PARTICULATED JUVENILE ALLOGENEIC ARTICULAR CARTILAGE TRANSPLANTATION

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DISCLOSURE

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Arthroscopy Journal &
Arthroscopy Association of North America

Royalties
Zimmer Biomet Sports Medicine
Wolters Kluwer Health

Particulated Juvenile Articular Cartilage

- DONOR POOL < 13 yrs / 0 – 35 days
- 1 VIAL = 1.5 – 2.5 cm²
- 1 mm AC CUBED FRAGMENTS
- MINCED ALLOGRAFT IMBEDDED
- AUTOGENOUS FIBRIN MONOLAYER
- EVICEL HUMAN FIBRIN

Lui, AJSM, 2013
Fahr, Cartilage, 2011
Auksson, AJSM, 2010
**JUVENILE ARTICULAR CARTILAGE**
- Optimal biosynthetic activities
- Enhanced regenerative potential
- Higher chondrocyte density
- Elevated glycosaminoglycans
  - Tompkins, Arthroscopy, 2013
  - Liu, AJSM, 2013
  - Fahn, Cartilage, 2011
  - Adkisson, AJSM, 2010
- Enhanced MMPs

**ADVANTAGES**
- Index point of care solution
- No harvest morbidity
- Technically feasible
- Juvenile chondral tissue
- Potential hyaline tissue
- Preliminary data

**DISADVANTAGES**
- Cost: 1 pack / $4,000 / 1.5 – 2.5 cm²
- Size treatment limitations
- Fibrin glue stability
- Need for arthroscopy
- Histology / outcomes
- Reimbursement
INDICATIONS
• SYMPTOMATIC LESIONS
• SIZE > 10mm² / MINIMAL BONY DEFECT
• CONTAINED / WELL - SHOULDERED
• ATTENTION: AGE / BMI / ALIGNMENT
• KNEE: CONDYLE / TROCHLEA / PATELLA
• ANKLE: TALAR OLT

REHAB PROTOCOLS
• NWB x 2 wks / FWBAT 6 – 12 wks
• PROGRESS EARLY ROM
• CPM for 2 to 6 wks
• PF JOINT: WBAT / Avoid Loaded Flexion
• RETURN TO ACTIVITIES 6 – 9 mons
• VTE PROPHYLAXIS

CASE : RG
• 25 yo construction worker
• Fell on scaffold / work injury
• Presented with knee pain / catching
• Recurrent swelling / PT / NSAIDS
• Referred by treating ortho p 3 mos
• Patellar Chondral injury / Defect
SECOND LOOK: 12 MONS POSTOP
EARLY OUTCOMES

- 15 Cases with Sx Grade 4 Patella Defects
- Mean age 26 years / Mean FU 29 months
- Single Stage Allografting
- Juvenile Particulated Articular Cartilage
- ICRS / KOOS / IKDC / Tegner / Postop MRIs
- Structural Results
  - 11/15 (73%) normal to nearly normal cartilage repair
  - 12/15 (80%) had 90% defect coverage

TOMPKINS & BONNER
ARTHROSCOPY, 2013

EARLY OUTCOMES

- 15 Pts / 29 Cases w Sx ICRS Grade 3-4 Defects
- Avg 2.7cm² / 68 % Condylar / 32 % Trochlear
- Mean age 37 years / Mean FU 29 months
- VAS / KOOS / IKDC / Postop MRIs / Histology
- CLINICAL RESULTS: KOOS-pain: 64 to 84
- STRUCTURAL RESULTS
  - MRI % FILL at 24 mos: 109.7
  - HISTOLOGY (8 Bx): Mixed Hyaline & Fibrocartilage
  - NO ADVERSE EVENTS / 2 Delaminations

FARR, AJSM, 2014
LEVEL 4 PROSPECTIVE CASE SERIES

MRI ANALYSIS: PATELLAR DEFECTS

- 45 Pts STUDIED with Gr 4 PATELLA DEFECTS
- FAST SPIN ECHO (QUAL) & T2 MAPPING (QUAN)
- Avg 2.8cm² / Mean age 26.5 years
- 93% UNDERWENT CONCOMITANT Sx
- 6, 12 & 24 MRI MONTH FU
- 82% GOOD TO EXCELLENT FILL
- T2 RELAXATION TIMES IMPROVED OVER FU
- PROGRESSIVE GRAFT MATURATION

GRAWE, CARTILAGE, 2017
RETROSPECTIVE LEVEL 4 CASE SERIES
TAKE HOME MESSAGE

• ALLOGENEIC OPTION
• JUVENILE CHONDROCYTES
• “UNDER THE BAR” TREATMENT
• VOLUME STABLE CONSTRUCT?
• EARLY PROMISING OUTCOMES

THANK YOU

Northwell Health Orthopaedics
Case: JP

- HPI: 26 year old male, recreational athlete
- Right knee injury 3 yrs ago while playing softball sustaining a patellar dislocation
  - No Subsequent Patellofemoral Instability
  - 2.5 yrs Ago: Scope Debridement: “Pain”
  - Op Report: Patella & LFC Chondroplasty
  - Has had pain when knee “slips” and “catches”
- Referred from for Consultation

HISTOLOGY

- CASE REPORT: TKR PATIENT
- 28 mons S/P PJAC PROCEDURE
- HISTOLOGY RETRIEVED AT TKR
- HYALINE / FIBROCARTILAGE MOSAIC
- HETEROGENOUS TISSUE

STEVENS, CARTILAGE, 2014
Physical Exam

Right Knee

- No antalgia / NL Alignment / NL Q - angle
- ROM 0-130 & Symmetric
- 3+ Patellofemoral crepitus with Pain
- Mild pain on palpation of lateral joint line
- Mobility: Lax: excursion to third quadrant
- No Patellar Apprehension or Patholaxity
- 5/5 strength

Preop Radiographs
Preop MRI
Imaging

- CT SCAN: TTTG DISTANCE: 15 mm
- Patella Alta
- Mild Condylar Squaring
- Irregular Medial / Central Facet
- No Osseous Loose Bodies
- LFC Marrow Edema
- Patella Chondral Defect
- LFC Chondral Defect
WHAT WOULD YOU DO?

- Dx: 26 yo w Bipolar osteochondral defects:
  - medial / central patella (30 x 15 mm) OC defect
  - lateral femoral condyle ( 22 x 11 mm ) OC defect
  ......with possible patellar instability?

- Treatment Options?
  - Cartilage Restoration
    - MFx vs. OATS vs. Cell – based ACI vs. OC Allograft Transplantation vs. Other?
  - Patellar stabilization ???
  - Alta??
  - Osteotomy??

Patella

Lateral Femoral Condyle
SO NOW WHAT WOULD YOU DO?

Patella

Comments / Discussion

- Plan:
  - Juvenile allograft cartilage transplant to patella and lateral femoral condyle, +/- patellofemoral stabilization
- Reasoning
  - Size
  - Multiple Lesions
  - One Stage
  - Patellar involvement ??
**Lateral Femoral Condyle**

| POST – IMPLANT OPEN IMAGE OF Patellar SITE INTACT GRAFT |
| POST – IMPLANT OPEN IMAGE OF LFC SITE INTACT GRAFT |
| POST – IMPLANT SCOPE IMAGE OF Patellar SITE WITH DISRUPTED GRAFT |
| POST – IMPLANT SCOPE IMAGE OF LFC SITE WITH INTACT GRAFT |

**Patella**

| POST – IMPLANT OPEN IMAGE OF Patellar SITE INTACT GRAFT |
| POST – IMPLANT OPEN IMAGE OF LFC SITE INTACT GRAFT |
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| POST – IMPLANT SCOPE IMAGE OF LFC SITE WITH INTACT GRAFT |
OPTIONS
- ACLR & LM Repair
- REMOVE FRAGMENT?
- MARROW STIMULATION?
- OATS?
- FIXATION?
- OTHER?

Would you ever?
Now What?

SO WHAT MATTERS
- CLINICAL: SO HOW HE FEELS?
- STRUCTURAL: HOW IT LOOKS?
- HISTOLOGICAL: WHAT IS IT?
- NATURAL HISTORY: FUTURE?

NEXT STEPS in REHAB, RECOVERY & COUNSELING?
RETURN TO PLAY?

OUTCOMES
• SUBJECTIVE: PAIN, SWELLING
• OBJECTIVE: TENDER, ROM,
• TESTING: MRI, SECOND LOOK
• FUNCTIONAL: RTP, WORK, LIFE
• WHEN TO RETURN OR HOW?
CASE: LS

6 months postop:
No Pain, No sense of instability
Atrophy
3 cm Circumference difference
Full Rom
Negative Lachman, AD, PS
Single leg Hop 80%

WHAT
WOULD
YOU
DO?

CASE: LS

6 months postop:
He wants to play
He is “getting recruited”
Both parents express understanding of risks
They request that you clear him
"HE WOULD LIKE TO AVOID SURGERY"

WHAT WOULD YOU DO?
TREATMENTS

• NONOPERATIVE
• INFLAMMATION REDUCTION
• NSAIDS, PHYS. THERAPY
• BRACING: UNLOADER
• INJECTION THERAPIES
• CS, HA, PRP, BMAC, “STEM CELLS”

INJECTION THERAPIES

• CORTICOSTEROIDS
• HYALURONIC ACID
• PRP
• BMAC
• OTHER ………

How About
“Stem Cell” Injections?
WHAT ABOUT BRACING?

WHAT’S NEXT?

TREATMENTS
- SURGICAL
- DEBRIDMENT / PMM
- ROOT REPAIR
- OSTEOTOMY
- UKA
Does JSN, Extrusion & chondral breakdown change MMRT surgery?

ARTHROSCOPY

- EXTENDED DEGENERATIVE TEAR
- CHONDRAL PATHOLOGY
- JOINT BREAKDOWN
- CONFOUNDERS: AC / Men. / Alignmt.

WHAT DID THE JOINT REALLY LOOK LIKE?
CASE: LK

24 yo athletically active
Physical therapist
Skier
w h/o 3 PF dislocations
and failed nonop Rx

- 3+ generalized laxity
- + apprehension
- pain w compression
- NL Q angle
- TT- PCL distance 10

3/13/2018
WHAT WOULD YOU DO?
MPFL OUTCOME

- 72 Isolated MPFL Reconstructions / Avg Age 18 yrs
- Technique: Gracilis Autograft / Bone Tunnels
- FU 24 mons (24 – 46): IKDC / TEGNER / VAS / Kujala
- 79% Satisfied / 100% RTS / 53% Same Level
- 10% persistent instability
TREATMENTS

• DEBRIDEMENT
• MARROW STIMULATION
• AUTOGRRAFTS / ALLOGRAFTS
• CELL – BASED THERAPIES
• SCAFFOLDS?
DISTAL REALIGNMENT
TIBIAL TUBERCLE OSTEOTOMY / TTO
ANTEROMEDIALIZATION / AMZ

BEST FOR
DISTAL / LATERAL LESIONS

TT – TG / TT – PCL DISTANCE
(10 mm)
OUTCOMES

I. DISTAL / CENTRAL  GOOD

IIA. LATERAL  GOOD

IIB. DUMBBELL (I&II)  GOOD

III. MEDIAL  GUARDED

IV. PROXIMAL  POOR

V. SULCUS  Variable

VI. LAT. SULCUS / PATELLA  Variable

VII. EXTENSIVE SULCUS & P  Variable

VII. MEDIAL POST – HAUSER  GOOD

Type I

Type II

Type III

Type IV

55% G to E

87% G to E

55% G to E

20% G to E

63% SATISFIED

81% FUNCTIONAL SUCCESS

8% COMPLICATIONS

PIORIANO, AJSM, 1997

Retro STUDY of 36 Pts

47 mon FU
NOW WHAT?
• REVISION ACLR & PMM
• GRADE 3 PIVOT SHIFT?
• ACL + ALL RECONSTRUCTION?
• INDICATIONS?
• TECHNIQUES?
• RESULTS?

WHAT ABOUT THE ALL?

EVLING ANATOMIC ELEGANCE
or "BACK to the FUTURE" with "MUCH ADO ABOUT NOTHING"
ANTEROLATERAL LIGAMENT

- Segond 1879 / Claes 2013 (J of Anatomy)
- DePhilipo & LaPrade / Levy (Arthroscopy, 2017)
- LCL: Proximal / Posterior or Anterior / Distal
- Weiser (Arthroscopy, 2017) - Posterior Fem Cortical Line & Sp Blumenaats
- Equidistant between Gerdy’s & Fib Head
- ALL shortens from Extension to Flexion?
- Tension at what degree? 0 to 60?
- Overcontrast / Failure / RCT

WHAT WOULD YOU DO?
**INDICATIONS**
- Grade 3 Pivot Shift
- Younger Contact Athlete
- Revision ACLR
- PMM: Meniscal Attrition
- Ligamentous Laxity
- Have Increased Stock Position

**TECHNIQUES**
- ITB Sling Rerouting
- Free Graft Reconstruction
- Order of Procedure
- Fixation Footprints
- Tension at What Degrees
- Postop Regimen

**ALL: ANY EVIDENCE?**
- 110 Pts: 53 ACL + ALL vs. 50 ACL
- Avg FU 27 (25 – 30 mons) / Mean Age 26 (20 – 32 yrs)
- Lysholm / Tegner / IKDC / KT1000
- Entire Pt Cohort: Grade 2 pivot shift
- ACLR: Hamstring Autografts / ALL: Gracilis
- Anterior & Proximal to LCL to G to fib midpt
- ALL: tensioned at 30 degrees & neutral
- No Significant Difference

*IBRAHIM, AJSM, 2017*
*LEVEL 2 RCT*
Comments / Discussion

- Plan:
  - Juvenile allograft cartilage transplant to patella and lateral femoral condyle, +/- patellofemoral stabilization
- Reasoning
  - Size
  - Multiple Lesions
  - One Stage
  - Patellar involvement ??

Lateral Femoral Condyle
Patella

Post - implant scope image of patellar site with disrupted graft

Post - implant scope image of patellar site with intact graft

Post - implant Patella Site

Post - implant scope image of LFC site with intact graft

Post - implant scope image of LFC site with intact graft
Post-Implant LFC Video

SO
NOW
WHAT?

Postop Radiographs
SECOND LOOK: 12 MONS POSTOP

- 15 Cases with Sx Grade 4 Patella Defects
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TOMPKINS, ARTHROSCOPY, 2013

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FARR, AJSM, 2014
LEVEL 4 PROSPECTIVE CASE SERIES
3/13/2018

What Would You Do?

• NO GENUALGUM
• NO FLEXION CONTRACTURE
• NO OTHER MS PATHOLOGY

What Would You Do?

What would you do?
EVIDENCE

- 35 Isolated Meniscus Repairs (3 Surgeons)
- 15 w PRP / PRFM and 20 Without
- FU 4 yrs (2 – 6) w 71 & 75% Retrieval
- Techniques: IO, OI, All – inside
- IKDC / Lysholm / Tegner
- No Difference: 27 and 25% Reoperation
- Underpowered / Selection & Transfer Bias

Griffin, CORR, 2015
Retrospective Case Series
Subchondroplasty Outcomes

- 66 Subchondroplasty Pts. + Scope
- Avg age 55.9 yrs / 91% FU at 2 yrs
- 96% had Mod Outerbridge 3 – 4 / - 8 to 8°
- VAS / IKDC / Outcomes: 70% Survivorship
- 39% Conversion to Arthroplasty
- Improvements in Pain & Function: 2 yrs

Level 4 Retrospective Cases series
COHEN, J Knee Surg, 2015
**PRP vs. HA in OA?**

- 111 Pts: 49 lp-PRP vs. 50 HMW- HA
- 3 DBlinded Injections: FU 6 & 12 mons
- Radiographic Inclusion: KL 0 – 4
- IKDC / VAS / WOMAC / Lysholm
- No Difference in PROM: WOMAC pain score
- Synovial Fluid Analysis
- PRP: "Trend" - decrease in IL – β & TNF-α at 12 wks

**HA SUMMARY**

- HIGHER MOLECULAR WEIGHT
- LESS SEVERE OA
- MORE DURABLE THAN CS
- RESPONDERS
- PATIENT DEMAND
- AAOS CPG
- CLINICAL EXPERIENCE

**PRP SUMMARY**

- PREP HETEROGENEITY
- POSSIBLE ANTI-INFLAMMATORY
- VERSUS HA / IAS / PLACEBO
- LESS SEVERE OA
- AGE / BMI / GENDER UNCLEAR
- INCOMPLETE CONCLUSIONS
- REIMBURSEMENT?
STEM CELLS

• PROGENITORS & AGE
• SOURCE / HARVEST
• CELL RELEASE / PREP
• DELIVERY / SCAFFOLDS
• CULTURED CELL CONSTRUCTS

STEM CELL SUMMARY

• SOURCE / HARVEST YIELD VARIABILITY
• AGE & PROGENITOR PROFILE
• AUTOGENOUS vs ALLOGENEIC
• REGULATORY RIGOR (351 PATH)
• DELIVERY METHODS?
• INCOMPLETE CONCLUSIONS
• REIMBURSEMENT?

What Do You Really Think?

• Injection Therapy Guideline / Algorithm?
• Corticosteroid vs. HA? / IA Injection Placebo?
• Reimbursement / Cost / Cash Business?
• Off – Label Consent?
• How Many Injection (s)?
• Spaced Out How?
• Best Indications?
CASE – BASED DISCUSSION

VISCOSUPPLEMENTATION

BIOLOGIC INJECTIONS
- PRP vs. Other
- HA vs. PRP
- LP – PRP vs. LR - PRP
- 1 vs. 2 – 3 Injections
- 6, 12, 24 months
- Adverse Events
- Indications: KL 1 – 3
- IA Targets: AC, Synovium, MSC, Menisci
MUST ADDRESS

• MENISCAL LOSS
• MALALIGNMENT
• CHONDRAL PATHOLOGY

3 – POINT PRESSURE TRANSFER

UNLOAD JOINT
GOALS

• UPDATE ON BIOLOGIC THERAPIES
• DEFINE CLINICAL INDICATIONS
• REVIEW PREPARATIONS & TECHNIQUES
• DISCUSS CURRENT EVIDENCE & TRENDS
• REGULATORY ISSUES / CHALLENGES
• CASE – BASED DISCUSSION

APPLES & ORANGES

• HETEROGENEOUS Pts
• VARIABLE PATHOLOGY
• DIFFERENT PREPARATIONS
• INCOMPLETE OUTCOMES
INDICATIONS

• SYMPTOMATIC OC DEFECT
• SYMPTOMATIC PAINFUL OA
• FAILED OTHER THERAPIES
• RADIOGRAPHIC STAGES
• POST – SURGERY ?
• PRE - ARTHROPLASTY

WHAT WOULD YOU DO?
Case: MS

57 yo female teacher presents with 3 yrs of aching medial knee pain now worse over 3 mons.
No h/o recent trauma.
20 yr s/p “successful” ACLR
Plays recreational competitive tennis 2 – 3x / wk.

Had a CS shot 2 mons ago.
Slightly better for 3 wks.
Has been icing, on NSAIDS, taking GS & CS, used a brace & switched to clay.
PMX: negative
BMI: 23
No antalgia, mild varus
Mild effusion, ROM 0 – 125
3 degrees varus
MRI: MFC Chondral wear, No MMT
**CHALLENGES**

- BURDEN OF SCIENTIFIC EVIDENCE
- COST EFFECTIVE: SHIFT TO VALUE
- REGULATORY HURDLES: HCT / Ps
- 351 vs 361 PRODUCT DESIGNATION
- HIGH vs LOW RISK
- MANIPULATION / AUTOGENOUS
  - NON – COMBINATION / HOMOLOGOUS

**HA vs. CS vs. PLACEBO**

- 11 Studies of HA vs IASteroid vs. IAPlacebo
- OMERACT – OARSI Criteria
- HA Pts. 15% & 11% More Likely to Respond
  vs. IAS and IAP (p < 0.05 for both)
- Recommended Indications: KL 2 & 3 / 40 – 60 yo
  - Systematic Review · Meta - Analysis
  - TROJIAN, Br JSM, 2016

**Viscosupplementation**

- Limits of Systematic Reviews
- “Best Evidence“ Studies (Blinding)
- Meets Minimally Important Difference
- Treatment Effect Size as a % of MID
- AAOS: “Cannot Recommend HA for Knee OA”
  - Jevsevar, JBJS, 2015
  - AAOS CPG, 2013
HA PRODUCT DIFFERENCES
• Differences in HA Products: MW
• HA Should Not be Treated as a Group
• 68 Study Meta – analysis
• Differentiate: < 3000kDa vs. > 3000kDa
• Larger MW Efficacy
• Biological Fermentation vs. Avian Derived
• Injection Flares

Meta -Analysis
ALTMAN, AJSM, 2015

Treatment Therapies for Knee OA
• 14 Meta – analyses: Level I - IV
• 20,049 Pts:
• 13,698 I-HA, 355 NSAIDS, 294 IAC, 5,702 IAP
• IA Injection vs. Oral Placebo Effects
• IA – HA is a Viable Option for Rx of OA
• Improvements in Pain & Function: 26 wks

Systematic Rev of Meta -analysis
CAMPBELL, Arthroscopy, 2015

PRP
Market Growth 45 to 126 million in 7 yrs
> 40 Commercial Systems
• NOVEL / EXCITING / INTEREST
• FORMULATION VARIABILITY / DATA / BILLING
• IMPROVE EFFICACY & CONSENSUS
• NEXT STEPS: SELECT OUT Rx
**PRP vs. HA in OA?**

- 150 Pts: 50 PRP / 50 LMW-HA / 50 HMW-HA
- 3 PRP Injections: in 28 d / FU 2 & 6 mons
- Radiographic Inclusion: KL 0 – 4
- IKDC / EQ VAS / WOMAC / VAS
- PRP Group Better at 6 mos: Milder OA
- LMW > PRP in More Severe OA
- Not Blinded

*Level 2 Prospective Comparative Study*
*KON, Arthroscopy, 2011*

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**PRP vs. Saline in OA?**

- 30 Pts: 15 lp-PRP / 15 Saline - Placebo injections
- 3 Injections x 3 wks / FU to 1 year
- Radiographic Inclusion: KL 2 & 3
- WOMAC scores improved 78 in PRP grp
- vs 7% in the Saline / Placebo patients

*Level 1 DB RCT*
*SMITH, AJSM, 2016*

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**What About PRP & OA?**

- 739 Pts / 817 Knees / 6 Studies Analyzed
- All Level 1 Data on Autologous PRP
- Mean age 59.9 / Avg FU 38 wks
- PRP & HA / PRP & IA Placebo
- KL 1 – 3 / Ahlback 1 - 3
- WOMAC Scores Better for PRP x 12 mons
- Limited Evidence: Leukocyte - Rich vs Poor

*Systematic Review of Level 1 Studies*
*MEHEUX, Arthroscopy, 2016*
STEM CELLS

• CIRCULATING BLOOD (1 - 40 cells / mL)
• BONE MARROW / BMAC (1 – 30 to 317k cells / mL)
• ADIPOSE TISSUE (4k – 1,555,000k cells / mL)
• UMBILICAL CORD (10k – 4,700,000k cells / mL)
• AMNIOTIC FLUID / TISSUE (> 25 x greater % msc)

VANGNESS, Arthroscopy, 2015

IS ALL PRP THE SAME?

• 5 Commercial Prep Systems Studied
• Single vs. Double Spin Prep
• Compared Plt concentration vs. Cytokines
• Factor Variability
• PDGF / TGF
• VEGF / FGF

> 40 Commercial Systems
Controlled Laboratory Study
OH, Arthroscopy, 2015

What About Amniotic Stem Cells?

• Amnion – Derived Tissues / Cells / Factors
• Human Amniotic Membrane / Chorion-free
• Regulatory Restriction (351 Pathway?)
• Promising Preclinical Data
• Limited Clinical Data

LANGE - CONSIGLIO, Cytetherapy, 2013
Case: LP

52 yo female pediatrician
18 yrs s/p ACLR & PMM
Did well until 3 yrs ago.
No new injury.
Increased medial pain with
activities. Now 3 mos of pain w
ADL
TREATMENT OPTIONS

- NONOPERATIVE
- LATERAL RETINACULAR RELEASE
- PROXIMAL (Non-MPFL) REEFING
- MPFL RECONSTRUCTION
- TROCHLEOPLASTY
- DISTAL REALIGNMENT
“COMMON BUT DIFFICULT”

- PAIN
- INSTABILITY
- CLICKING / POPPING
- SWELLING
- POSTERIOR SYMPTOMS

TAKE HOME

- INDICATIONS vs. NONOP
- PRECISE TECHNIQUE (S)
- AVOID COMPLICATIONS
- REALISTIC OUTCOMES

THANK YOU!
PATIENTS, CASES, and CLINICAL VIGNETTES….. DECISION-MAKING

CASE PRESENTATIONS
What would you do?
THANK YOU