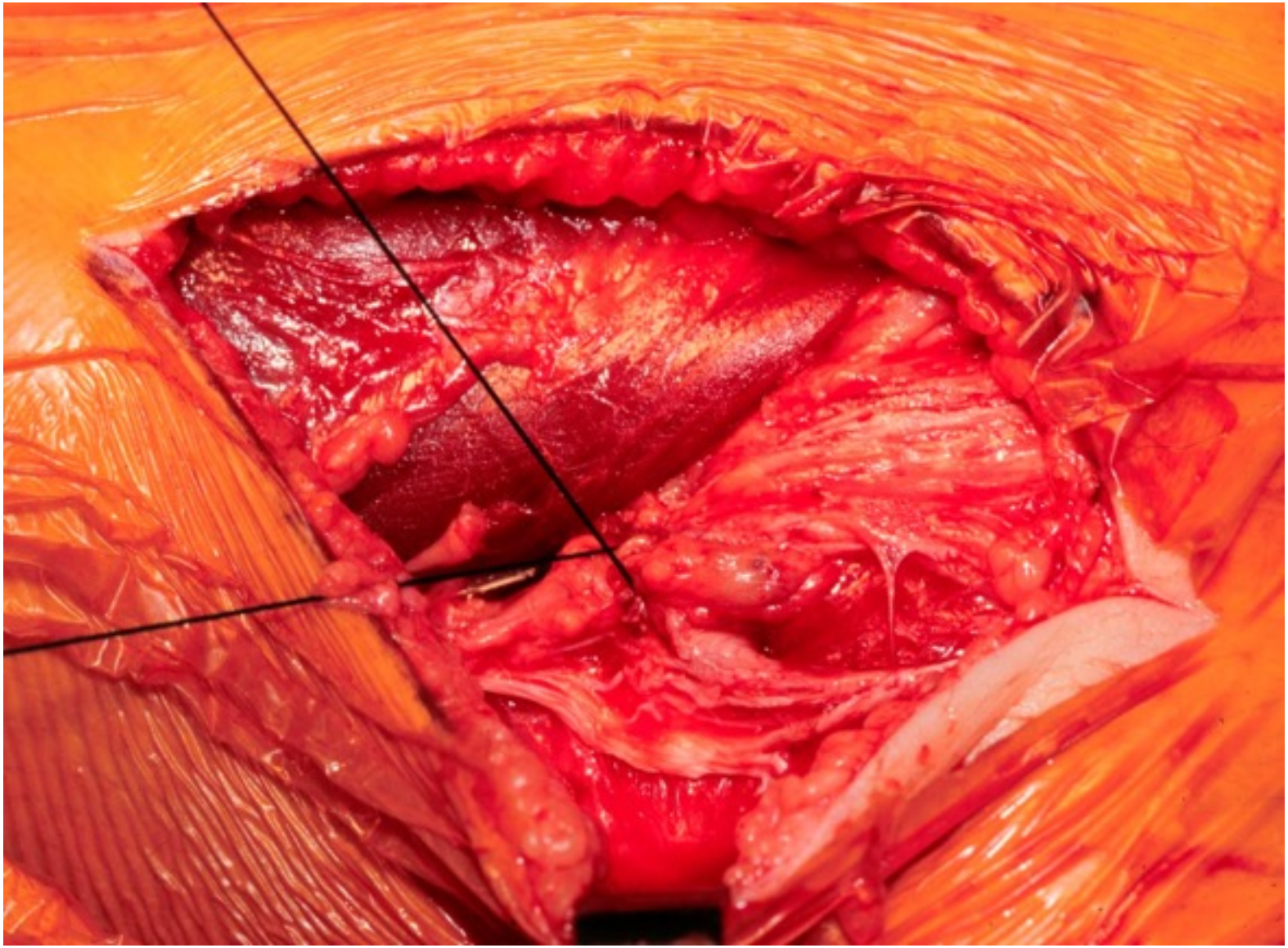
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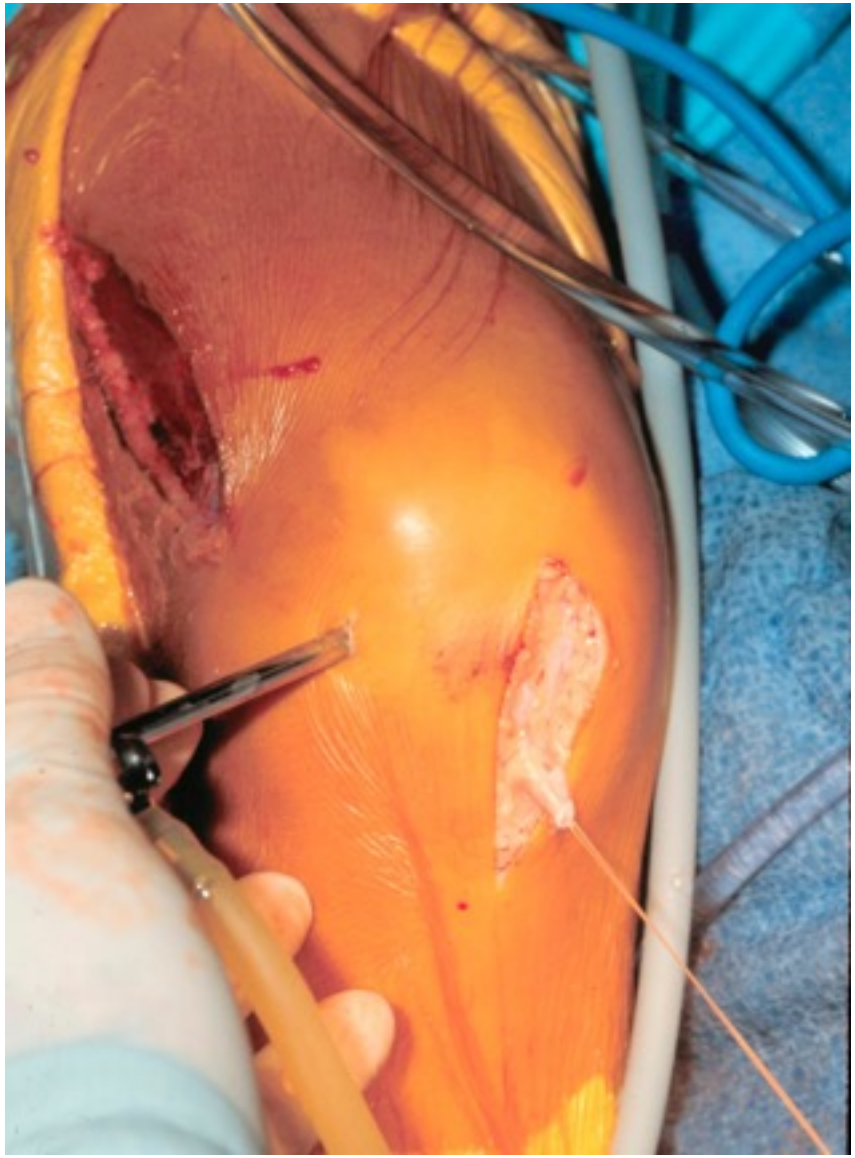


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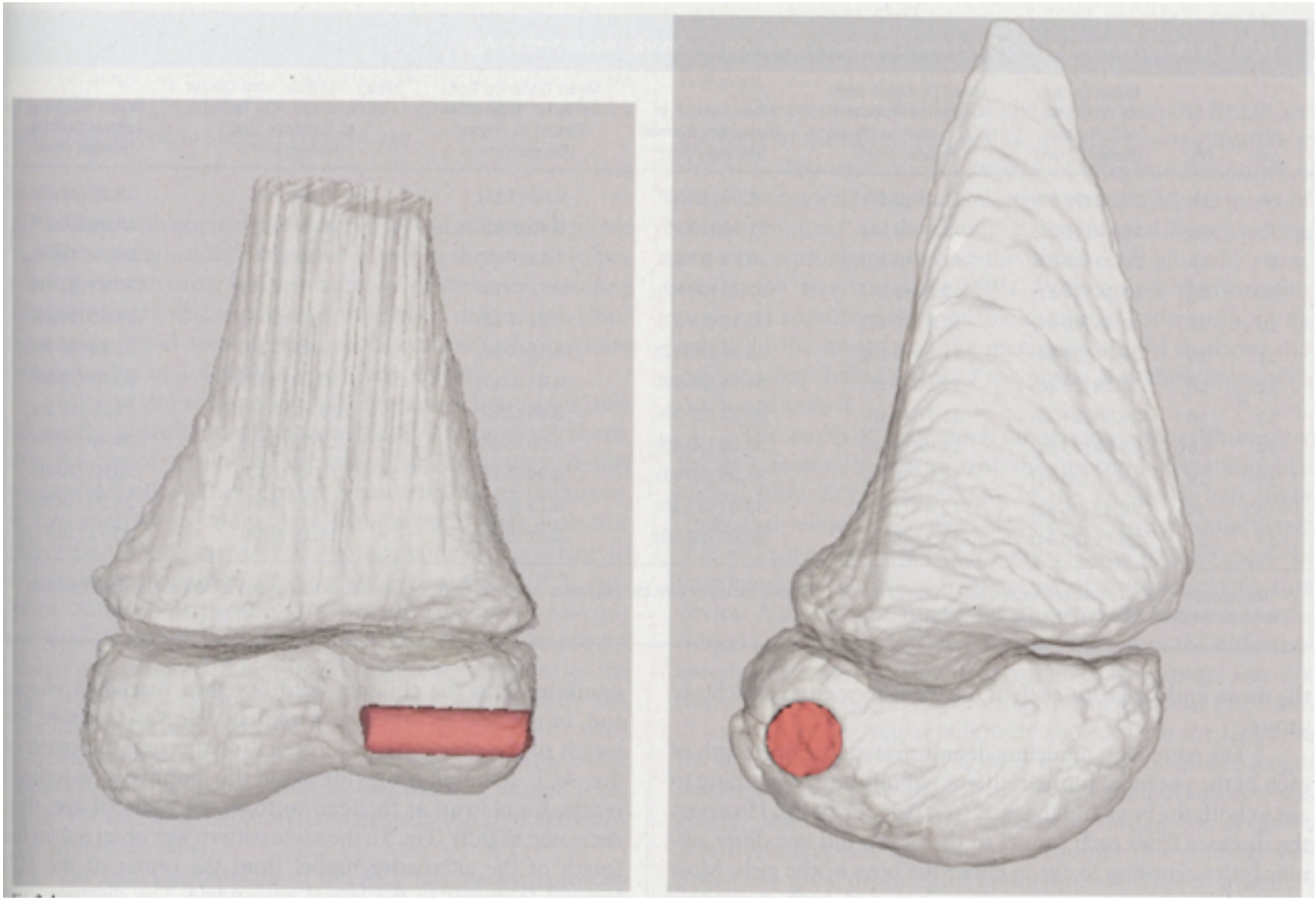


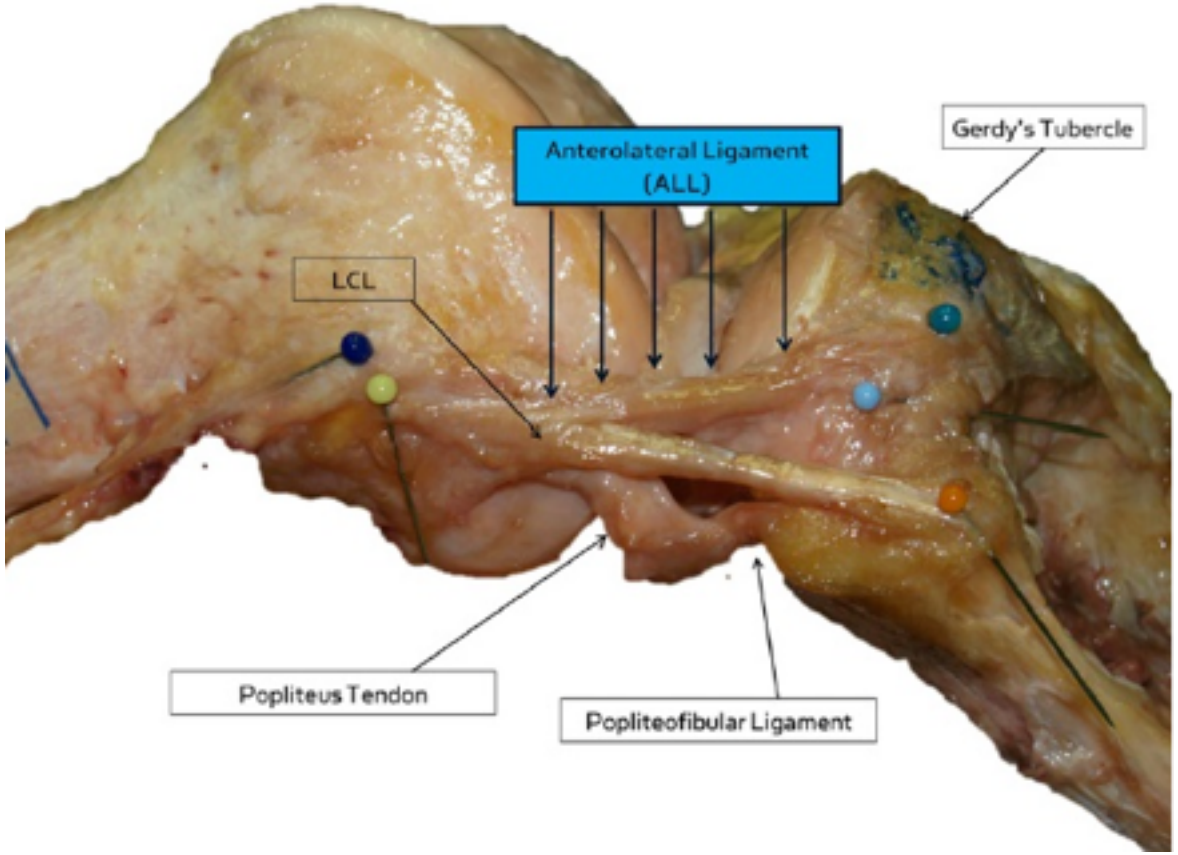




OUTCOME

- Brace, crutches x 6 weeks
- +10 to 40° x 2 weeks
- 0-90° at 6 weeks
- 6 weeks – 12 weeks, functional brace, PT
- Running at 12 weeks post op
- Cutting sports with sports brace at 6 months post op




Anterolateral Ligament
(ALL)
Gerdy's Tubercle
LCL
Popliteus Tendon
Popliteofibular Ligament

CASE #3

TIBIAL SPINE

15 YEAR OLD MALE

PATIENT HISTORY

- 15 year old male
- L knee injury
- Trampoline – twist, severe pain, swelling

EXAM / IMAGING

- 1 week post injury; effusion, + Lachman
- -10° extension
- Flexion 70°





WHAT WOULD YOU DO?

1. Cast in full extension after aspiration

2. Arthroscopy, reduction, fixation

3. Arthroscopy, fixation

TREATMENT

- 1 week of icing, PT
- Operation:
  - Arthroscopy
  - Resect fat pod
  - Debride base
  - Reduce, suture menisci
  - Reduction at 40° flexion
  - Cylinder cast x 4 weeks



IMG_001


L
EF


L
EF

DISCUSSION

1. Stability: Lachman

2. Size of bone fragment

3. Within 2 weeks

FIXATION









THANK YOU!

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www.themichelicenter.com

