MACI

MATRIX -INDUCED AUTOLOGOUS CHONDROCYTE IMPLANTATION

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Disclosures

- NO relationships financial or otherwise with any company whose products we are mentioning in this presentation including VERICEL (producers of MACI implant) nor Smith – Nephew (producers of OATS instrumentation).
- Consultant and stockholder Pristine Surgical manufacturer of a disposable camera in tip arthroscopy scope
- I hold small amounts of stock in multiple publicly traded healthcare companies

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- The problem
- The biologic challenges
- Historical options
- ACI Autologous Chondrocyte Implantation (two stage procedure)–initial
- ACI current
- Additional Simultaneous Surgeries
- Rehabilitation

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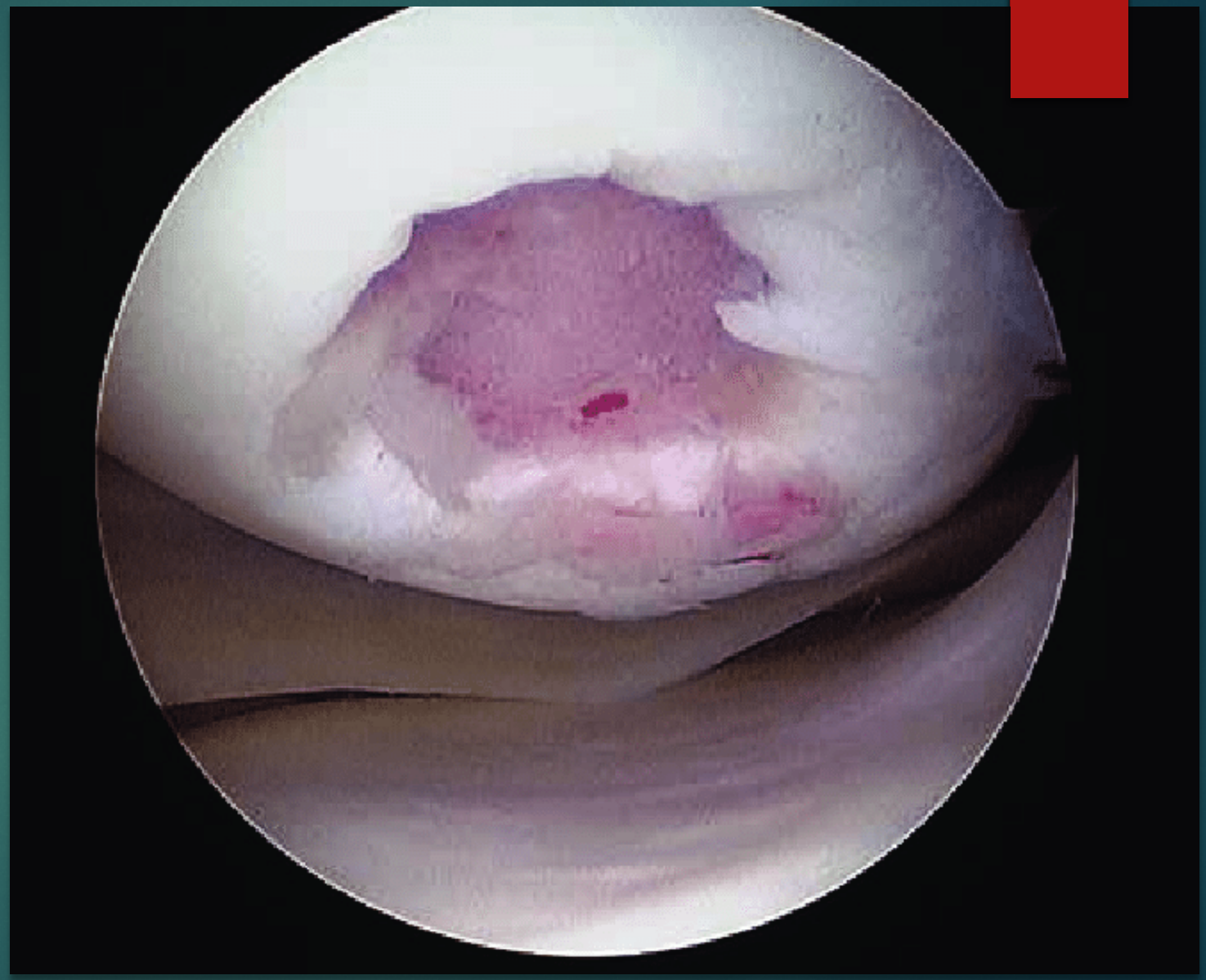
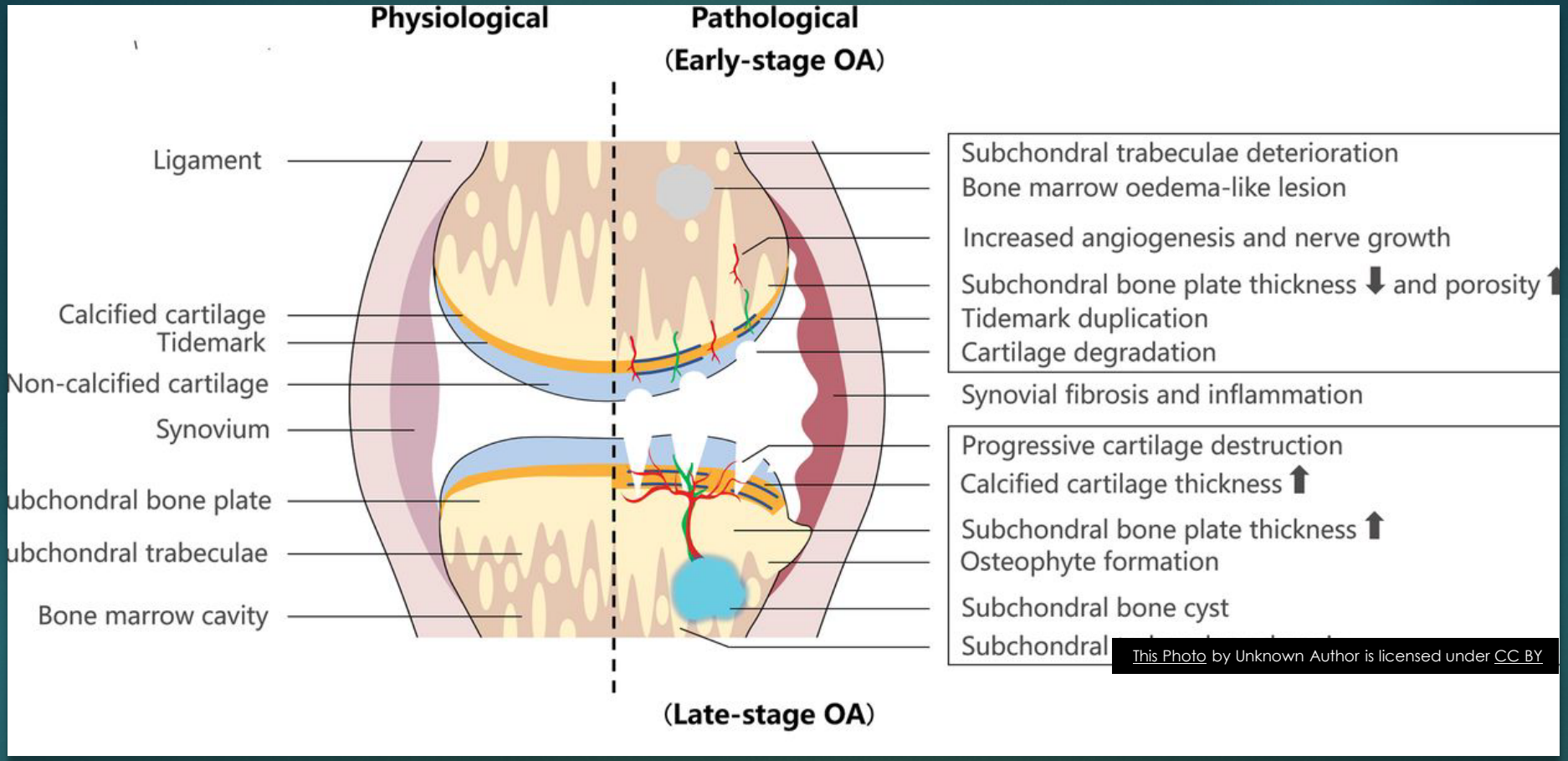
Full thickness Chondral Injury

- This is not generalized arthritis

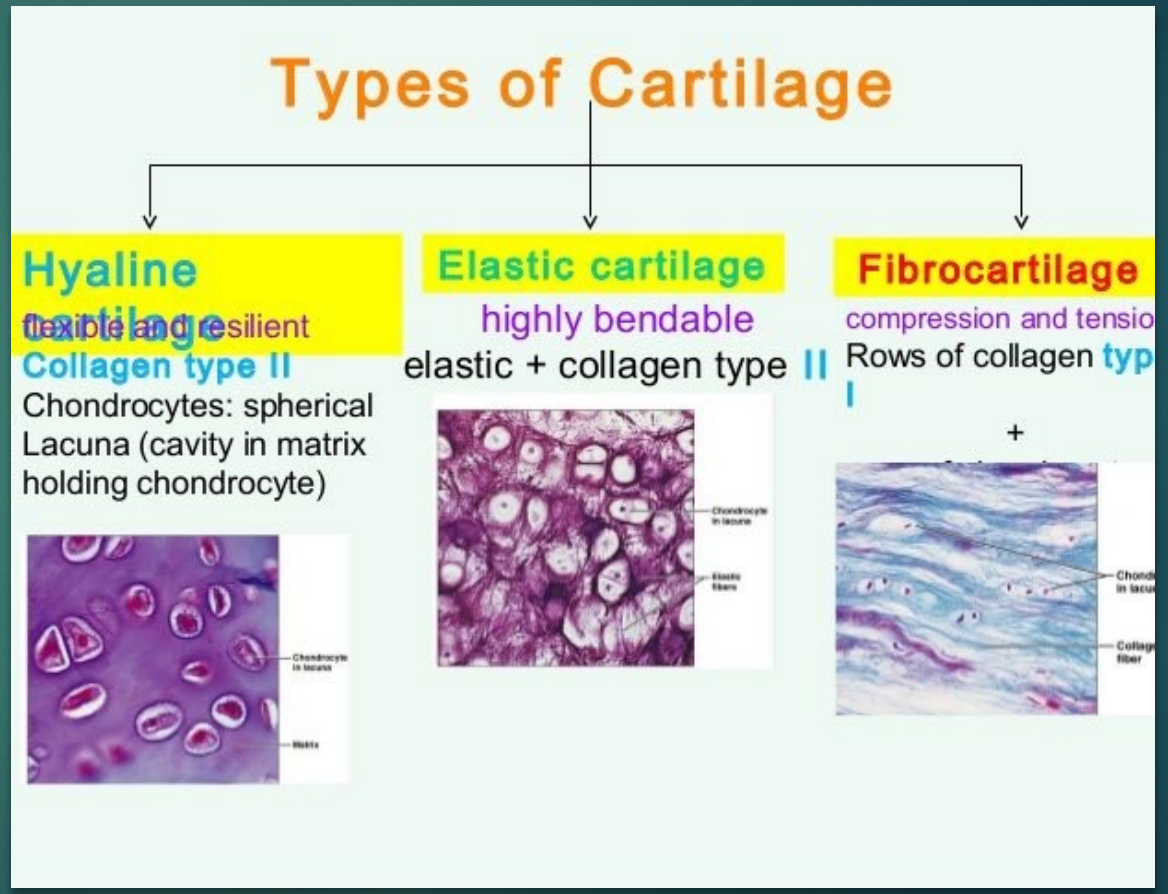




Osteoarthritis

Collagen types

- Hyaline- Joint
- Fibrocatilage-tendon
- Elastic- ear,epiglottis

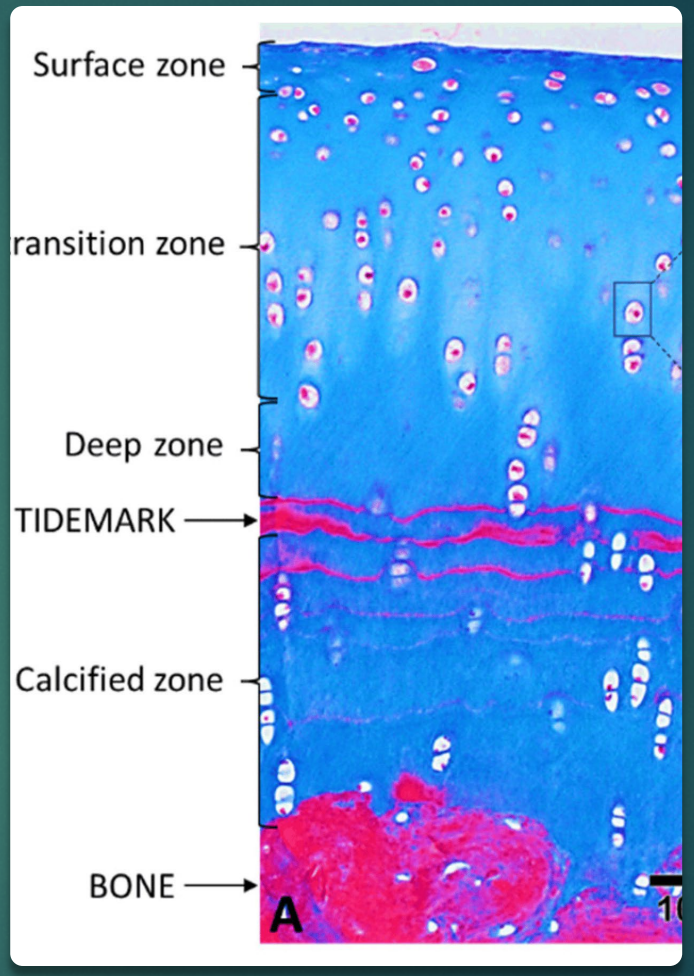


Articular Hyaline Cartilage

Challenges to healing/repairing/restoring

Avascular – nutrition from synovial fluid and bone

Low density of cells



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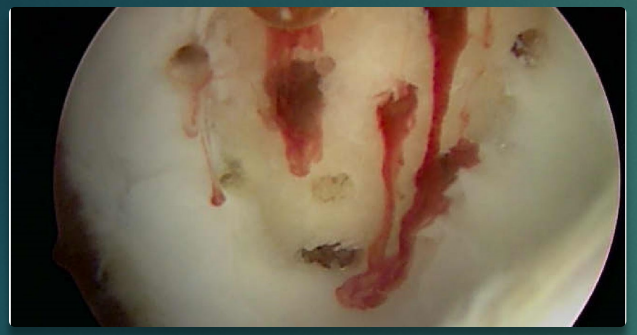
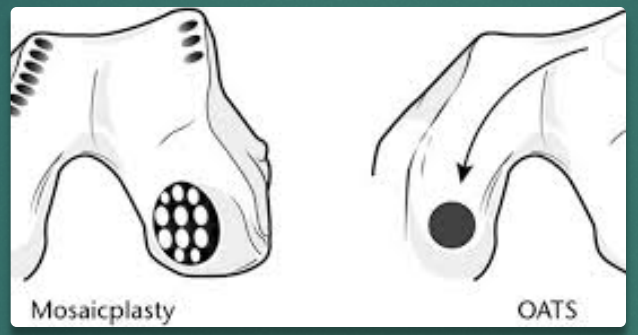
Historic Options



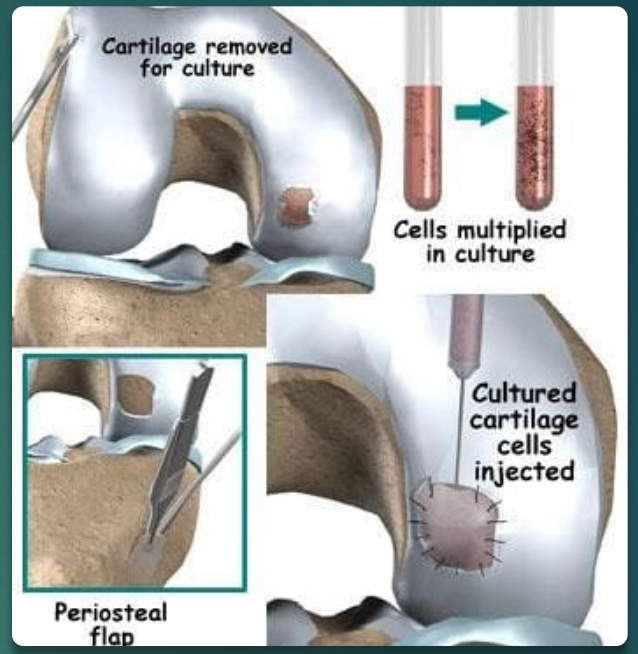
Microfracture

Abrasion Arthroplasty



Mosaicplasty

Smith Nephew OATS



ACI

Vericel/Genzyme/MACI

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Issues with microfracture/abrasion arthroplasty

-Bony Overgrowth

-Less Hyaline cartilage (more type 1)

Poorer short and longer term results

Issues with Osteochondral implants

- Autograft- limited harvest volumes
  - Thickness of hyaline layer
- Contouring vs number of implants
- Allograft – incorporation
  - Matching contour and thickness

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ACI (Original)

- Two stage procedure
- Overgrowth
- Bone formation (periosteum)
- Outcomes

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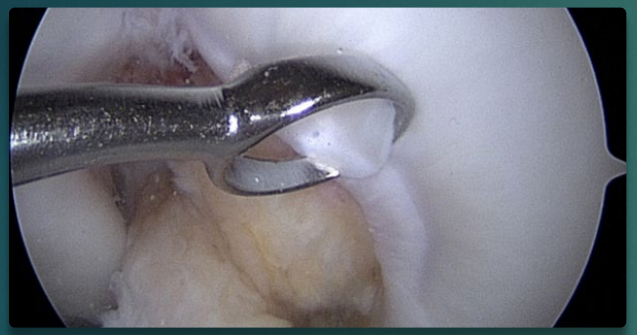
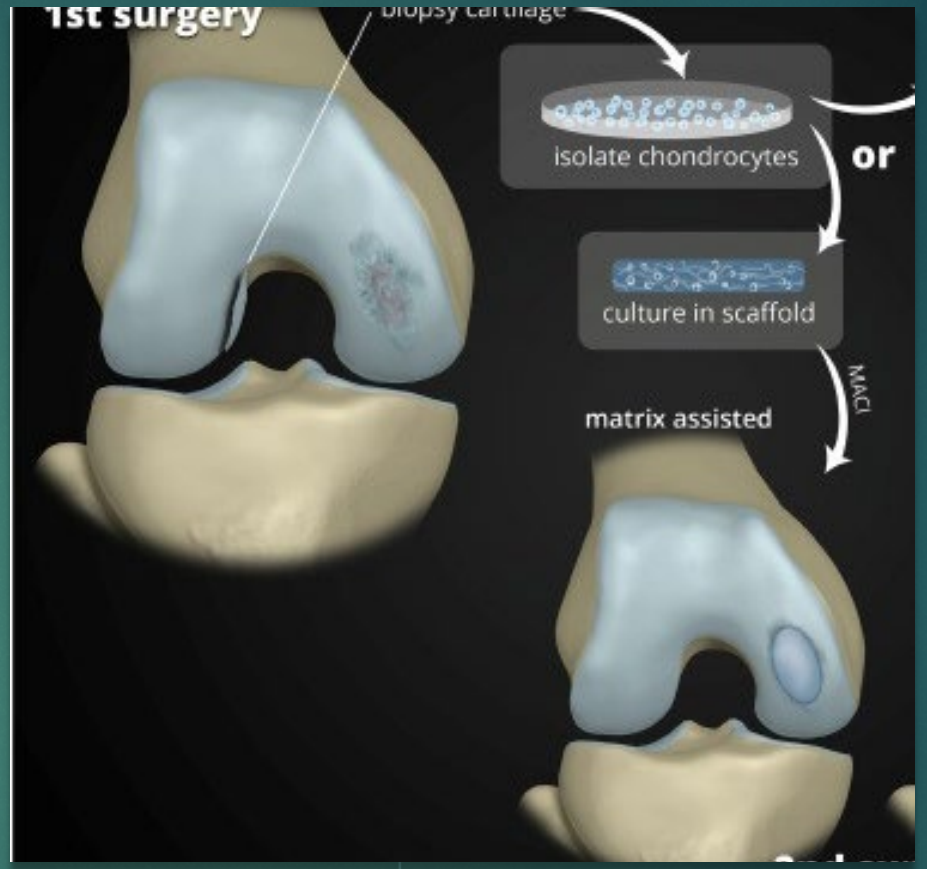
Next Generation MACI (2017) Summit study



Harvest



Grow and implant

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Surgical techniques
Open and Arthroscopic

open

arthroscopic

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General Rehab Protocol

Achieve routine

0–3 months

After the immediate post-surgery phase, patients will work towards a pain-free and full passive knee extension with limited weight bearing. Over time, the goal is to be free of ambulation devices and knee braces while becoming thoroughly independent with rehabilitation exercises.

Functional goals include:

- Mobile with crutches within first week
- Limited weight bearing and pain-free, full knee extension by 2-3 weeks
- Independent home exercise as early as 1 month
- Full weight bearing and full knee range of motion by 8-12 weeks post-surgery
- Free from knee brace by 8-12 weeks post-surgery

Build strength

3–6 months

During this phase, patients should begin to feel comfortable returning to recreational activities. An exercise program will help re-build muscle strength and endurance. Patients may feel ready for more strenuous activity, so you may need to give explicit direction on what activities they are ready for at this stage.

Functional goals include:

- Full and pain-free weight bearing and range of motion
- Continue progression of strengthening exercises without pain or swelling
- Transition to gym/home based rehab
- Free from crutches

Be active

6–9 months

Patients will enjoy a return to recreational activities and sports by gradually increasing the difficulty of their exercises. Every patient's recovery is unique and should be guided by your assessment of graft maturation as well as mental preparedness of the patient and the general physical function and level of specific knee strength, stability, and support.

Functional goals include:

- Increase distance, time, and difficulty of exercises
- Ability to tolerate lengthy walking distances
- Return to a pre-operative level of activity

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Rehab Considerations

- Location of lesion(s)
- Number and size of lesions
- Size of patient
- ?Age of patient
- Patient goals
- Additional Simultaneous Surgeries
- Surgeon “preference”

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Consensus Study

NOT AN EVIDENCE BASED OUTCOME STUDY FOR DETERMINING RECOMMENDATIONS

CARTILAGE OCT 2020; 13: 1782-1790 FLANIGAN ET AL.

WEIGHT BEARING, ROM, RETURN TO WORK, ADL'S, SPORTS

WITHIN EACH 4 PATIENT PROFILES (NUMBER OF LESIONS, SIZE OF LESIONS, PATIENT BMI, WORK/ACTIVITY DEMANDS, AGE

SEPARATED BY PATELLOFEMORAL AND FEMORAL

NORMAL ALIGNMENT AND NORMAL MENISCUS

WRITTEN SURVEY TO SURGEONS DOING AT LEAST 10 MACI PROCEDURES PER YEAR (AVG WAS 40). RESULTS SHARED, SECOND ROUND OF RESPONSE TO FIRST ROUND, THEN FACE TO FACE DISCUSSION. CONSENSUS DEFINED AS GREATER THAN 75%AGREEMENT 12 SURGEONS INITIALLY 8 IN FINAL ROUND

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Consensus
WB and ROM

Table 3. Consensus on Weightbearing: Summary Following Round 3.

	Patient 1 Description	Patient 2 Description	Patient 3 Description	Patient 4 Description
Defect location	Patella	Patella/trochlea[a]	Femoral condyle	
No. of defects	1	Multiple	1	Multiple
Primary lesion size, cm^2	<3	≥5	<3	≥5
Age, years	24	50	24	50
Activity level	Low to moderate exercise	Heavy labor	Low to moderate exercise	Heavy labor
Time to weightbearing at initiation	Immediately			
% of body weight at initiation	81% to 100%	<20%,[b] 81% to 100%[c]	<20	
Time to full weightbearing, weeks	Immediately	5-6	7-9	

[a]Nonkissing lesions; neutral joint alignment.
[b]Uncontained lesion.
[c]Contained lesion.

Table 4. Consensus on Range of Motion: Summary Following Round 3.

	Patient 1 Description	Patient 2 Description	Patient 3 Description	Patient 4 Description
Defect location	Patella	Patella/trochlea	Femoral condyle	
No. of defects	1	Multiple	1	Multiple
Primary lesion size, cm^2	<3	≥5	<3	≥5
Age, years	24	50	24	50
Activity level	Low to moderate exercise	Heavy labor	Low to moderate exercise	Heavy labor
Time to passive range of motion	Immediately			
Time to early active range of motion, weeks	2	4	Immediately	
Time to full active range of motion, weeks	6	8-10	As tolerated, 4 weeks	
Range of motion progression	0° to 45°, increasing by 15° each week following week 1			

Consensus Work and Sports

Table 5. Consensus on Work and Activities of Daily Living (ADL): Summary Following Round 3.

	Patient 1 Description	Patient 2 Description	Patient 3 Description	Patient 4 Description
Defect location	Patella	Patella/trochlea	Femoral condyle	
No. of defects	1	Multiple	1	Multiple
Primary lesion size, cm^2	<3	≥5	<3	≥5
Age, years	24	50	24	50
Activity level	Low to moderate exercise	Heavy labor	Low to moderate exercise	Heavy labor
Release to unrestricted ADLs		As early as 3 months		
Release to sedentary work		2[a] to 4 weeks		
Release to heavy labor, months	3-6	9-12 months	3-6 months	9-12

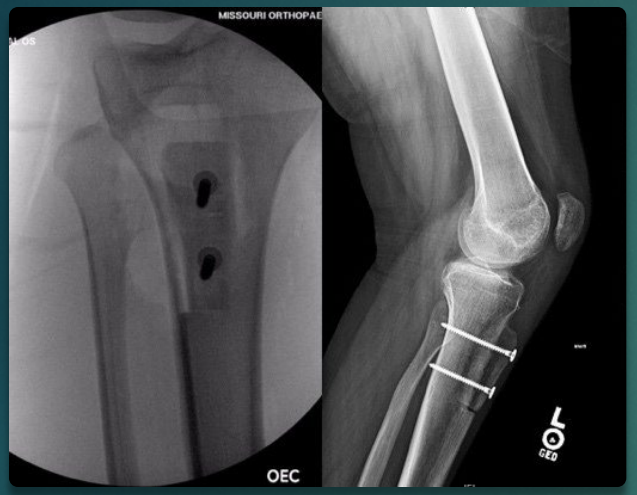
[a]As early as 2 weeks for patient types 1 and 3.

Table 6. Consensus on Return to Recreational Activities and Sports: Summary Following Round 3.

	Patient 1 Description	Patient 2 Description	Patient 3 Description	Patient 4 Description
Defect location	Patella	Patella/trochlea	Femoral condyle	
No. of defects	1	Multiple	1	Multiple
Primary lesion size, cm^2	<3	≥5	<3	≥5
Age, years	24	50	24	50
Activity level	Low to moderate Exercise	Heavy labor	Low to moderate exercise	Heavy labor
Evaluation for running, months	6	8	6	8
Release to running, months	7-9	10-12	7-9	10-12
Stationary cycling, weeks	3-4	5-6	3-4	5-6
Outdoor cycling, months	5-6	5-6	3-4	5-6
Release to tennis,[a] months	9	10-12	9	12+
Release to contact/collision sports,[b] months	12+	10-12	10-12	12+

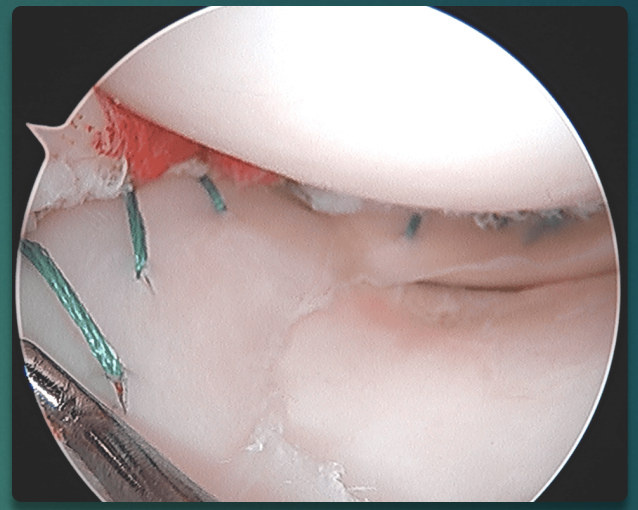
[a]Other examples of this type of sport are pickle ball, golf.
[b]Examples are soccer, football, hockey, combat sports.

Additional Simultaneous Surgeries



AMZ/ Anterior tubercleplasty

Osteotomy



Meniscal transplant

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QUESTIONS?

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