

# **5-Year Multicenter Outcome of Autologous Chondrocyte Implantation of the Knee**

ACL Study Club  
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# Cartilage Registry Advisory Board

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# Cartilage Registry Advisory Board

- Independent review and analyses of multicenter data.
- Interpret and disseminate information on the safety and effectiveness of ACI.
- Provide overall clinical and strategic oversight.

# ACI Femur: Study Objectives

- To report treatment outcomes on the first 100 eligible US patients who were treated with ACI 5 years ago.

# ACI Femur: Cohort

- The first 100 consecutive patients who met the following criteria:
  - ❖ Had at least one full-thickness lesions on the femur (medial/lateral condyles or trochlea).
  - ❖ Underwent an ACI 5 years ago.
  - ❖ No treated defects of the patella or tibia.
  - ❖ No restriction on defect size.

# ACI Femur: Study Design

- Multicenter, prospective.
- Evaluation at baseline and follow-up using modified Cincinnati Knee Rating Scale.
  - ❖ Primary outcome: patient self assessment.
  - ❖ Secondary outcome: clinician evaluations.
- Adverse events, including failures, captured.

# Modified Cincinnati Knee Rating System--Overall Condition

Rate overall condition at the present time

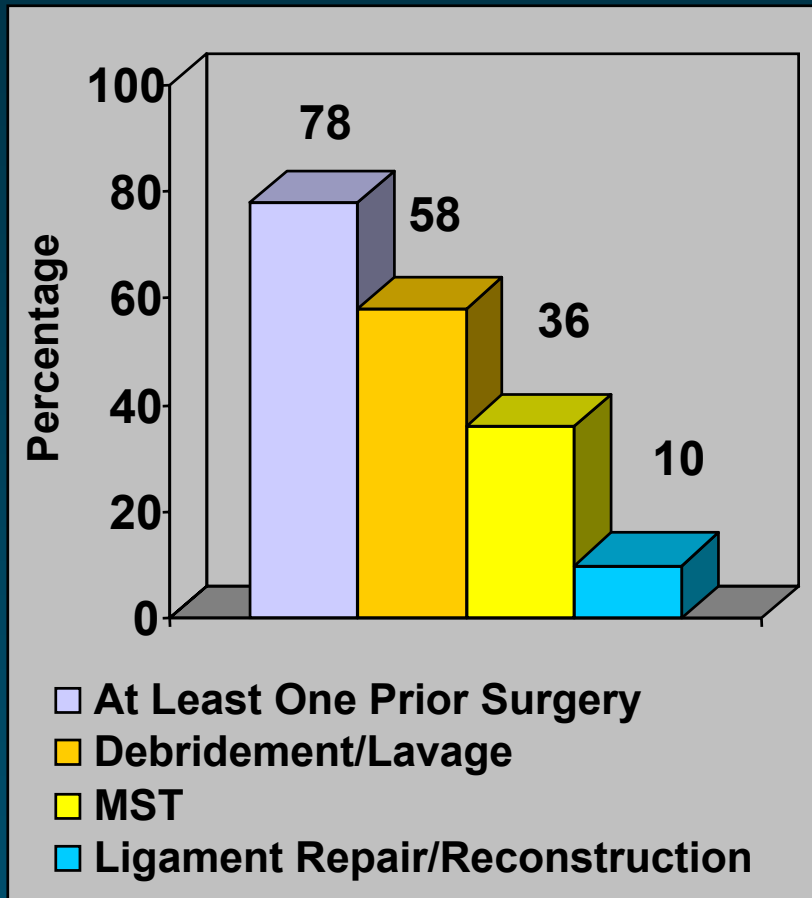


2 = Poor  
4 = Fair  
6 = Good  
8 = Very Good  
10 = Excellent

Significant limitations affect activities of daily living  
Moderate limitations affect activities of daily living, no sports  
Some limitations with sports but participate; I compensate  
Only a few limitations with sports  
Able to do whatever I wish (any sport) with no problems

# ACI Femur: Patient Baseline Characteristics (N=100)

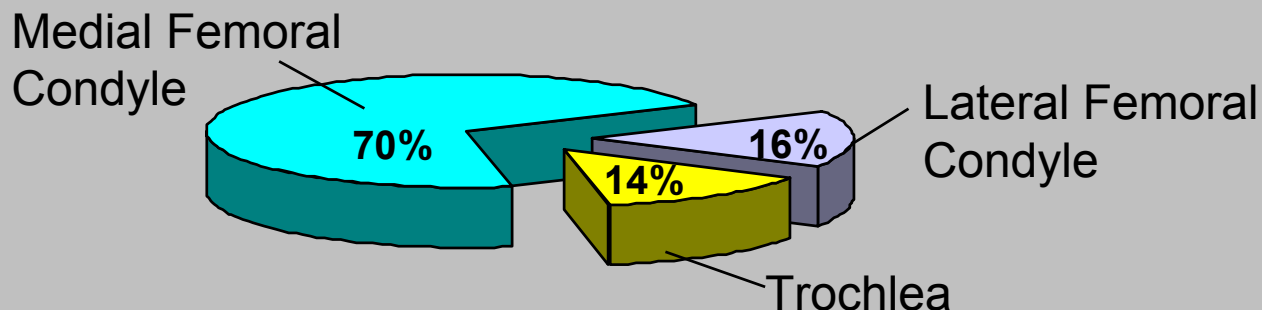
## Procedures Prior to Cartilage Harvest



- Mean Age: 37 (14-55)
- Gender: 65 Men/35 Women
- Worker's Compensation: 38 patients
- Overall modified Cincinnati Knee Score: 3.2

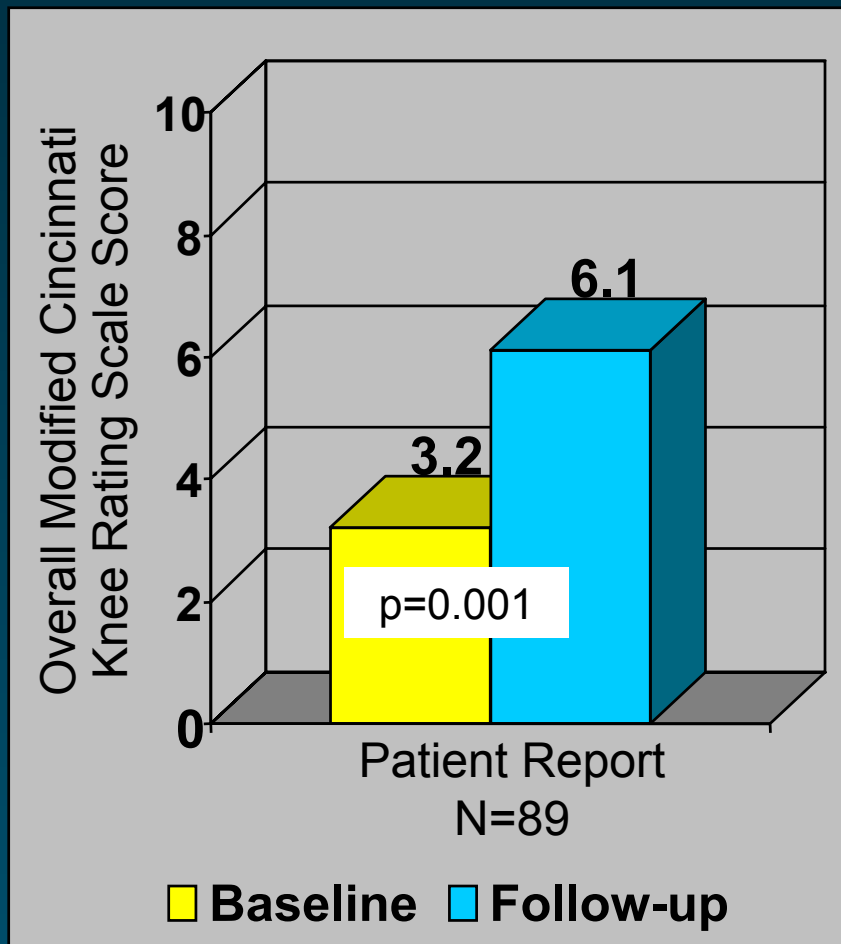
# ACI Femur: Defect Characteristics

## Location of All Defects



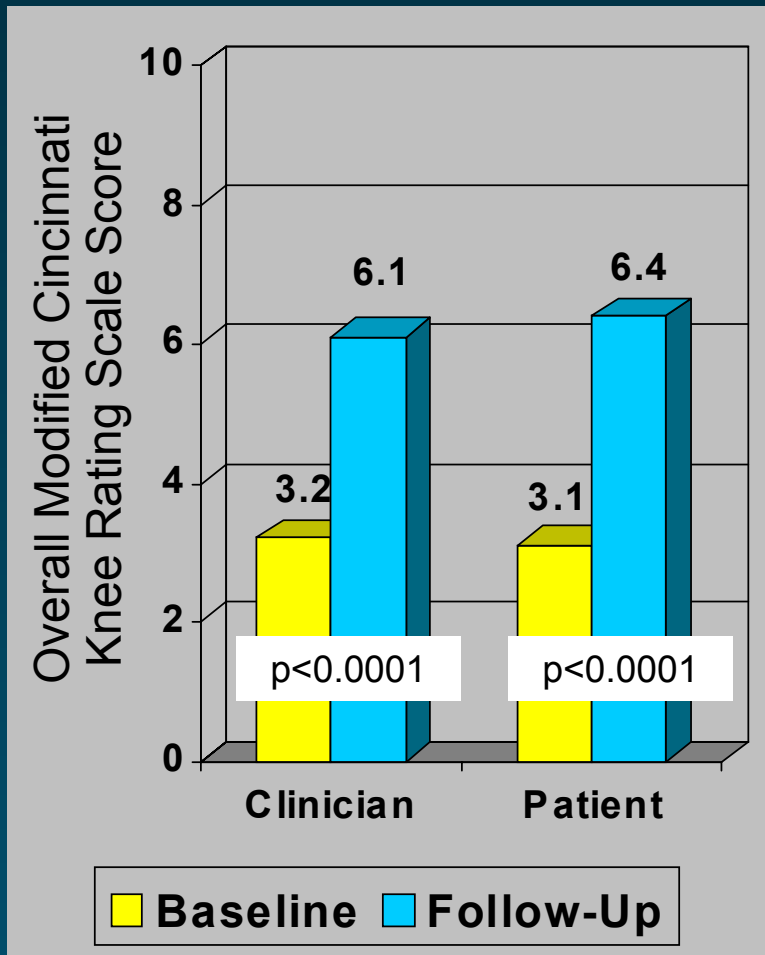
		Per Patient (N=100)
<b>Defect Etiology</b>		
	Acute, %	58
	Chronic, %	42
<b>Mean No. of Defects</b>		1.2
<b>Single Defect, %</b>		85
	mean size, cm <sup>2</sup>	4.2
<b>Multiple Defect, %</b>		15
	mean total surface area, cm <sup>2</sup>	9.0

# ACI Femur: Patient Outcomes - All Patients (N=89)



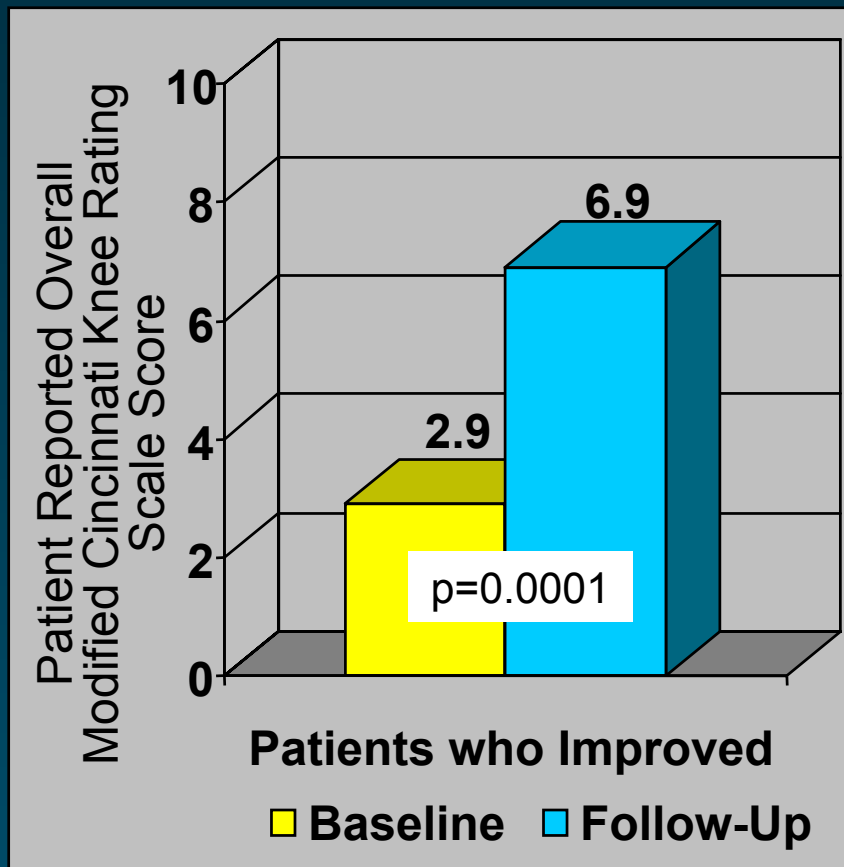
- 5-year data was obtained for 89% of patients.
- Patients reported significant functional improvement (2.9 points) from baseline to follow-up at 5 years ( $p=0.001$ ).

# ACI Femur: Patient Outcomes- Patients with Both Patient and Clinician Knee Scores (N=40)



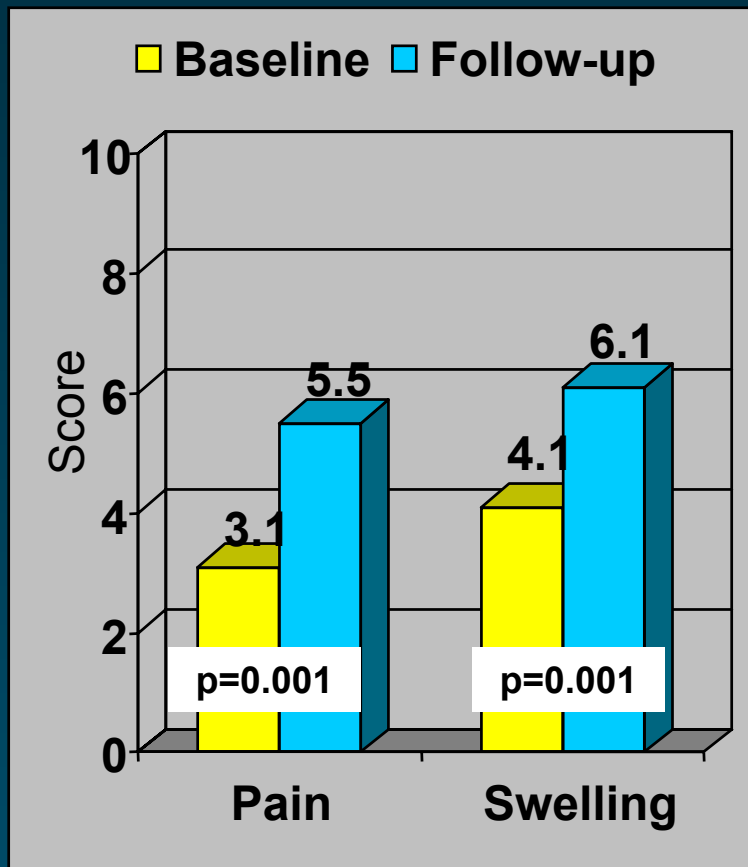
- Both clinician and patient overall scores correlated closely.
- From baseline to follow-up, clinician reported and patient reported overall knee scores improved 2.9 points and 3.3 points, respectively.

# ACI Femur: Patient Outcomes- Improved



- 70 of 89 patients improved at least 1 point on the overall rating of the Cincinnati Score at 5-years post ACI.
- At baseline, patients reported significant to moderate limitations with activities of daily living and an inability to play sports.
- At follow-up, patients reported an improvement of 4 points ( $p=0.0001$ ).

# ACI Femur: Symptoms-Pain and Swelling, (N=89)



- At baseline, patients reported moderate symptoms of pain that limited their ability to perform ADLs.
- At follow-up, patients reported significant reductions in pain and swelling ( $p=0.001$ ).

# ACI Femur: Complications and Subsequent Operations

- No septic arthritis complications.
- Overall, 38 patients underwent 52 operations.
  - ❖ 33% (13/38) of patients who had a subsequent operation met the definition of treatment failure and accounted for 48% (25/52) of all subsequent operations.
  - ❖ 66% (25/38) of patients who had a subsequent operation did NOT meet the definition of treatment failure and underwent 52% (27/52) of all operations following ACI.

# ACI Femur: Definition of Treatment Failure

## Criteria:

- Underwent a re-implantation with ACI.
- Underwent a procedure that violated the subchondral bone for the same defect.
- Complete delamination or removal of the graft.
- Underwent a total knee replacement.

# ACI Femur: Complications and Subsequent Operations

- Non-Treatment Failures (25/38):
  - ❖ All operations were arthroscopic except 1 (excision of a tibial cyst).
  - ❖ Common Findings:
    - ❖ Loose bodies, periosteal flap complications, adhesions hypertrophic changes of the graft, mal-tracking, synovitis.
- Treatment Failures (13/38):
  - ❖ Total knee replacements (3 cases).
  - ❖ Reimplanted with autologous chondrocytes (3 cases).
  - ❖ MST (2 cases).
  - ❖ Osteochondral autograft transplantation (1 case).
  - ❖ Debridement (2 cases).
  - ❖ Arthroscopic diagnosis of delamination, no further operations reported (2 cases).

# ACI Femur: Etiology of Treatment Failures

- Identifiable reasons for treatment failures:
  - ❖ 2 patients were grossly non-compliant with rehabilitation protocol.
  - ❖ 1 patient experienced direct knee trauma in a car accident.
  - ❖ 3 patients had uncorrected ligamentous instability/mal-alignment.
  - ❖ 1 patient had generalized osteoarthritis, considered a “salvage” patient by treating physician.

# ACI Femur:

## Patients who did not complete assessments at 5-Years (N=11)

<b>Patient</b>	<b>Latest F/U completed</b>	<b>F/U Score</b>
1	no follow-up	
2	no follow-up	
3	no follow-up	
4	1 year	2
5	1 year	8
6	3 year	8
7	3 year	10
8	4 year	2
9	4 year	9
10	4 year	5
11	4 year	8

# ACI Femur: Conclusions

- ACI demonstrates long-term effectiveness for patients with full-thickness chondral lesions of the knee.
- After 5 years post ACI, 79% (70/89) patients improved from having frequent moderate symptoms and limited ability to perform ADLs to having no symptoms with ADLs and the ability to perform light/work sports.
- 13 treatment failures accounted for approximately half of all operations following ACI.
- Results are promising given that 78% of patients had a prior surgery, 38% were on worker's compensation, 15% had multiple defects with a mean total defect area of 9 cm<sup>2</sup> and 35% of patients represent the surgeons first experience with ACI.

**Thank you.**