

1. What is autologous Cartilage replacement or how does cell therapy help in cartilage repair?

Autologous Cartilage replacement is an FDA-approved biologic product indicated for repair of articular cartilage of the joint (knee, ankle, shoulder) in adults designed to help replace areas of cartilage that are missing because of injury or wear and tear.

ACI literally means “same-site cartilage cell implantation” and it is a process where Cartilage cells (chondrocytes) are removed from the patient (knee, ankle or shoulder), cultured to grow and multiply in a lab into a surplus population of several million and then re-implanted in the area of damaged cartilage in a minimally invasive surgical procedure called autologous chondrocyte implantation (ACI). These cells will grow new and repair tissue with properties like that of normal cartilage present in other joints.

This therapy poses no risk of disease transmission to you since it comes from your own tissue.

2. Who would be a suitable candidate for cartilage repair with cell therapy / ACI?

This procedure is only appropriate for patients with relatively small areas of cartilage damage. Patients with widespread, generalized cartilage damage or arthritis of the knee are not candidates for ACI. Patients who the criteria for Autologous Chondrocyte Implantation would have the following characteristics:

- An area of cartilage damage but not widespread arthritis, between the age of 18-65 years
- Knee pain or swelling that limits their activity

In addition, there are general guidelines regarding the size of the defect and the status of the knee. As many of these points are fairly technical, it is best for you to talk with an Orthopedic Surgeon trained and experienced in the application of this therapy.

3. Who is a not a candidate for cartilage repair with cell therapy / ACI?

Those with the following conditions are not suitable for ACI

- Active autoimmune connective tissue diseases.
- Patients with concomitant malignancies

(A concomitant malignancy is a second illness occurring at the same time as a primary illness. For example, a person with cancer may develop an infection because of a weakened immune system. The primary illness can make it difficult to diagnose or treat the concomitant illness, such as when a person with mental illness develops an infection, heart disease, cancer or diabetes and cannot communicate symptoms with his physician or be accountable for treatment.)

4. Am I a candidate for cartilage repair with cell therapy / ACI if I've undergone other treatments for knee pain?

Yes, if you are experiencing pain and swelling in your knee, and you are limiting your daily activities.

5. Am I too old for autologous cartilage replacement therapy to work for me?

Ideal age is between 18-65 years

It has not been tested in children or in patients over the age of 65 years.

6. How does the doctor collect my cartilage tissue to be able to regrow it later?

In patients undergoing ACI, the surgeon performs an initial biopsy procedure of arthroscopy, a key hole surgery in which small pieces of cartilage, including cartilage cells are taken. The cartilage pieces are then sent to a laboratory, where the cells are isolated and cultured (multiplied) for 3–5 weeks to obtain sufficient number of cells (usually between 12-48 million cells).

It is a simple day care procedure in the hospital where discharge is given the same day after the procedure has been completed.

(Key hole surgery is a minimally invasive surgical procedure on a joint in which an examination and sometimes treatment of damage is performed using an arthroscope, an endoscope that is inserted into the joint through a small incision).

7. How long does it take to grow the cells?

After your biopsy is taken, it is sent to Regrow's FDA-licensed and regulated cell therapy manufacturing facility in Lonavla, Maharashtra for processing.

In total, it takes about 3 to 5 weeks for the cells from your biopsy to increase to approximately 12-48 million cells.

8. How are the cultured cells implanted back into the damaged site ?

The surgeon first prepares and smoothens the damaged area, injects the chondrocytes that have been grown in the laboratory underneath the membrane.

The cells then grow and mature in the joint, and gradually replace the damaged area with living, healthy cartilage. The patient needs to be admitted in the hospital and retained for a period of 2-3 days post which discharge is sanctioned.

9. Will I need physical therapy following this surgery?

Yes, you will need to follow a rehabilitation program, your doctor and physical therapist will design a program for you based on the size, location and severity of your cartilage injury. Of course, rehabilitation requires dedication but once you get through it you should be able to enjoy a long-lasting and positive clinical outcome.

10. What is the post-operative protocol for the patients undergone autologous chondrocyte implantation?

The day after the surgery, the limb will be placed on a on a continuous or intermittent basis.

During this time, the physiotherapist will instruct you how to go about walking with crutches wearing a straight-leg splint touching the operated foot to the ground without putting weight on the leg.

The brace should be worn during day and removed only when doing your knee curl exercises (lying on your stomach) and for showering. You will continue to do your quadriceps contraction exercises hourly, throughout waking hours, without removing the brace

11. What is a typical recovery/ week wise rehabilitation plan post discharge?

- Weight bearing

It is recommended to keep you in non-weight bearing until 4 weeks after ACI. You can increase the weight bearing gradually and he/she may be able to sustain his/her partial weight bearing at 5 weeks to 8 weeks after ACI.

- Range of Motion

Recovery on your range of motion is gradually increased with a continuous passive motion (CPM) machine and may be completed to 140 degrees of range of motion at 8 weeks after AC

- Indoor exercise

Muscle strengthening of the surrounding knee joint can be done with four point exercise, isometric exercise, hamstring exercise and squatting exercise. At 12 weeks after ACI, you may start performing stationary bike activity without resistance and increase the resistance gradually.

- Outdoor exercise

At 13 weeks after ACI you can start walking lightly and at 6 months after ACI you can perform jogging. Later you may enjoy higher intensity exercise and sports activity 9 months after ACI.

You will be advised to not to use any non-drug therapies like massage, acupuncture, acupressure, or any other method of joint manipulation for the affected joint during the course of the study.

Please Note - *This rehabilitation information is recommendation only, it may be differentiated with one's condition and should consult with doctor.

12. What is my Activity Level after the therapy? When can I start playing sports again?

You and your doctor will decide when you are ready to return to sports. Depending on the size and location of your cartilage injury and your rehabilitation, you may resume low impact activity such as swimming, cycling, and skating as early as 6 months following treatment.

You may perform high impact sports such as jogging, running, and aerobics at 8 to 9 months for smaller injuries or 9 to 12 months for larger injuries.

High impact, pivoting sports such as basketball, football, baseball, or tennis may compromise the durability of the repair and should generally not occur until 12 to 18 months post-treatment after discussing with your physician.

13. How is activity measured after cartilage repair?

Many outcome scores have been developed and validated for evaluating function after articular cartilage repair. Of the various available outcome measures, the ICRS score, the International Knee Documentation Committee (IKDC) score, and the Knee Injury and Osteoarthritis Outcome Score (KOOS) score are considered the very important ones in cartilage repair patients.

All these validated scores and MRI of the joint/ defect site can be helpful to compare and evaluate patients after cartilage repair procedures.

To know more, you can discuss this with your concerned doctor.

14. Are there any complications of this therapy?

There have been more than 30,000 surgeries of Autologous chondrocyte implantation procedures that have been performed since the last 25 years worldwide. In India, almost more than 350 patients have been treated with a success rate of more than 95%. Hence, as such no major complications have been recorded proving utmost efficacy and safety of the procedure.

There is no fear of implant rejection as chondrocytes are harvested from patients' own body. However, rarely surgical procedure-linked complications may surface unless it is done by experts.

15. How is this therapy superior and more efficient than other procedures currently being offered for cartilage problems?

- Mosaicplasty:- ACI offer more durable clinical results as observed at minimum 4 year follow up the functional outcome of those patients with a surviving graft was significantly better in patients who underwent ACI compared with mosaicplasty.
- Microfracture:- In the research studies and clinical trials, the groups treated with ACI presented a better improvement of the IKDC scores of activity / mobility level at 2 year follow-up compared to Microfracture patients
- Economic modelling using some assumptions about long-term outcomes that seem reasonable suggests that ACI would be cost-effective because it produces hyaline cartilage, which is more likely to be durable and to prevent osteoarthritis in the longer term (e.g. 20 years).

Inferior medical procedure such as microfracture and mosaicplasty only temporarily relieves pain by producing fibrous cartilage, which further leads to onset of osteoarthritis and joint replacement in the patient.

16. What data has been under observation that leads you to conclude that ACI it is successful and safe procedure ?

We have done clinical trials with a total 14 patients with articular cartilage defects which were successfully implanted with Autologous Adult Live Cultured Chondrocytes (CHONDRON®) and monitored for the safety and efficacy of the implant. Patients were followed for up to 6 months post implant of CHONDRON® and were found to be free of any adverse effects as well they regained back their mobility and activity level as before the surgery following with the rehabilitation programme. We have done 500 successful cases in the past with this treatment.

17. When Can I Return to Work?

The time when you are ready to return to work depends on the individual as well as your type of job. As a general guideline:

Sedentary jobs from 1 week can be allowed. We do not recommend long periods in a car for the first 1 weeks following surgery.

Non-sedentary jobs should not be considered for 6 weeks. Your health and the condition of your leg will be reviewed at a 6-week post-operative clinic, when a decision can be made. It is likely that any return to work would be between 4 TO 6 weeks at the earliest.

18. How well does this therapy work?

Autologous chondrocytes implantation is utmost effective in treating cartilage defects in the knee. The regenerated cartilage and careful rehabilitation assures 90% restoration of the original strength.

19. What are the advantages of ACI therapy?

- It produce hyaline-like cartilage.
- It fills defects regardless of size with functional repair tissue.
- Moderate to large defects that have failed previous intervention.
- Repair tissue which matures, rather than deteriorates over time.
- Expected outcome.
- It's a natural biological process unlike metal or foreign material going inside the body .

20. Will my insurance pay for ACI therapy?

Yes , this procedure is covered under insurance. For Further enquiries, please consult your doctor and relevant authority for complete information and procedures.

21. Can any orthopedic treat me with ACI therapy?

Only experienced orthopedics with extensive training in diagnosing and assessing cartilage injuries of the knee that have clinical expertise with Chondron may perform the treatment.