DONT IGNORE PAIN, REGROW!

A New Regenerative Biological Cell Based Treatment for Knee and Hip Problems

A PATIENT GUIDE FOR REGROW BIOLOGICAL CELL BASED TREATMENT
Regenerative Medicine and Cell-based Biological Products

Our body is made up of cells and tissues and organs and systems. Cells are the basic unit; and are regenerated from the Mother Cells in our body as and when required. This helps the body to manage the continuous wear and tear; and also, is an integral part of body’s repair system.

Normally, a disease arises because of a lack of enzyme or a particular chemical in the body, e.g. insulin deficiency. Conventional medicine aims at replacing such a chemical or repairs the mechanism within the body that makes this chemical. Likewise, if the cellular structure and function in certain organs or tissues is hampered and becomes defective, one should replace these defective cells. Number of various modalities are being tried for this purpose; and are included under a broader term, Regenerative Medicine. It is a new branch of medicine that deals with regenerating and/or replacing cells, tissues and/or organs so as to restore the structure and thus function, achieving repair thereby. The effort world-over is to address the unmet medical needs thus far. The overall approach is to offer curative, permanent solutions to a disease condition rather than disease management.

In certain diseased conditions, the cellular pathology has been identified, meaning destruction or degeneration of a specific type of cells is responsible for that disease. This makes it relatively easy for cell biologists to develop a cell therapy product that can help repair and complete cure from the disease.

Regrow Biosciences Pvt Ltd (RBPL) is a biotechnology research organization working on such translational research. OSSGROW™ and CARTIGROW™ is the first Biological Cell Based Treatment, approved by Regulatory Authorities of India and the Ministry of Health and launched in the Indian market by RBPL.

OSSGROW™ caters to the patients suffering from Avascular Necrosis and CARTIGROW™ is meant specifically for cartilage defects. These products are natural, safe and offer a permanent curative treatment. OSSGROW™ and CARTIGROW™ will hopefully completely replace the currently available medical approach and artificial devices/implants that are not curative and just manage the disease condition

This Patient Guide-book explains about these two diseased conditions, conventional treatments; and how OSSGROW™ and CARTIGROW™ work and how these products are natural, safe and a permanent cure.

Disclaimer:

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A Patient Guide to Biological Cell Based Treatment for Avascular Necrosis of the Hip
Bones are living tissue, and like all other living tissues, they rely on blood vessels to bring blood to keep them alive. Most living tissues have blood vessels that come from many directions into the tissue. If one blood vessel is damaged it may not cause problems, since there may be a backup blood supply coming in from a different direction.

But certain joints of the body have only a few blood vessels that bring in blood. In such joints, if the blood supply through the vessel is hampered or diminished, may lead to dysfunction of that tissue.

One of these joints is the hip. Interrupted blood supply in the hip joint results in Avascular Necrosis (AVN), Avascular means absence of blood vessels, thereby diminished blood supply and hence Necrosis, meaning death of cells and tissue. It is also known as Osteonecrosis. It includes AVN and death of bone cells and tissue due to reasons other than hampered blood supply.

This Handbook will help you understand:

- How AVN develops
- Diagnosis of AVN
- Treatments available for AVN
- Biological Cell Based Treatment for Bone OSSGROW™
- Rehabilitation Program
- What are the benefits of OSSGROW™
- Do’s and Don’ts
- FAQ’s
Hip Joint Anatomy

The hip joint is one of the true ball-and-socket joints of the body. The hip socket is called the acetabulum and forms a deep cup that surrounds the ball of the upper thigh bone. The thigh bone itself is called the femur, and the ball on the end is the femoral head. The surface of the femoral head (ball) and the inside of the acetabulum (socket) are covered with articular cartilage, like many other crucial joints of your body. Articular cartilage is a tough, slick material that allows the surfaces to slide against one another without damage.

The long bone i.e. the femur extends into thin, slender neck (femoral neck) that holds the ball and helps fit it in the socket. The blood vessels to the ball pass through this neck. If this blood supply is damaged, there is no backup. Damage to the blood supply can cause death of the bone that makes up the ball portion of the femur. Once this occurs, the bone is no longer able to maintain itself.

Living bone is always changing. To maintain a bone’s structure and strength, bone cells are constantly being supplied through continuous blood supply. These bone cells also help in repairing the wear and tear that affects the bone tissue. If the blood supply is hampered, the bone can begin to weaken, just like rust can affect the metal structure of a bridge. Eventually, just like a rusty bridge, the bone structure begins to collapse.

01 HOW AVN DEVELOPS?

When AVN occurs in the hip joint, the top of the femoral head (the ball portion) collapses and begins to flatten. This occurs because this is where most of the weight is concentrated. The flattening creates a situation where the ball no longer fits perfectly inside the socket. Like two pieces of a mismatched piece of machinery, the joint begins to wear itself out. This leads to osteoarthritis of the hip joint, and pain.
Severity of AVN

The severity of AVN depends upon the total volume, depth of the lesion; and the side or location on the surface of the femoral head. Obviously, more the volume occupied by the lesion, it will be more severe. If the lesion is on the lateral side, there are more chances of it to collapse and actually fall out.

CAUSES

Why do I have this problem?

If you are a male, and in the young age group (30 to 40 years), you are more prone to suffer from AVN. Data suggests that AVN is 5 times more common in males than females.

There are many causes of AVN. Anything that damages the blood supply to the hip can cause AVN. Trauma, use of steroids and alcohol abuse are three main reasons for AVN.

Trauma:

Injury to the hip itself can damage the blood vessels. Fractures of the femoral neck (the area connecting the ball of the long hip bone) can damage the blood vessels. A dislocation of the hip out of the socket can rupture the blood vessels. Such traumatic injuries are responsible for 15% of AVN cases. It usually takes several months or even up to 2 years.

Steroids:

Some medications are known to cause AVN. Steroid like cortisone is the most common drug known to lead to AVN, with reported 35% of all cases. This is usually only a problem in patients who must take cortisone every day as treatment for asthma or to prevent rejection of any organ transplant. Sometimes there is no choice, and cortisone must be prescribed to treat a condition, knowing full well
that AVN could occur. AVN has not been proven to be caused by short courses of treatment with cortisone, such as one or two injections into joints to treat any infection.

**Alcohol:**

A clear link exists between AVN and alcoholism. Chronic alcohol abuse is found to be the sole reason for AVN in about 20% of diagnosed patients. Alcohol in excess directly destroys bone cells and damages the blood vessels; though the exact mechanism is still unclear.

**Idiopathic:**

In almost 15% of patients AVN occurs without any specific reasons.

**Others:**

Certain blood disorders, like sickle cell anemia, are marked by presence of AVN during disease. In some patients undergoing chemotherapy and/or radiotherapy for treatment of cancer also are found to suffer from AVN in later life.

Deep sea divers and miners who work under great atmospheric pressures also are at risk for damage to the blood vessels. The pressure causes tiny bubbles to form in the blood stream which can block the blood vessels to the hip, damaging the blood supply.

**SYMPTOMS**

What does AVN feel like?

The first symptom of AVN is pain when you put weight on your hip. The pain can be felt in the groin area, the buttock area, and down the front of the thigh. As the problem progresses, the symptoms include development of a limp when walking and stiffness in the hip joint. Limping while walking is a classic symptom of AVN. Eventually, the pain will also be present at rest and may even interfere with sleep.
How do doctors identify the condition?

The diagnosis of AVN begins with a history and physical examination. Your doctor will want to know about your occupation, what other medical problems you have, and your medication use. You’ll be asked whether you drink alcohol. A physical examination will be done to determine how much stiffness you have in the hip and whether you have a limp. Usually, a standard set of questions is used to score your pain severity and hip movement limitation.

Once this is done, X-rays will most likely be ordered.

X-rays will usually show AVN if it has been present for long enough. In the very early stages, it may not show up on X-rays even though you are having pain. In the advanced stages, the hip joint will be very arthritic, and it may be hard to tell whether the main problem is AVN or advanced osteoarthritis of the hip.

If the X-rays fail to show AVN, you may have a CT scan done to determine if the pain in your hip is coming from early AVN. For a CT scan a large camera is used to take a picture of the bone around the hip joint. If there is no blood supply to the femoral head, the picture will show a blank spot where the femoral head should be outlined on the film.

The CT scan has pretty much been replaced with magnetic resonance imaging (MRI) today. The MRI scan is probably the most common test used to look for AVN of the hip. The MRI scanner uses magnetic waves instead of radiation. Multiple pictures of the hip bones are taken by the MRI scanner. The images look like slices of the bones. The MRI scan is very sensitive and can show even small areas of damage to the blood supply of the hip, even just hours after the damage has occurred. Doctors more rely on a CT scan and X-ray for AVN diagnosis as well as follow up than MRI.
What can be done for the condition?
Once AVN has occurred, the treatment choices are determined by how far along the problem is and your symptoms. While the symptoms may be reduced with pain medications and anti-inflammatory medications, no medical treatments will restore the blood supply to the femoral head and reverse the AVN.

NONSURGICAL TREATMENT
If AVN is caught early, keeping weight off the sore-side foot when standing and walking may be helpful. Patients are shown how to use a walker or crutches to protect the hip. The idea is to permit healing and to prevent further damage to the hip. Patients may be shown stretches to avoid a loss of range of motion in the hip. Anti-inflammatory medicine is often used to ease pain. In some cases, surgeons also prescribe an electrical stimulator to get the bone to heal. Sometimes these measures may help delay the need for surgery, but they rarely reverse the problem. You may also be asked to take bisphosphonate medication (e.g. Alendronate); however, these may lead to some serious side effects like digestive system disturbances, ulcer formation, necrosis of the jaw bones and even transient kidney failure. This treatment may relieve you off the pain, but does not treat the root cause i.e. interruption of blood supply and death of bone tissue.

WHERE IS THE GAP?
If you are diagnosed with AVN at stage II or even III, then it is too early for a total hip replacement. Your surgeon will ask you to take medication to manage your pain; or perform core decompression. Since any of these treatment modalities do not reverse the disease, you are bound to require hip replacement in the future. Artificial hips do not restore all types of joint movements. You can only walk, sit on a chair or sofa and climb stairs. You may be refrained from routine activities like running, jogging, routine exercises like suryanamaskara, sitting down of floor with crossed legs. This artificial hip also has a life span, and needs to be changed after about 10-12 years.
OSSGROW™ by Regrow Biosciences Pvt Ltd is the GOLD STANDARD biological cell based treatment that has shown promising results in more than 250 patients with more than 98% success rate. It is done in two simple steps.

Stage I: Biopsy

Since OSSGROW™ is personalized and autologous, you will be asked to admit in the hospital. A small quantity (4 ml) of your bone marrow (thick blood tissue within the flat or round ends of bones) will be taken out with a long needle. A special Biopsy Kit will be used to collect and transport this bone marrow biopsy to our GMP certified processing and manufacturing facility.

REGROW™ Culture/Preparation of personalized cell dose

The bone marrow biopsy will be processed by highly skilled technicians in our facility. A personalized cell dose tested for purity and quality will be manufactured. It takes about 4 weeks for this to get ready.

Stage II: Implantation of OSSGROW™

Once the cell dose is ready, you will be again asked to get admitted in the hospital. The entire process takes not more than 30 minutes, and is done under anesthesia.
Core Decompression:

The simplest procedure is to drill one or several holes through the femoral neck and into the femoral head, trying to reach the area that lacks blood supply. The drill bores out a plug of bone within the femoral head. This operation is thought to do two things: (1) it creates a channel for new blood vessels to quickly form into the area that lacks blood supply, and (2) it relieves some of the pressure inside the bone of the femoral head. Relieving this pressure seems to help decrease the pain patients experience from AVN.

This operation is done through a very small incision in the side of the thigh. The surgeon watches on a C-Arm as a drill is used. A C-Arm is a type of X-ray that shows the bones on a TV screen. The surgeon uses the C-Arm to guide the drill where it needs to go. This operation is usually done as an outpatient procedure, and you will be able to go home with crutches the same day.

Curettage:

Core decompression is followed by removal of the dead bone tissue in the ball space. This helps minimizing the toxic effects of the dead tissue and also allows empty space for the new bone making cells to stay and regenerate new bone. This is done using scoop like small instruments, as a guided procedure to ensure accuracy.

Implant:

After the decompression and curettage is done, OSSGROW™ is injected using the proprietary delivery system. OSSGROW™ settles within 8-10 minutes in form of a gel and occupies the space within the ball of hip.
What happens after the implant?

The aim of this treatment is to help body for forming completely new healthy bone tissue and stop the disease process. To achieve this-

1. You will be on bed rest for 2 to 3 days and will be discharged as appropriate.
2. You must follow all the precautions that your surgeon will tell you.
3. A physiotherapist will train you through a personalized protocol for your rehabilitation. This rehabilitation program helps you to regain the bone and joint strength and restore all your movements. Since the body takes considerably long time for regeneration of new bone the rehabilitation program is a well-planned, structured exercise program, spread over upto 6 weeks. You must follow the rehabilitation schedule to improve your capacity and capability of weight bearing, range of motion, and activities. You will be asked to continue with certain exercises on regular basis even after you have completed the rehab-program.
REHABILITATION PROGRAM

0-1 week

1-3 weeks

3-6 weeks

6-12 weeks

12 weeks onwards
WHAT ARE THE BENEFITS OF OSSGROW™?

- Completely natural way of regenerating true bone tissues. The disease process stops and reverses. Patient no more suffers from pain, limping.
- Manufactured and customized for each patient. No possibility of any side effects or rejection. Completely safe.
- Hip joint is preserved, so repeat procedures not required. One time treatment. No need of repeat surgery in future.
- Backed by Clinical Trials. Approved by Ministry of Health & Family welfare of India. Proven and experienced by surgeons.
When you take such proper care, OSSGROW™ helps your body regenerate your new bone tissue and mechanically strong bone. Proper rehabilitation and exercises will help you regain all normal movements and activities including sitting down, using the stairs, walking without limp and support. The whole process of new bone formation takes weeks and months; hence the rehabilitation program is so personalized and elaborate.

OSSGROW™ can also be used for regeneration of bone loss in specific dental conditions, nonunion fractures (fractures that do not heal for a long time), bone cyst. Complex cases like fibrous dysplasia and limb lengthening can also be treated using OSSGROW™.

You may please contact our local representative or call us on 1800-209-0309 | visit www.regrow.in for any further information on OSSGROW™.

<table>
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<tr>
<th>Do’s</th>
<th>Don’ts</th>
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<td>1. Take your hip pain (pain starting from groin, passing through your thigh to the knee) seriously.</td>
<td>1. Don’t take too long to treat you AVN. It may unfortunately worsen.</td>
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<td>2. Get treated with OSSGROW™ while your disease is still reversible.</td>
<td>2. Don’t do any high-impact activities like running.</td>
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<td>3. Follow the rehabilitation program very seriously.</td>
<td>3. Don’t smoke or consume alcohol.</td>
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<td>4. Avoid wrong postures and weight-bearing.</td>
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<td>5. Maintain healthy lifestyle.</td>
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<td>6. If you are on steroids, consult your doctor and ask for an alternative.</td>
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Do’s AND DON’TS

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You may please contact our local representative or call us on 1800-209-0309 | visit www.regrow.in for any further information on OSSGROW™.
1. **Who would be a suitable candidate for bone implantation treatment?**
   Candidate having hip joint pains due to Avascular Necrosis leading to pain weakness immobility, non-union fractures due to accident. Within the age group of 18 - 65 years.

2. **Who is not a candidate for autologous bone implantation?**
   Generally people who have previously undergone hip joint replacement.

3. **What are the common areas affected by AVN?**
   AVN is most common in the hip and the shoulder, but can affect other large joints as well, such as knee, elbow, wrist and ankle.

4. **Are there any complications of autologous bone implantation?**
   No. As it is Autologous Implantation, it is very safe since cells are harvested from patients’ own body.

5. **What is the success rate of ABI - OSSGROW™?**
   A 98% success rate has been observed in hundreds of cases performed in India and worldwide.

6. **Will my insurance cover the ABI Procedure?**
   Yes, this procedure is covered under insurance. For further enquiries, please consult your doctor and relevant authority for complete information and procedures.

7. **Is OSSGROW™ a safe and successful procedure?**
   Autologous Bone Implantation, OSSGROW™ is safe and it is India’s First FDA approved Biological Cell Based Treatment for Bone regeneration.

*Consult your Doctor for treatment and medical advice*
CARTIGROW™
BIOLOGICAL TREATMENT FOR CARTILAGE REGENERATION

A Patient Guide to Biological Cell Based Treatment for Cartilage Defects
INTRODUCTION

Most of the orthopedic conditions that lead to pain and restricted mobility involve bone injury, like fractures. Such conditions need immediate attention. In the same manner, cartilage defects in the joints also lead to severe pain and restriction in mobility. Cartilage defects need patient-specific treatment and a long duration of complete recovery amounting to resuming all routine activities. Ignoring cartilage defect may lead to severe arthritic condition regardless of the age.

This Handbook will help you understand:

- Cartilage Defects
- Diagnosis of Cartilage Defect
- Treatments available for Cartilage Defect
- Biological Cell Based Treatment for Cartilage - CARTIGROW™
- Rehabilitation Program
- Benefits of CARTIGROW™
- Do's and Don’ts
- FAQ’s

It is important to understand the basics of bones, joints, cartilage in relation to cartilage defects and treatments.

Bones, Joints and Cartilage:

The basic frame work of human body is made up of bones. An adult has 206 bones and 360 different joints. Cartilage is a specialized tissue that lies in between two bones that face each other to make a joint. Cartilage works as cushion, allowing easy, smooth movements of bones; without any friction. It is made up of cells called chondrocytes, collagen fibers present in a ground substance. There are three types of cartilage, based on the proportion of these
three components, namely Hyaline, Elastic and Fibrous. The structure, composition and properties and functions of these three types of cartilage varies accordingly.

Let us see the structure of joints where cartilage plays a major role.

> Knee joint:
  Your knee joint is made up of-
  > Femur: the long bone of the thigh
  > Tibia and Fibula: the long bones of the calf or the sheen bone
  > Patella: a cap-like structure covering the femoral end

The femoral end has rounded portion called femoral condyle; while the upper end of tibia has meniscus. The round end of femoral condyle perfectly fits on to the saucer-shaped meniscus of tibia. This is protected by cartilage. The ligaments and tendons make the support system of the joint and make the joint more stable.

Shoulder Joint: this ball-and-socket joint is made up of long bone of your hand, the humerus, that fits in the shoule plate.

The elbow joint is similar to the knee joint in its movement while the ankle joint made up of the lower ends of tibia, fibula and the talus bone, mainly. Ankle joint has gliding movement.

The hyaline cartilage is of vary special composition, with chondrocytes wrapped in small bags (lacunae) and type I collagen. This makes the cartilage very tough, yet smooth. It helps the knee, hip and ankle joints to hold the body in standing posture, gives strength to the bones to bear the weight of body; and works as a shock absorber too. The thickness of
Hyaline cartilage differs with joint and the location. Direct weight bearing locations have thicker cartilage, offering more shock absorbing strength.

Hyaline cartilage is not supplied with blood (avascular) and nerves (aneural). Hence, any damage to cartilage may go unnoticed (unless adjoining bone or ligament is also injured); and there is no natural process to repair it.

Hence, it is very important to understand various types of cartilage defects and their management.

01 CARTILAGE DEFECTS

Cartilage is a very tough tissue and is a great shock absorber. Activities like running, jumping, climbing and other sports-specific actions happen with ease because of the hyaline cartilage present in various joints involved in these actions and movements. Many of these actions are high-impact actions, and can lead to traumatic or accidental cartilage injuries. Most of the times, such cartilage damage is associated with ligament and/or tendon and/or bone injury. Such traumatic injuries lead to a tear in cartilage. Sometimes, the injury can be deep so as to expose the underlying bone.

The cartilage defects are classified based on the degree of softness of cartilage tissue, fissures (gaps) that develop and the width and depth of these gaps and whether the subchondral bone is exposed or not. Thus, cartilage defect is categorized from Grade I to Grade IV, as in the figure.

Damaged cartilage most often leads to acute pain and it essentially restricts the movement. Activities like sitting on and getting up from chair, walking can be painful. You may hear a clicking sound, or kind of locked joints. If such injury is in shoulder, then raising your hand or rotation of hand (as required while swimming or sports like tennis and badminton) will be painful and hampered. All this amounts to considerable effect on your daily routine, may be requiring absence at work. Not attending to these and such injuries in case of a sportsman or a professional dancer may also drastically affect their career. In today’s world, young working professionals are required to travel and be mobile; and cannot afford to risk their career.
Sometimes, the blood supply to the bone which supports the cartilage may be hampered. There are no known reasons for such restricted blood supply. In such a situation, the cartilage holding capacity of the bone is lost; and a portion of cartilage gives way. This results in what is called as Osteochondritis Dissecans or OCD, meaning, separation between the bone and the cartilage resulting in detachment. OCD is most commonly seen in the knee joint as it is the most used joint.

Since cartilage has no ability to repair, area of damage keeps increasing making it more deeper and larger. Slowly, the cartilage cannot hold itself and starts degenerating. It may eventually show up the bone; and when bone starts rubbing against another bone, the pain is very severe and unbearable. Thus, cartilage damage, when ignored, eventually leads to severe arthritis.

Patella forms equally important part of the knee joint and is covered with hyaline cartilage on its inner surface. Unstable patella can easily lead to dislocation, or even rub the edge of patella on the femoral bone, leading to cartilage defect. Patellar cartilage defect is called Chondromalacia Patellae.

To summarize, causes/ reasons for cartilage defect or damage are:

- Excessive use (in runners, cyclists and athletes)
- Accidents and trauma (bikers, dancers or unexpected)
- Sports injury (e.g., football, badminton)
- Obesity and sedentary lifestyle
- Ageing
- Pathology (as in OCD)
Typical complaints are:

- Joint pain
- Stiffness
- Joint locking
- Swelling
- Clicking

Severity and frequency of pain and other symptoms may relate to the extent of damage and defect caused. Overall, the restricted mobility affects your daily routine, leads to dependency on care-giver and keeps you away from work. So, any of such symptoms should be taken as a warning, and you should see your doctor.

Your doctor will ask you the few easy to answer questions and your answers will be coordinated with your profession and lifestyle. Based on this, your doctor will judge the severity and extent of your cartilage damage.

A Sample of questions are here:

**General:**

- What is the highest level of activity you can do without knee pain?
- At what interval you get knee pain? And, how severe it is?
- Do you feel stiffness in the joint? Or, do you feel your joint is getting locked?
- Can you sit on chair or floor with comfort?
If you are a housewife or if your shoulder is affected:

• How difficult you find doing daily activities like brushing, cooking, washing clothes?

If you are a sports-person:

• Is your exercise endurance affected? Eg running, jogging
• Which all movements are restricted?

Your doctor may ask you to do an X-ray and an MRI. X-ray will help to rule out possibility of bone defect or fracture; while MRI will detect the exact location and type of cartilage injury. Cartilage is soft type of tissue and MRI gives a minute details necessary for locating the damage area, and helps your doctor to design your treatment. A 1.5T MRI is the minimum requirement and 3T MRI gives very good quality images.

An arthroscopy also reveals a clear picture of the soft tissue like cartilage. It is camera-view fitted in an instrument and can be viewed on a TV monitor.

Doctor may ask to do a CT scan only if there is a bone damage along with cartilage damage.

At times, you may also be asked to do cartilage mapping that gives a coloured picture and indicates even thinning of cartilage as well as type of cartilage for accurate diagnosis.
In absence of body’s ability to regenerate hyaline cartilage, treatment for cartilage defect is aimed to fill the damaged area with cartilage like material. The similarity and closeness to native hyaline cartilage as well as complete integration with the native cartilage and bone will help restore the function of the joint fully. The methods employed so far revolve around stimulating the blood supply, or replacing the defect area with similar body part picked out from healthy party of the knee.

**Goal of Cartilage Repair**

• Restore smooth articular cartilage surface
• Relieve patient symptoms and improve function
• Match biomechanical/biochemical properties of normal hyaline cartilage
• Prevent or slow progression of focal chondral injury to end - stage arthritis

Biological Treatment is a branch of Regenerative Medicine that aims to regenerate hyaline-like cartilage, developed/cultured from your own cartilage making tissue. Though body is very slow in making new cartilage and cannot repair damaged cartilage; these cells can be multiplied (cultured) to obtain a large number (in millions) under controlled environment in a duly certified cell processing center/facility. This made cartilage Biological Treatment available for treatment for 22 years in various countries.

Autologous Chondrocyte Implantation is procedure that uses patients own cartilage tissue to prepare a dose of chondrocytes (cartilage-making cells) which once ready, is implanted in the defect area. Dr. Peterson and Dr. Brittsberg from Sweden are the pioneers and inventors of this novel treatment, and was made available in European market, followed by the USA and other countries. It is a GOLD STANDARD treatment, as mentioned in some Textbooks of Orthopedics.
CARTIGROW™ by Regrow Biosciences Pvt Ltd is the first ACI product available in India. As mentioned, when cartilage injury of any type and grade is diagnosed, your orthopedic surgeon will suggest you undergo CARTIGROW™ treatment. It is a simple two-step process.

**Step I: Biopsy**

In a minor arthroscopic procedure, a punch biopsy of healthy cartilage along with subchondral bone will be picked up and transported in specially designed kit to the cell processing center. Temperature maintenance during the transit is very important.

**REGROW™ Cell Culture/Preparation of personalized cell dose**

Cartilage making chondrocytes will be isolated and multiplied to obtain a dose of 48 million containing chondrocytes. A number of quality analysis tests are performed on this cell dose, personalized for you, and is now ready to be transported to your hospital. This takes about 4 weeks.

**CARTIGROW™ Procedure**
Step II: Implantation

You will be asked to get admitted on a planned day. In an open procedure that requires about 30 minutes, the defect area is prepared and the personalized dose of chondrocytes, made from your own tissue, will be implanted into the defect area. The cell-gel mixture takes the shape of the defect area and settles in a firm jelly within 8-10 minutes. The suturing is done, and the knee is bandaged.

What happens after the implant?

The implanted chondrocytes will adhere to the bone and get integrated with the adjacent cartilage tissue within the defect area. Slowly, over time, the new cartilage forms, that is almost like the native hyaline cartilage merges with the old cartilage tissue.

It is important that the strength and weight-bearing also is regained completely; for which, the personalized rehabilitation program is very important.

While you are in the hospital, a physiotherapist will explain you exercise and physiotherapy protocol, customized for you. Physiotherapy, exercises and rehabilitation is equally important phase post-implant for you to be up and active.

Following implantation there is a period of restricted weight-bearing for up to 4 weeks. During this time, physical therapy emphasizing range-of-motion of the knee and strengthening activities is prescribed. A surgeon may also recommend the use of continuous passive motion (CPM) machine to improve the graft’s success. Return to light sports activities is typically allowed at approximately 3-4 months with return to full sports activities between 6 and 9 months following the procedure based on the recovery and the level of sport you want to resume. A hardcore professional may require even longer time, e.g., a badminton player to resume his back-hand shot.
BENEFITS OF CARTIGROW™?

- Completely natural way of regenerating true cartilage tissues.
  - The disease process stops and does not progress to arthritis

- Manufactured and customized for each patient.
  - No possibility of any side effects or rejection. Completely safe.

- Hyaline like cartilage produced. Knee biomechanics restored.
  - One time treatment. No need of repeat surgery in future.

- Backed by Clinical Trials. Approved by Ministry of Health & Family welfare of India.
  - Proven and experienced by surgeons.
When you take such proper care, CARTIGROW™ helps your body regenerate your new cartilage tissue and mechanically knee joint cartilage. Proper rehabilitation and exercises will help you regain all normal movements and activities including sitting down, using the stairs, walking without locking and support. The whole process of new cartilage formation takes weeks and months; hence the rehabilitation program is so personalized and elaborate.

You can resume your high impact sports like badminton and football.

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Who is a not a candidate for autologous chondrocyte implantation (CARTIGROW™)?
Generally people who have previously undergone knee replacement.

Am I a candidate for cartilage replacement / cartilage repair even if I’ve undergone other treatments for knee pain?
If you are experiencing pain and swelling in your knee, and you are limiting your daily activities, you may be a candidate for this therapy. Within the age group of 18 - 65 years.

How long does it take to grow the cells?
In total, it takes about 3 to 4 weeks for the cells from your biopsy to increase.

How well does autologous chondrocytes implantation work?
Autologous chondrocytes implantation is utmost effective in treating cartilage defects in the knee. The regenerated cartilage and careful rehabilitation assures 98% restoration of the original strength.

Will my insurance pay for Autologous cartilage replacement/ cartilage repair treatment?
Yes, this procedure is covered under insurance. For Further enquiries, please consult your doctor and relevant

Is CARTIGROW™ a safe and successful procedure?
Autologous Chondrocyte Implantation, CARTIGROW™ is safe and it is India's First FDA approved Biological Cell Based Treatment for Cartilage regeneration.

*Consult your Doctor for treatment and medical advice
REGROW BIOSCIENCES PVT. LTD.

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Head Office: Mumbai
Cell Processing Centre: Lonavala, Maharashtra
Email: info@regrow.in | Website: regrow.in
Tel: 91-22-67330300 | Fax: 91-22-28390556
Toll-free No: 1800-209-0309

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