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REHABILITATION PROTOCOL

Matrix Autologous Chondrocyte Implantation (MACI) – Patellofemoral Joint



autologous cultured
chondrocytes
on porcine
collagen membrane

REHABILITATION MANUAL

Guidelines for the functional recovery of
patients following MACI for the treatment
of cartilage defects of the knee

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INTRODUCTION

The purpose of this manual is to provide guidance for the development of a physician-prescribed rehabilitation program to foster early mobilization and load protection, promote graft maturation, and reduce the risk of graft delamination, postoperative thromboembolic events, and joint stiffness.

The MACI® (autologous cultured chondrocytes on porcine collagen membrane) Rehabilitation Manual is based on clinical experience* that supports the use of a controlled rehabilitation program to promote a progressive return to full range of motion (ROM) and weight bearing (WB), as well as muscle strengthening and conditioning. The rehabilitation program was designed using the knowledge of basic science, anatomy, and the biomechanics of articular cartilage, as well as the natural course of healing following implantation. It is not intended as a substitute for individual clinical judgment, and a patient-specific rehabilitation program should be implemented.

The goal is to restore optimal function in each patient as quickly and safely as possible. Although timeframes have been established as a guide, **it is more important that goals are reached at the end of each phase prior to progression to the next.**

*Ebert JR, Fallon M, Robertson WB, Lloyd DG, Zheng MH, Wood DJ, Ackland T.

KEY POINTS OF CONSIDERATION

- Patient adherence to the prescribed rehabilitation program is critical.
- Consider lesion size, location and patient characteristics when determining a rehabilitation program.
- Emphasis should be placed on reaching the goals of a given phase over rigid adherence to time schedule.
- It is important to avoid excessive load/WB on the graft site to allow proper healing.
- Pain and swelling must be carefully monitored throughout the rehabilitation process. Ignoring these symptoms may compromise the success of the surgery and the patient's outcome.
- If sharp pain with locking or swelling is experienced, the patient should notify their surgeon immediately. Activity should be adjusted to lessen the irritation. Cryotherapy may be used to control the swelling.

MACI REHABILITATION MATURATION PHASES*

	REHABILITATION PHASE	FOLLOWING SURGERY	STAGE OF TISSUE DEVELOPMENT
1	IMMEDIATE POST-OP	0-1 week	Implantation and Protection Cells adhere to bone and begin to proliferate throughout the defect
2	RESTORE MOBILITY	2-3 weeks	
3	STRENGTHEN & STRAIGHTEN	4-6 weeks	
4	INDEPENDENT MOVEMENT	7-12 weeks	Transition and Proliferation Continued proliferation forms a defect-spanning matrix
5	RETURN TO DAILY ACTIVITY	3-6 months	Remodeling Expansion of the cell matrix into putty-like consistency
6	RECREATIONAL ACTIVITIES	6-9 months	
7	RETURN TO FULL ACTIVITY	9-12 months	Maturation Progressive hardening until a durable repair tissue is formed

*Based on clinical observations. Individual results for timeline and repair tissue progress will vary.

MACI POST-OPERATIVE REHABILITATION TIMELINE*

*Based on clinical observations. Individual results for timeline and repair tissue progress will vary.

	1 IMMEDIATE POST-OP 0-1 week following surgery		2 RESTORE MOBILITY 2-3 weeks following surgery		3 STRENGTHEN & STRAIGHTEN 4-6 weeks following surgery	
	Tibiofemoral joint	Patellofemoral joint	Tibiofemoral joint	Patellofemoral joint	Tibiofemoral joint	Patellofemoral joint
Weight bearing (WB) % of body weight	<20%	<20%	Progress from <20%–30%	Progress from <20%–50%	Progress from <40%–60%	Progress from 75%–full
Range of motion (ROM)	Passive and active, progress from 0°–30°	Passive and active, progress from 0°–20°	Active, progress from 30°–90°	Active, progress from 30°–60°	Active, progress from 110°–125°	Active, progress from 90°–125°
Protective knee bracing	Progress from 0°–30°	Locked at full knee extension	Progress from 30°–45°	Locked at full knee extension	Progress from 45°–full extension	Use brace as required (beginning Week 6)
Ambulatory aids	2 crutches	2 crutches	2 crutches	2 crutches	1-2 crutches	1-2 crutches (Weeks 4-5); 1 crutch as required (Week 6)

The MACI Post-Operative Rehabilitation Timeline outlines the importance of a progressive rehabilitation protocol. It stresses the importance of a tailored approach to each individual's rehabilitation that will protect the graft while stimulating the cells to promote optimal maturation. Mechanical loading is an important regulator of chondrocyte differentiation. Key types of loading include cyclic compressive loading (enhances chondrogenesis); shear loading (increases matrix production and improves biomechanical structure); and excessive WB (which can be detrimental to development and repair of cartilage).

4		5		6		7	
INDEPENDENT MOVEMENT		RETURN TO DAILY ACTIVITY		RECREATIONAL ACTIVITIES		RETURN TO FULL ACTIVITY	
7-12 weeks following surgery		3-6 months following surgery		6-9 months following surgery		9-12 months following surgery	
Tibiofemoral joint	Patellofemoral joint	Tibiofemoral joint	Patellofemoral joint	Tibiofemoral joint	Patellofemoral joint	Tibiofemoral joint	Patellofemoral joint
Progress from 80%–full (Weeks 8-10)	Full	Full	Full	Full WB and ROM		Full WB and ROM	
Active, full (Weeks 7-8)	Active, full (Weeks 7-8)	Full and pain-free active ROM	Full and pain-free active ROM	Ability to tolerate walking distances of more than 3 miles		Ability to commence a running program	
Allow full knee flexion within brace	No brace	No brace	No brace	Ability to effectively negotiate uneven ground, including soft sand		Resumption of dynamic recreational activities (activities that generate high compression, shear and rotational loads are to be avoided until 12-18 months or as directed by the orthopedic surgeon)	
Full WB indoors, single crutch outdoors and in unfamiliar areas	No crutches	No crutches	No crutches	Ability to return to pre-operative low-impact recreational activity			

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PHASE

1

IMMEDIATE POST-OP

0-1 week following surgery

Immediately following surgery, it is important to maintain joint mobility and muscle tone without placing undue stress on the implant area. Prior to discharge, the patient also must be proficient in, and comfortable with, all aspects of home exercise and functional activities.

goal

- Maintain joint mobility and muscle tone while adhering to all post-operative precautions.

patient expectations

The week immediately following surgery will be spent managing pain and swelling with the careful introduction of movement.

- A comfortable setting is recommended and unnecessary movement should be restricted to protect the implant (rest, immobilization)
- RICE as directed (rest, ice, compression, elevation)
- Continuous passive motion (CPM) and basic exercises and activities as directed



PRIOR TO DISCHARGE

1. Ensure the patient has an initial appointment (or appropriate contacts) for outpatient physical therapy.
2. Ensure that the patient is aware that the next post-operative appointment with the orthopedic surgeon normally occurs within 4–6 weeks post-operative.
3. If required, ensure that patient has an appointment for the removal of sutures/staples, or is aware when they must be removed (generally within 8–10 days post-operative).
4. Instruct and educate the patient on the importance of following the RICE guidelines for edema control.
5. Reinforce WB and brace guidelines.
6. Review the home exercise regimen, ensuring the patient is proficient in safely performing these activities.
7. Review (and educate on) techniques for performing functional activities (i.e., stairs, bed transfers, showering, etc.), ensuring the patient is independent in safely performing these activities.
8. Ensure the patient is educated in wound healing, and how to assess changes in the wound and surrounding soft tissue that may indicate infection.

CONTRAINDICATIONS

1. Excessive load bearing (>20% of patient body weight) especially in combination with knee flexion
2. Ambulation without crutches and a protective knee brace
3. Generation of shear forces within the knee
4. Knee flexion beyond 30° for tibiofemoral grafts or 20° for patellofemoral
5. Active knee extension (especially against resistance)

REHABILITATION PLAN

Tibiofemoral joint	Patellofemoral joint
Weight bearing (WB) % of body weight	
<20%	<20%
Range of motion (ROM)	
Passive and active, progress from 0°–30°	Passive and active, progress from 0°–20°
Protective knee bracing	
Progress from 0°–30°	Locked at full knee extension
Ambulatory aids	
2 crutches	2 crutches

Initiate on post-operative Day 1 unless otherwise instructed by the operating surgeon.

1. Provide appropriate analgesics for pain control.
2. Commence CPM 12-24 hours post-operative, for a minimum of 1 hour daily to reduce the chance of intra-articular adhesions¹ and potentially speed up and improve the quality of tissue repair.^{1,2}
3. Fit a post-operative ROM control brace; this should be worn 24 hours per day for the first 3 weeks, unless PT is utilizing the CPM.
4. Apply cryotherapy as standard edema control (20 minutes with ice, at least 3 times per day).
5. Perform active dorsi-flexion and plantar-flexion exercises of the ankle to encourage lower extremity circulation.
6. Encourage isometric contraction of the quadriceps, hamstrings, and gluteal musculature to help maintain muscle tone and minimize muscle loss.^{3,4}
7. Oversee breathing exercises to ensure proper technique during therapeutic exercise.
8. Offer instruction and practice in proficient toe-touch ambulation (using 2 crutches, with 20% of body weight through the operated limb, unless otherwise indicated by the operating surgeon), and safety with bed transfers and stairs.
9. Provide detailed verbal and written instruction on how to perform activities of daily living and functional tasks, while adhering to post-operative precautions and appropriate WB status.

PHASE

2

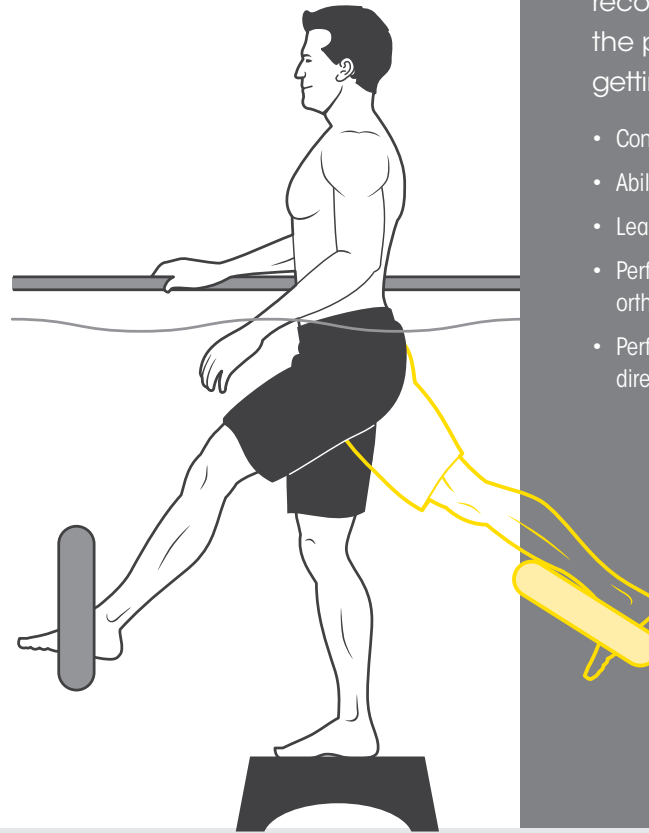
RESTORE MOBILITY

2-3 weeks following surgery

As the immediate surgery phase is past, the patient should achieve pain-free and full passive knee extension, as well as limited WB. Additional focus is placed on maintaining muscle tone and ensuring proper wound healing and edema control.

goals

- ❑ Pain-free knee flexion of 90° for tibiofemoral grafts and 60° for patellofemoral grafts.
- ❑ Pain-free full passive knee extension.
- ❑ Independent in heel-toe gait using 2 crutches and a knee brace.
 - 30% of body weight for tibiofemoral grafts
 - 50% of body weight for patellofemoral grafts
- ❑ Adequate control of post-operative pain and swelling.
- ❑ Ability to generate an active, isometric quadriceps contraction.
- ❑ Independent with home-exercise program.



patient expectations

The stage following immediate recovery from surgery should provide the patient with the roadmap for getting back to a normal daily routine.

- Continue to manage pain, swelling, and wound care
- Ability to properly put on knee brace
- Learn to use crutches for daily activities
- Perform limited WB as directed by orthopedic surgeon
- Performance of home exercise program as directed by surgeon and physical therapist

INITIAL OUTPATIENT PT SESSION

1. Review the patient's level of pain and medication use.
2. Ensure the appropriate knee brace is obtained, correctly fitted, and adjusted appropriately (0°–30° of knee flexion, or as directed by the orthopedic surgeon).
3. Ensure proficiency with crutches, both during normal ambulation and while negotiating stairs.
4. Provide appropriate education, training, and proficiency with the desired level of partial WB ($\leq 20\%$, or as directed by the orthopedic surgeon).⁵
5. Review instructions and movement contraindications outlined by the orthopedic surgeon and hospital physical therapist as needed.
6. Review and progress the home exercise program based on the current post-operative timeline and patient status.

REHABILITATION PLAN

Tibiofemoral joint	Patellofemoral joint
Weight bearing (WB) % of body weight	
Progress from <20%–30%	Progress from <20%–50%
Range of motion (ROM)	
Active, progress from 30°–90°	Active, progress from 30°–60°
Protective knee bracing	
Progress from 30°–45°	Locked at full knee extension
Ambulatory aids	
2 crutches	2 crutches

ROM and flexibility exercises

- Use CPM at the end of each session for 20–30 minutes to reduce the chance of intra-articular adhesions⁶ and potentially speed up and improve the quality of tissue repair^{1,2}
- Passive and active heel slides
- Full knee extension
- Careful patellar mobilization in all directions

Strengthening exercises

- Isometric quadriceps contraction and co-contraction activities (aided with the use of neuromuscular electrical muscle stimulation to stimulate voluntary muscular contraction)
- Isometric gluteal, hamstrings, adductor, and calf contractions
- Straight-leg-raise activities (hip flexion, abduction, adduction, and extension)

Hydrotherapy exercises

- Deep-water walking (forwards, backwards, and sideways)
- Deep-water calf raises
- Straight-leg hip flexion, extension, abduction, and circumduction (with or without floatation devices for additional resistance)
- Passive knee flexion
- Stretching of hamstring and calf musculature

Symptom control

- Perform clearance and lymphatic remedial massage as needed to assist in the reduction of soft-tissue edema
- Perform cryotherapy, compression, and elevation regularly to assist in the reduction of soft tissue edema

PHASE

3

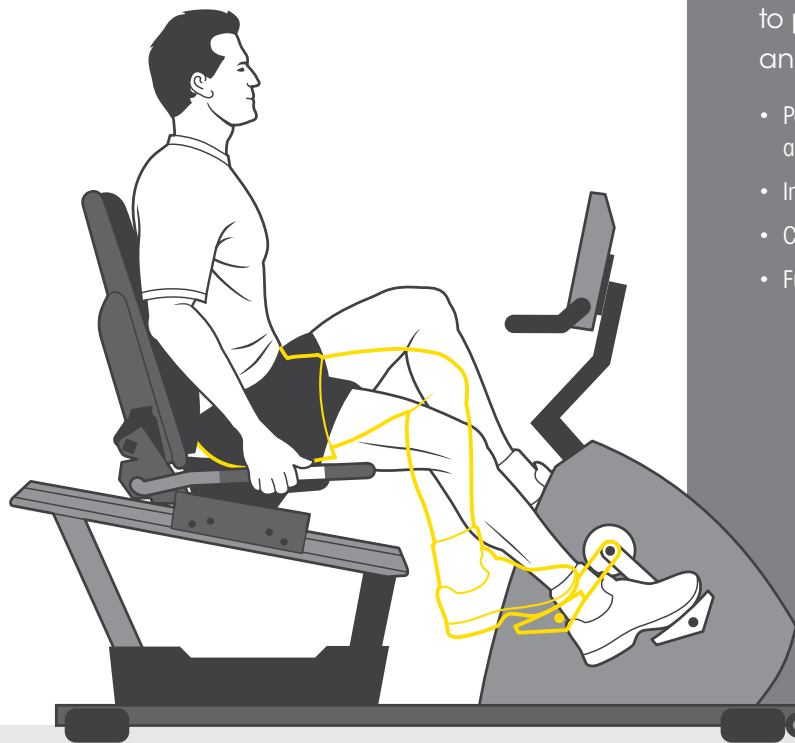
STRENGTHEN & STRAIGHTEN

4-6 weeks following surgery

Now that the patient is ambulating (with crutches), increasing WB and ROM, as appropriate, is called for. Strengthening exercises should also be augmented.

goals

- ❑ Pain-free active knee flexion to 125°.
- ❑ Independent in performing home exercises, including a straight-leg raise.
- ❑ Tibiofemoral graft patients should achieve a pain-free gait using 1-2 crutches. (dependent on WB status), a knee brace, and 60% WB pressure.
- ❑ Patellofemoral graft patients may be progressed to full WB as tolerated, following clearance from the orthopedic surgeon.



patient expectations

Independent with crutches for activities of daily living and established in a PT program, patients at this point should be able to progress with strengthening, WB, and ROM exercises.

- Performance of home exercise program as directed
- Independent use of crutches
- Continued increase in WB as directed
- Full extension ROM of the knee

REHABILITATION PLAN

Tibiofemoral joint	Patellofemoral joint
Weight bearing (WB) % of body weight	
Progress from <40%–60%	Progress from 75%–full
Range of motion (ROM)	
Active, progress from 110°–125°	Active, progress from 90°–125°
Protective knee bracing	
Progress from 45°–full extension	Use brace as required (beginning Week 6)
Ambulatory aids	
1-2 crutches	1-2 crutches (Weeks 4-5); 1 crutch as required (Week 6)

ROM and flexibility exercises

- Continue Phase 2 flexibility/stretching exercises
- Stretch hamstrings and calf musculature
- Carefully mobilize patella in all directions
- Use CPM to maximum comfortable range as required
- Focus WB on heel-to-toe pattern to encourage more natural gait

Strengthening exercises

- Continue Phase 2 strengthening exercises
- Progress straight-leg-raise activities (e.g., supine straightleg hip-flexion half-seated and/or with externally rotated foot)
- Introduce:
 - side-lying gluteal exercises with a flexed knee
 - standing-calf raises (dependent on WB status)
 - seated or standing weighted-hip adduction and abduction
 - trunk-strengthening exercises (e.g., supine sit-ups, weight-supported trunk flexion)
- Recumbent cycling (modified knee flexion; 90°) (Weeks 5–6)

Hydrotherapy exercises

- Continue Phase 2 hydrotherapy exercises
- Introduce:
 - active knee flexion (with floatation devices for additional resistance)
 - shallow-water walking (waist depth, dependent on WB status)
 - shallow-water calf raises
 - deep-water squatting activities
 - pool cycling (full knee ROM)

Symptom control

- Perform clearance and lymphatic remedial massage as required for edema
- Perform cryotherapy, compression, and elevation as required for edema



PHASE

4

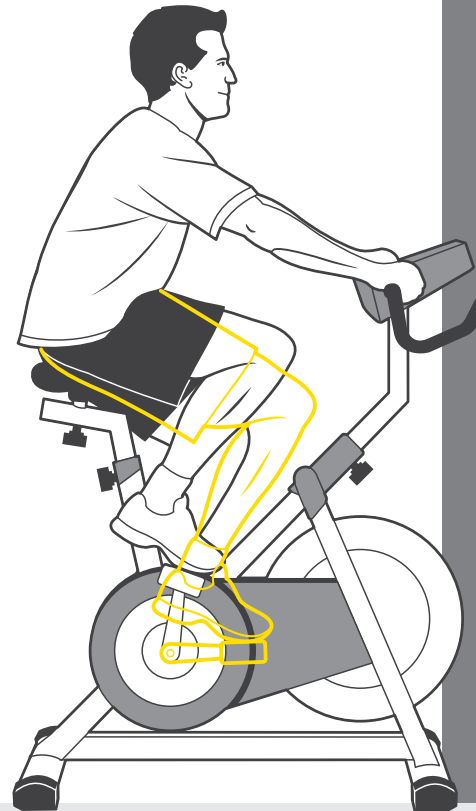
INDEPENDENT MOVEMENT

7-12 weeks following surgery

Working toward movement free of ambulation devices and knee braces is a key aspect of this phase. Focus is placed on becoming thoroughly independent with the rehabilitation exercises, as clinic visits become less frequent.

goals

- ❑ Active knee ROM within anatomical limits.
- ❑ Pain-free six-minute walk test^{7,8} without the use of crutches or other assistive aids.
- ❑ Begin the use of an upright stationary bike without knee brace.
- ❑ Independent in performing home and gym-based exercises, for continuation of rehabilitation following clinic discharge, as instructed by surgeon and physical therapist.
- ❑ Begin proprioception exercises.
- ❑ Progression to full WB.



patient expectations

Phase 4 is a transitional stage of rehabilitation as the dependence on crutches and the knee brace are minimized and then discontinued.

- Independent with home exercise program and a clear understanding on how to safely progress as physical therapy visit frequency decreases
- Discontinue use of ambulatory devices, as directed by surgeon and physical therapist
- Progression to full WB

REHABILITATION PLAN

Tibiofemoral joint	Patellofemoral joint
Weight bearing (WB) % of body weight	
Progress from 80%–full (Weeks 8-10)	Full
Range of motion (ROM)	
Active, full (Weeks 7-8)	Active, full (Weeks 7-8)
Protective knee bracing	
Allow full knee flexion within brace	No brace
Ambulatory aids	
Full WB indoors, single crutch outdoors and in unfamiliar areas	No crutches

ROM and flexibility exercises

- Introduce passive knee ROM on rowing ergometer (Weeks 9–10)
- Carefully mobilize patella in all directions
- Conduct CPM to maximum comfortable range as required
- Continue Phase 2–3 strengthening exercises
- Continue standing weighted hip adduction and abduction
- Introduce weighted knee flexion (Week 8)
- Introduce upright (knee flexion: 105°–110°) cycling (Weeks 9–12)
- Continue Phase 2–3 flexibility/stretching exercises
- Stretch quadriceps musculature (Weeks 9–10)

Hydrotherapy exercises

- Continue Phase 2–3 hydrotherapy exercises
- Stretch quadriceps musculature
- Progress water squatting activities
- Introduce weight-supported lunge activities
- Introduce weight-supported “step up and down” activities

Symptom control

- Perform clearance and lymphatic remedial massage as required for edema
- Perform cryotherapy, compression and elevation as required for edema

Proprioception exercises

Introduced following the return to full WB, both within the hydrotherapy pool and the clinic setting. Slowly progress proprioceptive activities from partial to full WB positions by altering:

1. The patient’s postural position (i.e., seated to standing).
2. The environment in which the activity is to be undertaken (e.g., gym- or pool-based).
3. Proprioceptive input mechanisms (e.g., eyes open or closed).
4. The speed of movement.
5. The magnitude of the base of support (i.e., 2-legged to 1-legged).
6. The stability of the base of support (i.e., introduction of unstable surfaces including a soft mat or pillow, wobble board, dura disc, theraball or mini-trampoline).
7. Introducing “weight transfer” and/or “activity-specific drills” with other equipment.

Following the completion of Phase 4, patients generally undergo a 3-month post-operative assessment, and a written report is sent to the orthopedic surgeon to coincide with the patient’s review.



PHASE

5

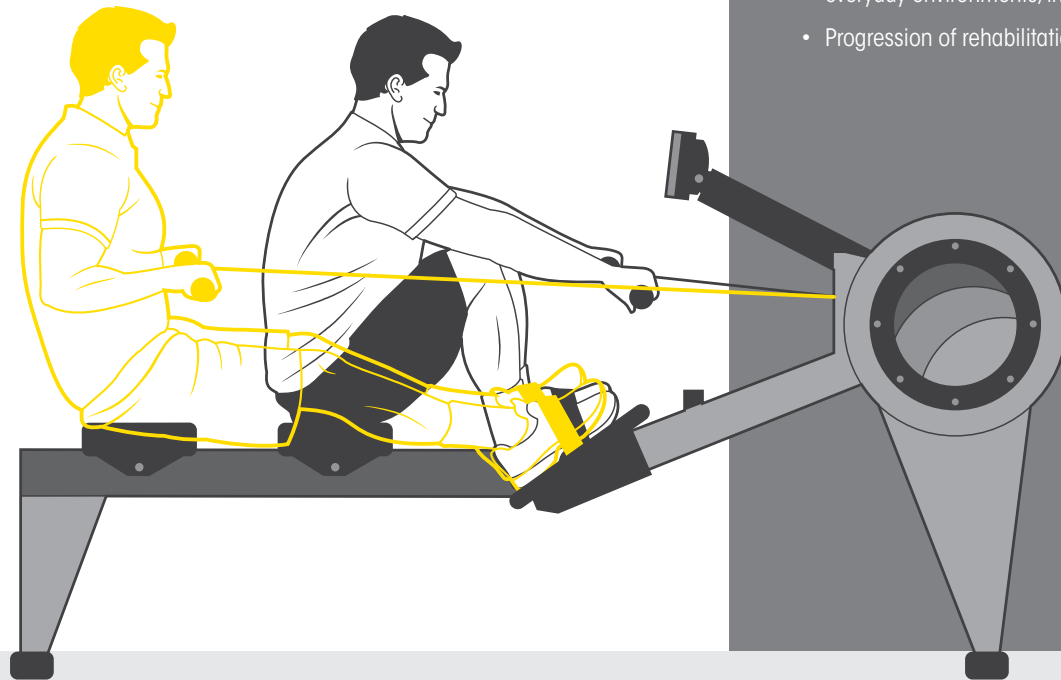
RETURN TO DAILY ACTIVITY

3-6 months following surgery

The majority of patients can return to strenuous daily activities on a limited basis upon reaching this phase. Patients can either continue to attend the outpatient clinic once or twice per week independently (though group supervised), or should continue with their prescribed gym and home rehabilitation program independently.

goals

- ❑ Normal gait pattern without walking aids or a knee brace.
- ❑ Ability to negotiate stairs and mild gradients.
- ❑ A return to work, depending on the demands of the job.
- ❑ Proficiency in performing a weighted-leg press through 60°–90° of knee flexion, and with ≤50% of body weight pressure.
- ❑ Independent in performing full WB proprioception activities.



patient expectations

Patients will continue to progress with full WB rehabilitation activity. Patients should be able to return to everyday activity.

- Unimpeded, pain-free movement through everyday environments, including stairs
- Progression of rehabilitation activity

REHABILITATION PLAN

Tibiofemoral joint	Patellofemoral joint
Weight bearing (WB) % of body weight	
Full	Full
Range of motion (ROM)	
Full and pain-free active ROM	Full and pain-free active ROM
Protective knee bracing	
No brace	No brace
Ambulatory aids	
No crutches	No crutches

ROM and flexibility exercises

- Continue Phase 3–4 flexibility/stretching exercises and strengthening exercises
- Continue Phase 3–4 strengthening exercises
- Introduce bridging exercises
- Introduce standing single-leg calf raises
- Introduce modified open kinetic chain (OKC) exercises (i.e., terminal leg extension, with appropriate use based on lesion location and knee joint biomechanics)
- Introduce modified closed kinetic chain (CKC) exercises (e.g., inner range quadriceps and leg press activities)
- Progress upright stationary and outdoor road cycling
- Introduce rowing ergometry as tolerated



PHASE

6

RECREATIONAL ACTIVITIES

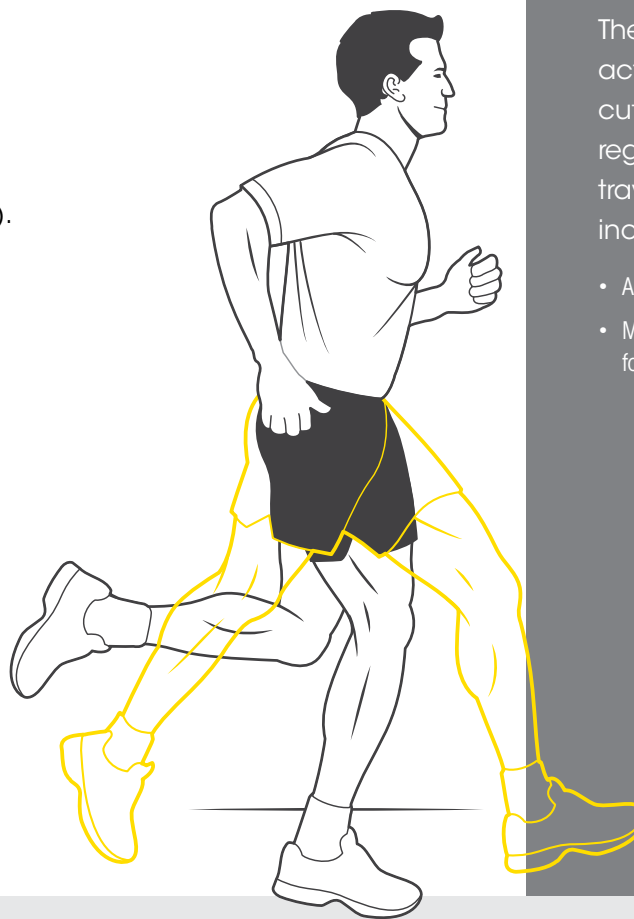
6-9 months following surgery

The patient returns to low-impact recreational activities

by gradually increasing the difficulty of their exercises.

goals

- ❑ Hamstring and calf strength within 80%–90% of the contralateral leg.
- ❑ Ability to tolerate walking distances of >3 miles (5 km).
- ❑ Ability to effectively negotiate uneven ground, including soft sand.
- ❑ Ability to return to low-impact recreational activities.



patient expectations

The patient can return to recreational activities, avoiding heavy impact, cutting, or pivoting. The patient has regained everyday function including traversing uneven or soft ground, inclines, and other obstacles.

- Ability to return to low-impact recreational activity
- Maintaining rehabilitation program is essential for continued progression

REHABILITATION PLAN

ROM and flexibility exercises

- Continuation of Phase 3–4 flexibility/stretching exercises

Strengthening exercises

- Continuation of Phase 3–4 strengthening exercises
- Progression and increased difficulty of OKC exercises
- Progression and increased difficulty of CKC exercises (e.g., step ups/downs, modified squat activities)
- Introduction of controlled running on a mini-trampoline



PHASE

7

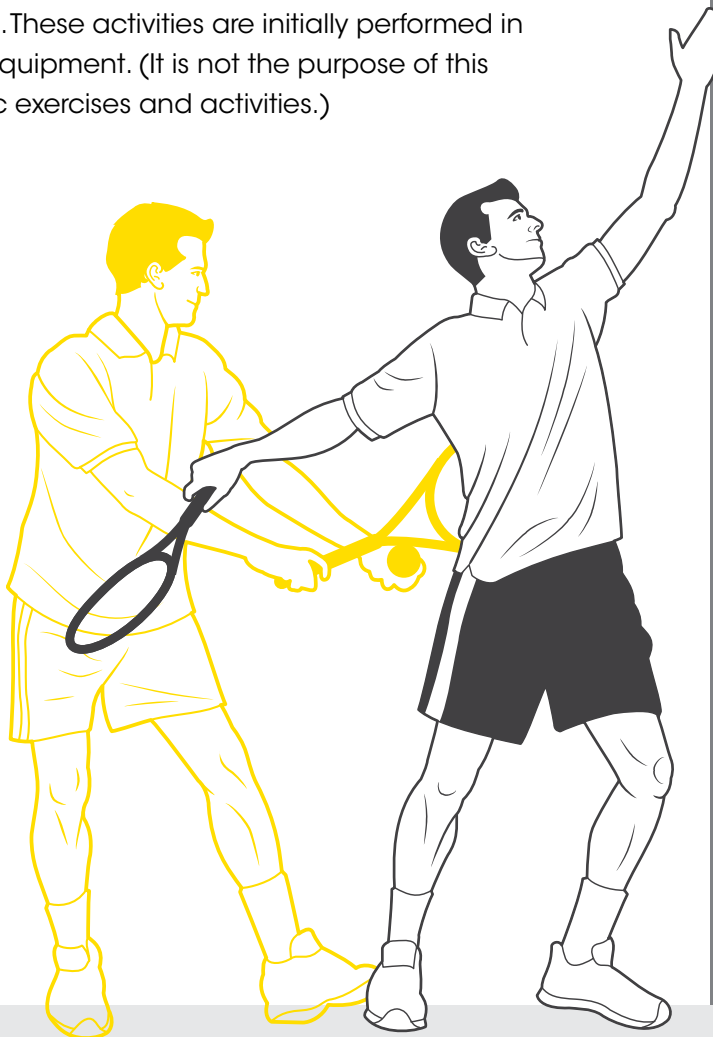
RETURN TO FULL ACTIVITY

9–12 months following surgery

In this final phase patients should be able to resume normal functionality as well as low compression recreational activities. These activities are initially performed in isolation, and then with the appropriate equipment. (It is not the purpose of this document to outline a protocol of specific exercises and activities.)

goals

- ❑ Ability to perform all activities of daily living.
- ❑ Ability to commence running program.
- ❑ Resume dynamic recreational activities.



patient expectations

The patient is working toward the ability to make full demands on their knee as the repair tissue continues to mature.

- Commence a return to running program
- Expanded agility as these activities are added to their program
- A full return to recreational activities, working toward individual goals as the implant matures

RETURN TO ACTIVITIES*

It is not the purpose of this document to outline a protocol of specific exercises and activities. Both the patient and therapist must use their own discretion. Not only the graft maturation process should be considered but also the mental preparedness of the patient and the general physical function and level of specific knee strength, stability, and support. Individual patient variations must be evaluated when considering a patient's long-term outcome and ability to return to activities. In addition to the commitment and psychological profile of the patient, specific considerations include whether:

1. The patient's graft has matured to the point at which it is able to withstand the specific demands of the chosen activity.
2. The patient has been appropriately rehabilitated to the point at which he or she is able to physically and psychologically undertake the demands of the chosen activity.
3. The patient has undergone appropriate clinical assessment with an orthopedic surgeon experienced with the results of a MACI implant.

Cellular regeneration, matrix production, and adaptation of the regenerating tissue to natural function take time, and it is unrealistic and impractical to expect patients to return to their normal activities within the first post-operative year.

*Individual results may vary.

REHABILITATION PLAN

ROM and flexibility exercises

- Continuation of Phase 3–6 flexibility/stretching exercises and strengthening exercises
- Continuation of Phase 3–6 strengthening exercises
- Progression and increased difficulty of CKC exercises
- Introduction of agility exercises relevant to the patient's activities

Activities that generate high-compression, shear, and rotational loads are to be avoided until 12-18 months, or as directed by orthopedic surgeon.

