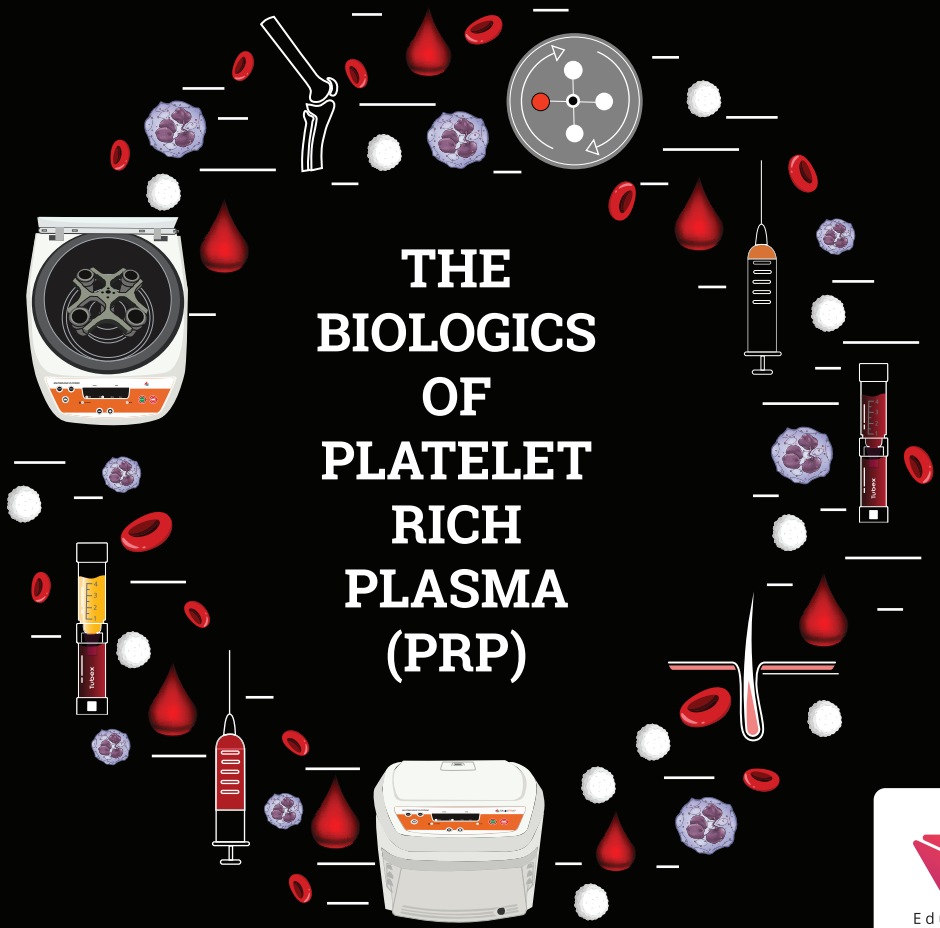

An Initiative by

TriCell ACADEMY

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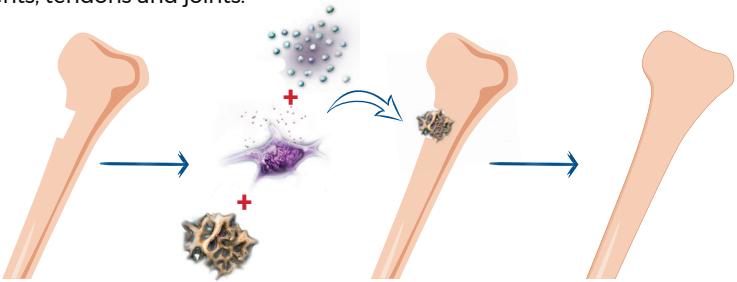
Index

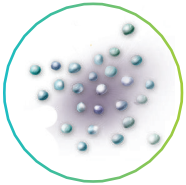
What is **Orthobiologics?**

Orthobiologics include autologous or allogeneic substances that are used to improve the healing of fractures, injured muscles, tendons and ligaments. These substances accelerate self-healing mechanism and rejuvenate any tissue injuries to the musculoskeletal system relating to bones, muscles, ligaments, tendons and joints.



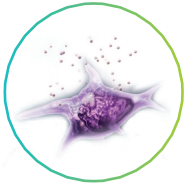
Preface on **Orthobiologics?**

Regenerative treatments using biological substances eliminate the need for long-term medication or surgery. These substances aid in **osteoconduction, osteogenesis, osteoinduction** and **vascularity** to stimulate bone growth and formation.



Blood derived substances

These include Autologous Conditioned Serum or Platelet-Rich Plasma that deliver growth factors to call stem cells to the injury site where they develop into "repair" cells and stimulate the healing process.



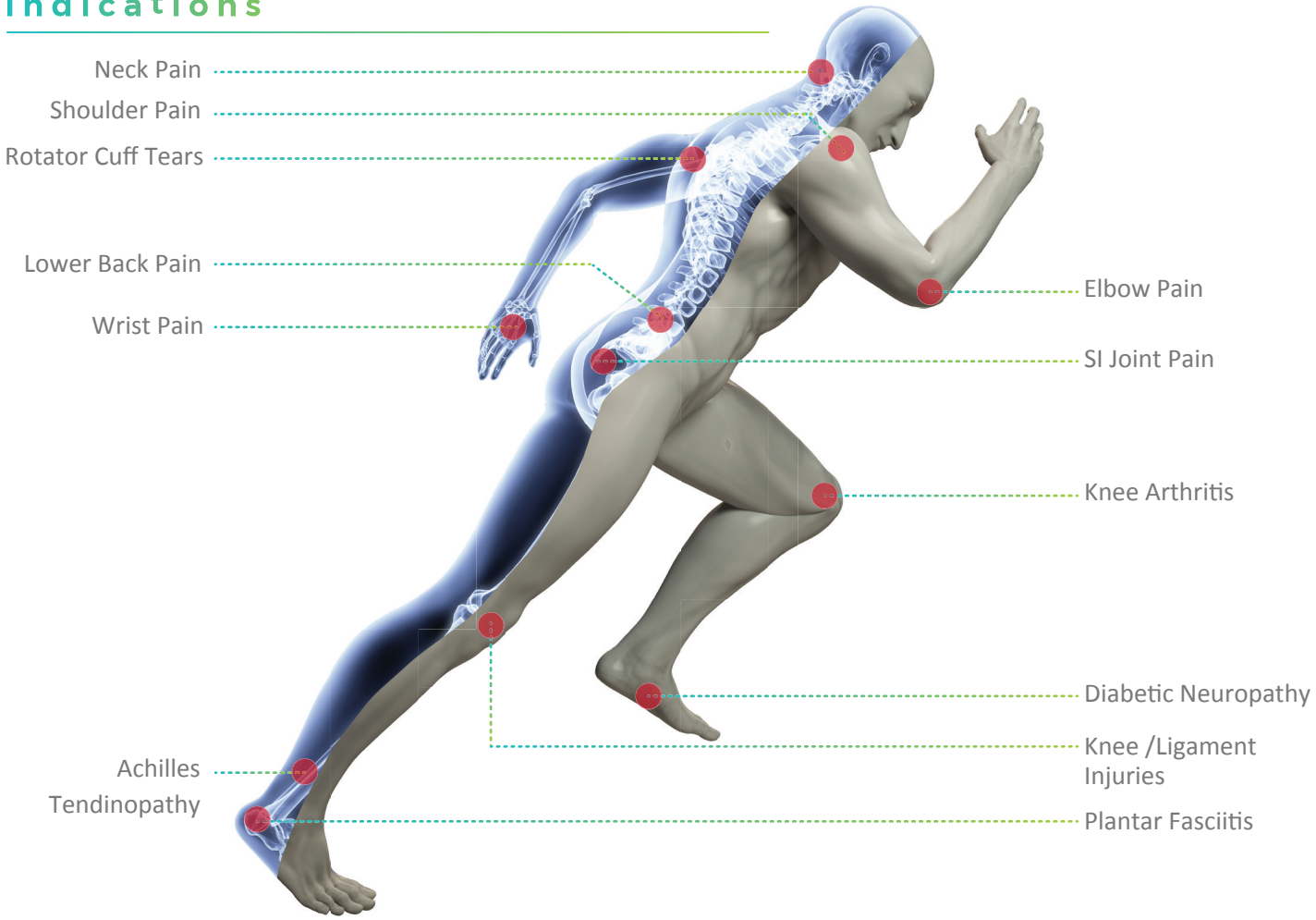
Stem cell containing products

Bone grafts act as a scaffold that fill voids in torn tissue to support bone growth and vasculature required stimulate new bone formation.

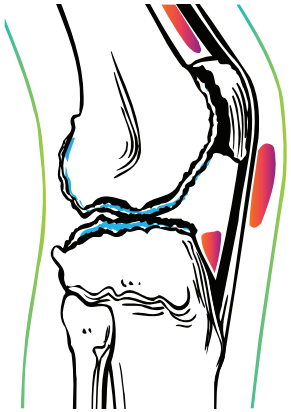
Extra cellular matrices

Stem cells have the regenerative potential to develop into muscle, tendon, bone or cartilage that replenishes the dead or dying cells in injured site.

Indications



Osteoarthritis(OA)



Osteoarthritis is the most common form of arthritis, affecting millions of people worldwide. It is characterized by joint stiffness, pain and occurs when the protective cartilage that cushions the ends of the bones wears down over time. It commonly affects the joints in hands, knees, hips and spine.

Types of Osteoarthritis

Risk factors for Osteoarthritis

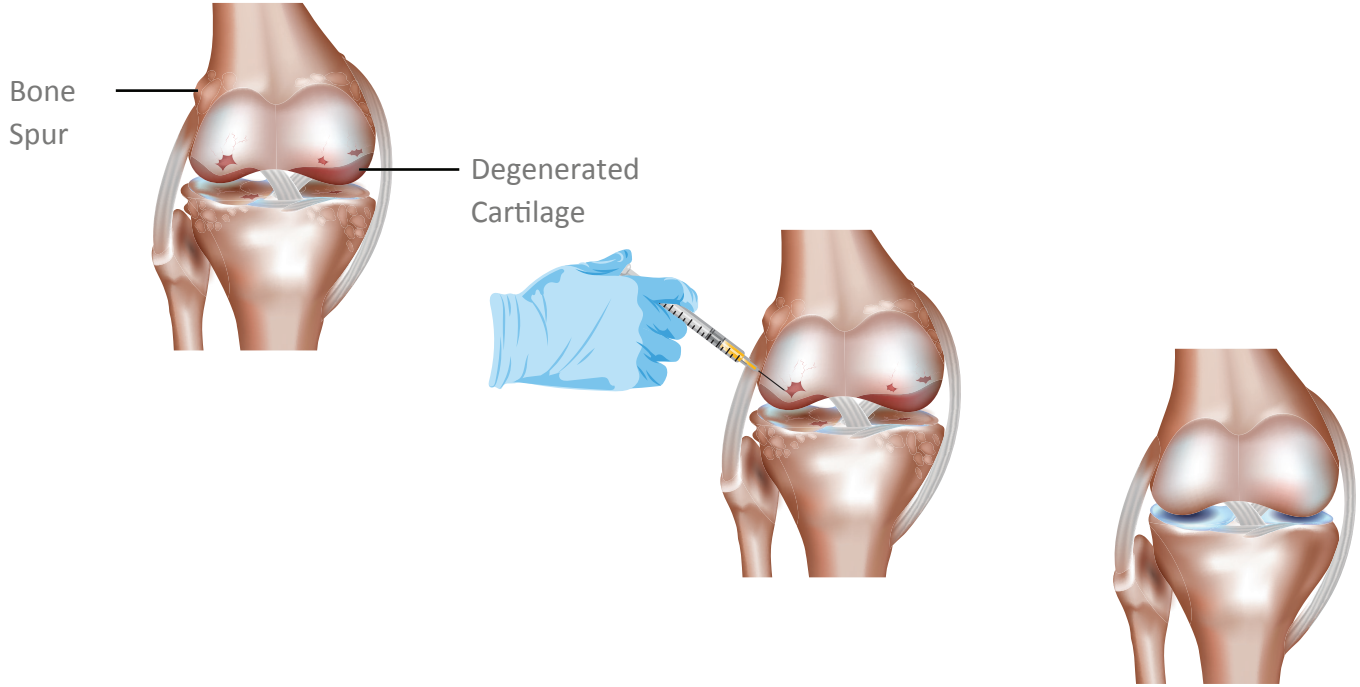
Conventional Treatment Practices

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Corticosteroids
- Lubrication hyaluronic acid injections
- Joint replacement surgery

How does Orthobiologics help?

PRP has been widely used in early osteoarthritis to improve cartilage structure and retard the progression of the disease. It is an effective treatment in managing pain associated with knee osteoarthritis.

Intra-articular PRP injections devoid of white blood cells for mild to moderate osteoarthritis (OA) has been reported to reduce pain and heal tissues without any excessive inflammation or swelling for the patient.



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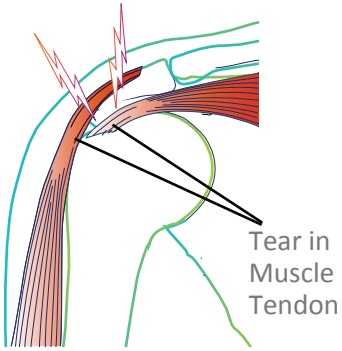
Rotator Cuff Injury



The rotator cuff is a group of muscles and tendons that surround the shoulder joint, keeping the head of the upper arm bone firmly within the shallow socket of the shoulder. It stabilizes the shoulder and aids in movement. A rotator cuff tear is a common injury that occurs due to gradual wear and tear of cuff over time or due to intense activity.

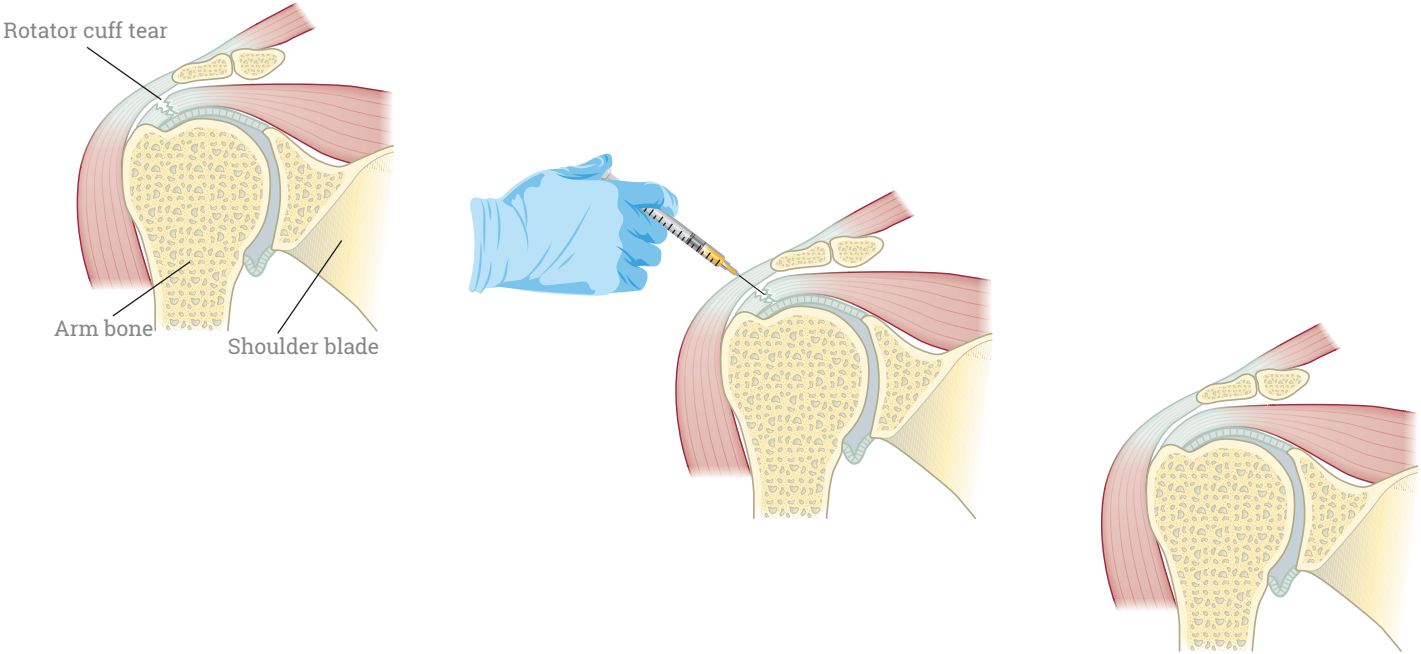
Risk factors for Rotator Cuff Injury

Conventional Treatment Practices

- Steroid Injections
- Physical Therapy
- Surgery
- Arthroscopic tendon repair
- Open tendon repair
- Tendon transfer
- Shoulder replacement

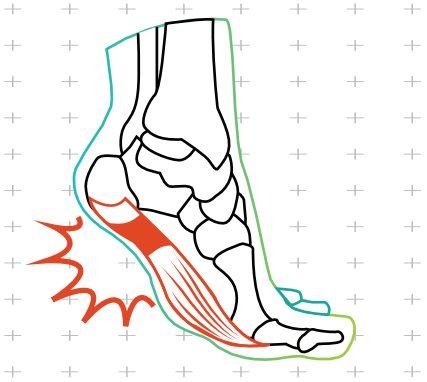
How does **Orthobiologics help?**

PRP injections are given to trigger patient's own healing system to accelerate the healing of injured tendons and ligaments. When PRP is injected into the damaged area, it stimulates the tendon or ligament to activate the healing cascade. In the treatment of rotator cuff tears, PRP has been found to significantly decrease should pain and inflammation. It has the potential to improve movement, stimulate healing and reduce heavy dependence on strong medications. Specifically, PRP has been studied as an alternative to surgery.



Andrew Schneider (2018). Platelet-rich plasma and the shoulder: clinical indications and outcomes. Current Reviews in Musculoskeletal Medicine, 593-597.

Plantar Fasciitis



Plantar fasciitis is characterized by the inflammation of a thick band of tissue that runs across the bottom of the foot connecting the heel bone to the toes (plantar fascia). It is associated with sharp heel pain while walking, swelling and tenderness of the bottom (sole) of the foot.

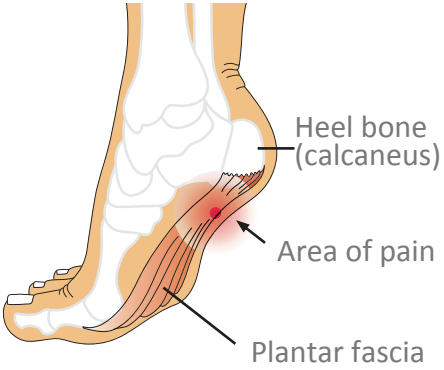
Risk factors for Plantar Fasciitis

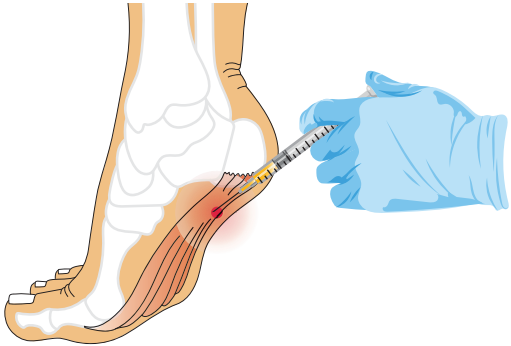
Conventional Treatment Practices

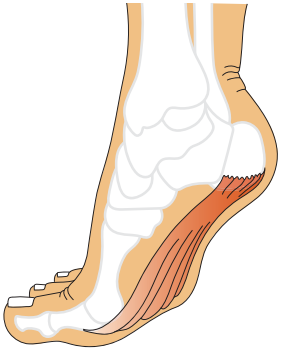
- Medications
- Physical therapy
- Night splints
- Orthotics
- Extracorporeal shock wave therapy
- Prolotherapy
- Steroid Injections
- Ultrasonic tissue repair
- Surgery

How does **Orthobiologics help?**

PRP injections have been used as a non-invasive method for plantar fasciitis to help soothe pain, improve function and promote healing of the foot. Normally, at the base of the plantar fascia, connecting the heel to foot front is devoid of sufficient blood supply resulting in deprivation of growth factors and cells needed for healing process. PRP injections alleviate this issue by enabling direct delivery of these GF and platelets to the lesion site thereby facilitating healing and repair of the ligament.







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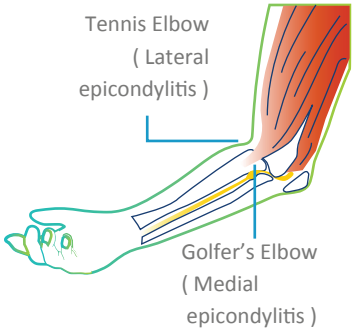
Elbow Pain

Tennis Elbow/Golfer's Elbow



Lateral epicondylitis, or "tennis elbow," is defined as an inflammation of the tendons that join the forearm muscles to the outside of the elbow.

Medial epicondylitis, or "golfer's elbow," is an inflammation of the tendons that attach your forearm muscles to the inside of the bone at your elbow.

Risk factors for Tennis Elbow

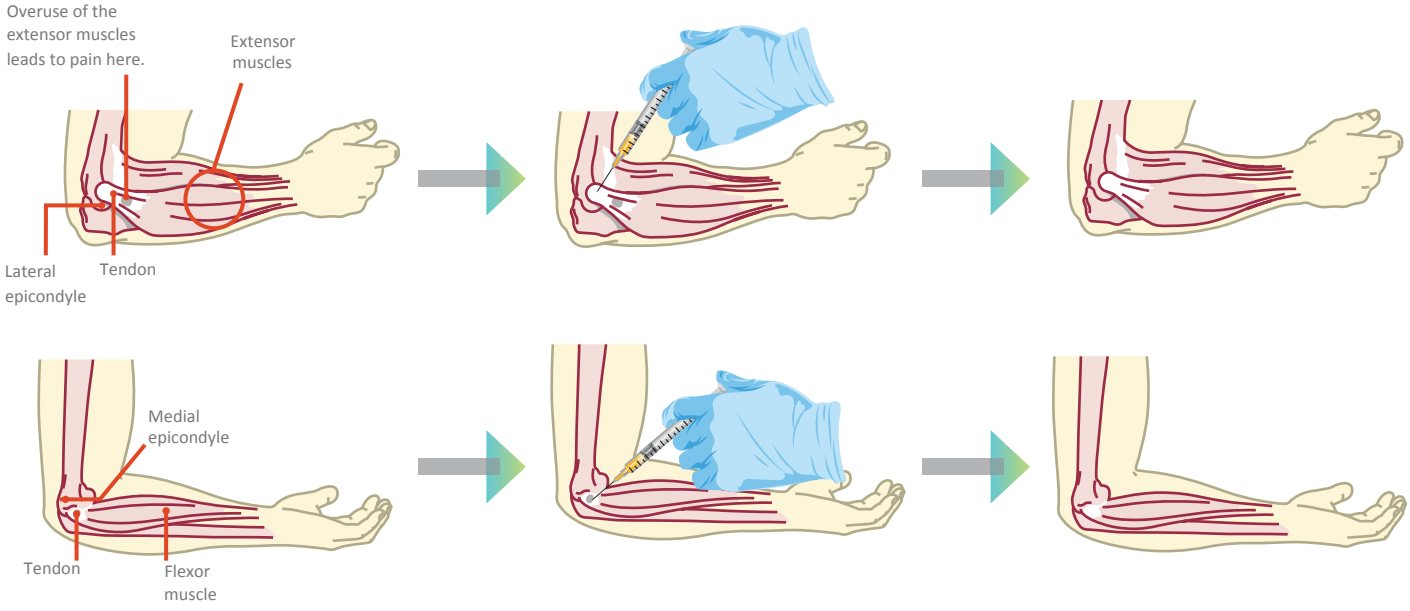
Golfer's Elbow

Conventional Treatment Practices

- Icing the elbow
- Elbow strap
- Nonsteroidal anti-inflammatory (NSAIDs)
- Physical therapy
- Steroid Injections
- Braces, Splints, Sports Gear, and Tools

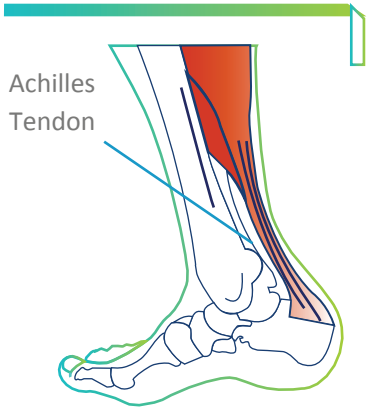
How does **Orthobiologics help?**

People who have tendinopathies such tennis elbow or golfer's elbow experience severe pain and swelling due to disorganized blood vessels and inflamed tendons. Because they get very little blood, injured tendons tend to heal rather slowly. PRP therapy has demonstrated to improve function and reduce pain in people who have such conditions. It stimulates the tendon to activate the healing cascade thereby new collagen begins to form in the injured tissue. It provides longer benefit and pain relief over physical therapy and cortisone injections eliminating the need for elbow surgery.



Andrew Schneider (2018). Platelet-rich plasma and the shoulder: clinical indications and outcomes. Current Reviews in Musculoskeletal Medicine, 593-597.

Achilles Tendon



The Achilles tendon is a strong fibrous tendon at the back of the ankle that connects the calf muscles to the heel bone. Achilles tendinopathy is a common overuse injury that affects the back of the lower leg. It mainly occurs in recreational sports persons due to repetitive energy storage and release with excessive compression. This can lead to a sudden injury, or rupture of the Achilles tendon. It is associated with sharp pain in the back of ankle and lower leg affecting the ability to walk or move.

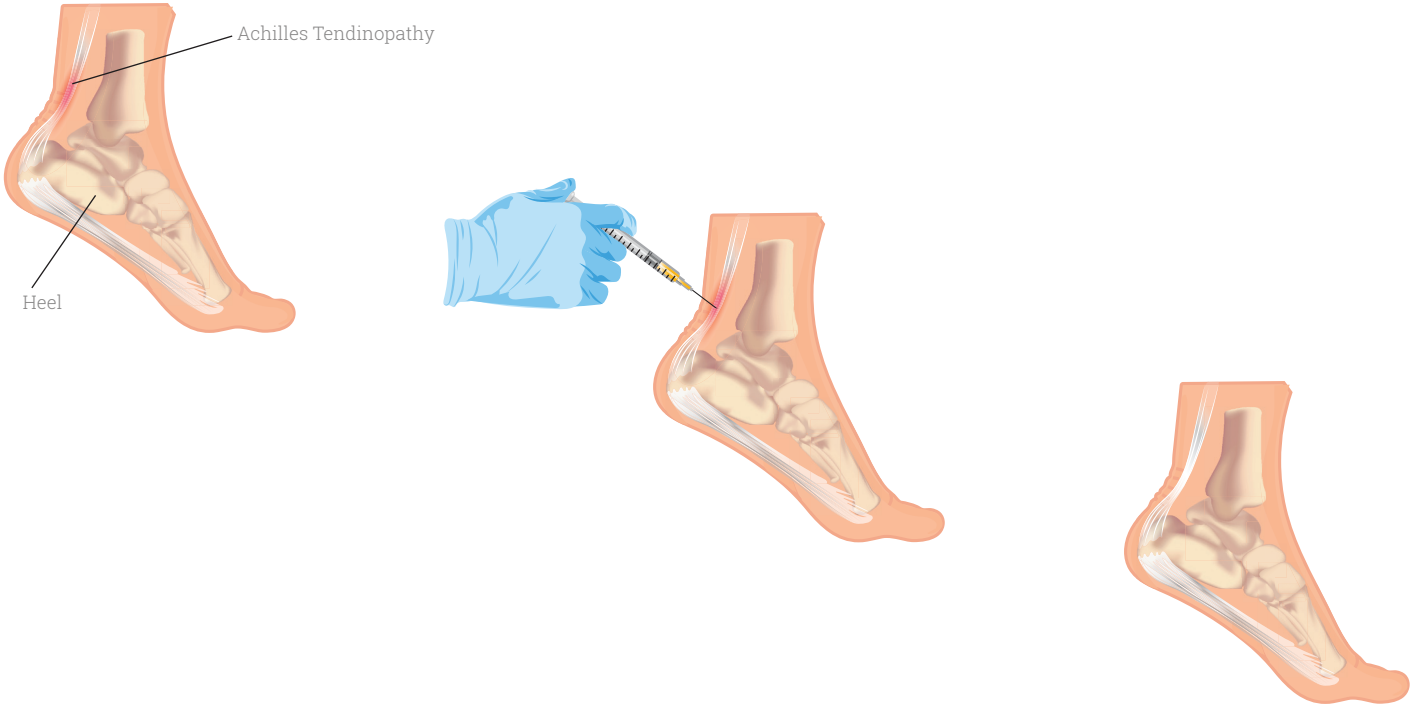
Risk factors for Achilles Tendon

Conventional Treatment Practices

- Medications - Ibuprofen (Advil, Motrin IB, others)
- Physical therapy
- Low-level laser therapy
- Dry needling
- Shoe inserts or wedges
- Surgery

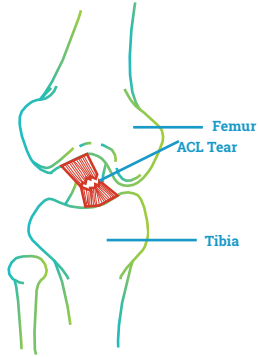
How does **Orthobiologics help?**

People who have Achilles Tendinopathy experience severe pain and stiffness due to disorganized blood vessels and inflamed tendons connecting heel bone and calf muscles. PRP contains platelets that store and release a wide range bioactive factors that promote healing of soft tissues such as tendons. Apart from platelets, PRP also has white blood cells and plasma, which release various bioactive factors and proteins that further assist in the healing process of Achilles tendon.



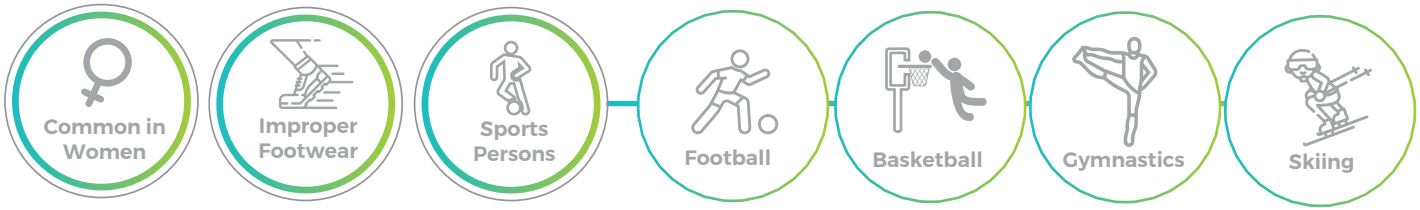
Wang, Y. Z.-C. (2016). PRP Treatment Efficacy for Tendinopathy:A Review of Basic Science Studies. BioMed Research International

Anterior Cruciate Ligament



ACL or anterior cruciate ligament is one of the four major ligaments presents in the knee. It connects the knee joint to the tibia (shin bone) and femur (thigh bone). The ligament supports tibia and prevents excessive stretching. It also provides rotational stability to the knee. An ACL injury is associated with the tear or sprain of the ACL ligament. It is a common condition in athletes involved in sports like football, rugby, hockey etc.

Risk factors for **ACL**

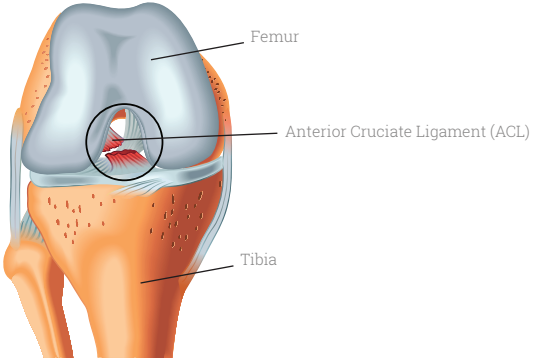


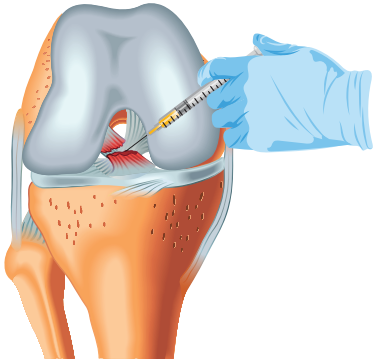
Conventional Treatment **Practices**

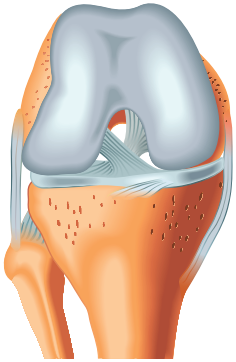
- Physical therapy and Rehabilitation
- Surgical treatment: tendon replacement using a substitute graft
- Patellar tendon autograft
- Hamstring tendon autograft
- Quadriceps tendon autograft

How does **Orthobiologics help?**

PRP contains a high concentration of growth factors and bioactive proteins that promote accelerated healing and tissue regeneration. When PRP is injected into the damaged area, it stimulates the tendon or ligament to activate the healing cascade thereby forming new cartilage at the injured tissue. As this collagen matures, it becomes stronger and tighter, eventually allowing the tendon or ligament to withstand stress of daily and sports related activities. It acts as a synergist factor in acquiring maturity faster in ACL grafts and partial tears.







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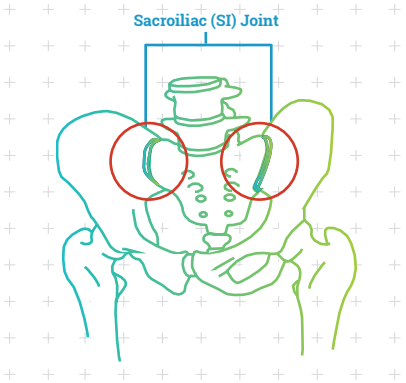
Sacroiliac Joints



Sacroiliac joints connect the bottom of the spine (*sacrum*) to the outer part hip bone (*ilium*). Sacroiliac joints help control the hip area when you move by transferring forces from your lower to upper body. Pain caused by sacroiliac joint disorder is usually felt in the lower back, buttocks, or legs.

Risk factors for Sacroiliac Joints


Traumatic Injury

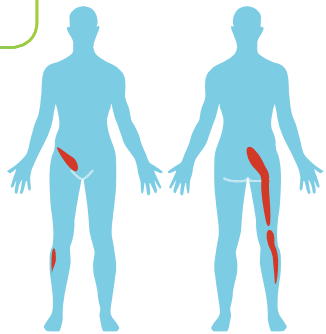

Arthritis


Pregnancy


Infection

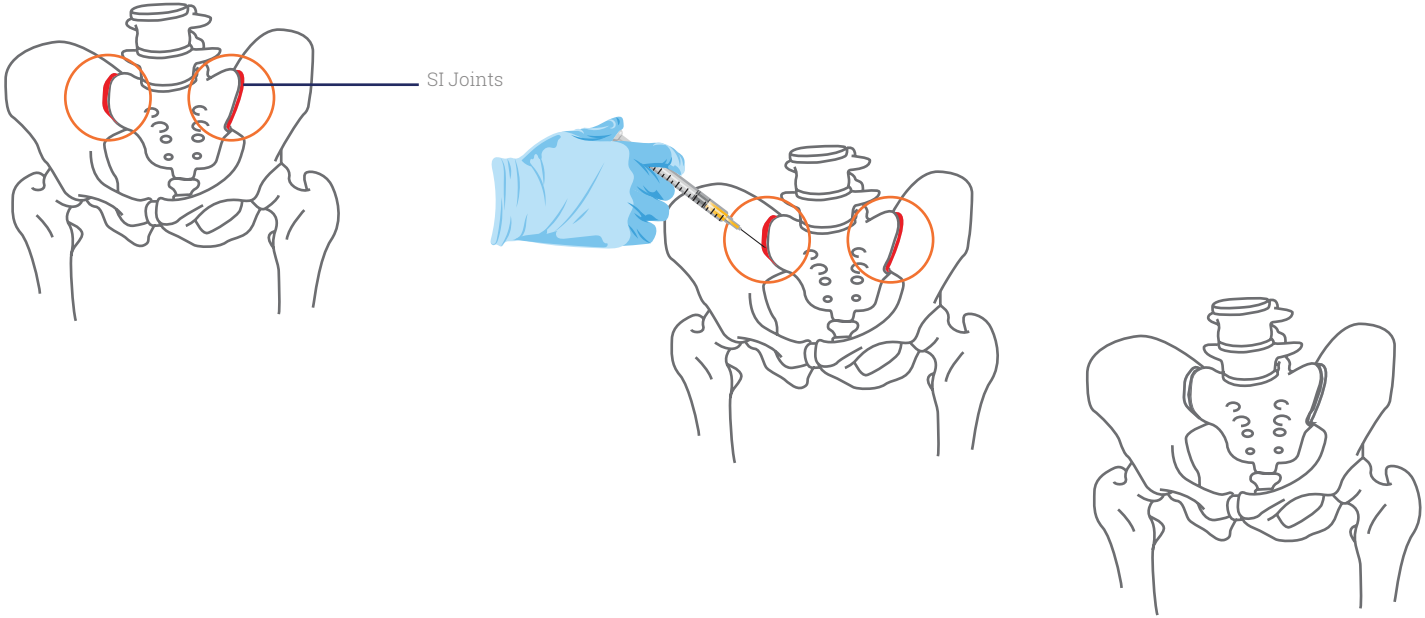
Conventional Treatment Practices

- Chiropractic manipulation
- Anti-inflammatory medications
- Topical patches, creams, salves
- Mechanical bracing
- Joint Injections
- Radiofrequency Nerve ablation
- Surgery
- Titanium Metal Implants



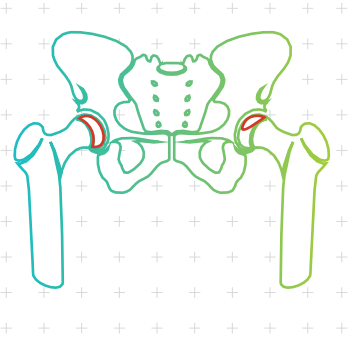
How does **Orthobiologics help?**

Platelets initiate tissue repair by releasing growth factors. These growth factors start the healing process by attracting cells that repair, including critical stem cells thereby significantly strengthening the body's natural healing. PRP therapy enhances this process by delivering a high concentration of platelets. PRP has been used in cases where other conventional treatment methods fail to address SI dysfunction and instability. The results normally seen include dramatic reduction in pain and mobility enhancement for the patient with little risk of side effects.



Navani, Annu & Gupta, Deepak. (2016). Role of intra-articular platelet-rich plasma in sacroiliac joint pain. Techniques in Regional Anesthesia and Pain Management. 19. 10.1053/j.trap.2016.09.010

Avascular Necrosis (AVN)



Avascular necrosis (AVN) is a disease that results from temporary or permanent loss of blood supply to the bone. When blood supply is cut off, the bone tissue dies and collapses. It most commonly happens in the ends of a long bone. It may affect one or several bones at one time or different bones at different times.

Risk factors for Avascular Necrosis

- Injuries or Trauma
- Medications like steroids or bisphosphate
- Alcoholism
- Radiation or transplantation procedures

Conventional Treatment Practices

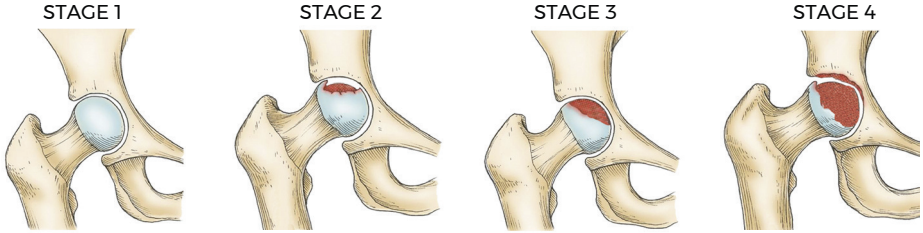
- Medications and therapy
  - Osteoporosis drugs
  - Cholesterol-lowering drugs.
  - Blood thinners.
- Electrical stimulation
- Surgical and other procedures
  - Core decompression.
  - Bone transplant (graft)
  - Bone reshaping (Osteotomy)
  - Joint replacement.

How does **Orthobiologics help?**

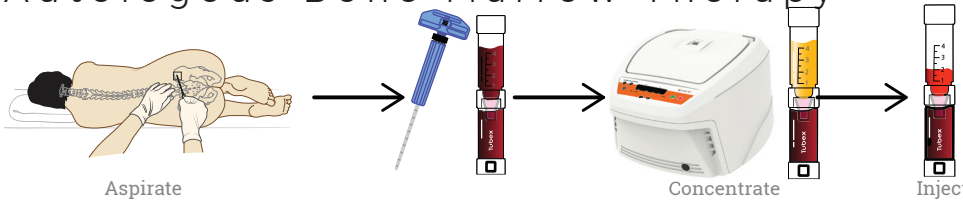
AVN is treated using a surgical procedure called core decompression which involves drilling holes into the femoral head of the hip to relieve pressure in the bone and create new blood vessels to stimulate blood circulation and nourish the affected areas to aid in bone rebuilding. Surgeons also fill these holes with a cocktail mixture of Platelets and Stem cells derived from Bone marrow concentrate facilitating faster healing and bone regeneration.

During this procedure, Bone Marrow Aspirate drawn from Iliac Crest is processed with our **TriPReP™ BMC** kit to produce enhanced concentrate of platelets, stem and progenitor cells. Then, the doctor will create a small incision to hip and the necrotic part (dead bone) is removed. Finally, the processed Bone Marrow Concentrate is slowly implanted into the defect area.

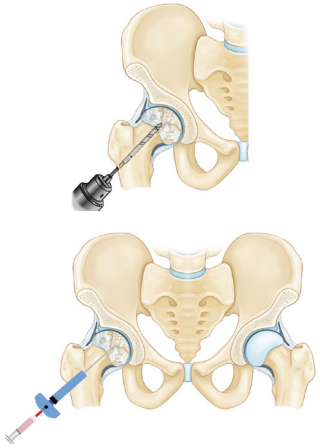
Stages of **Avascular Necrosis**



Autologous Bone Marrow Therapy



Route of **Administration**



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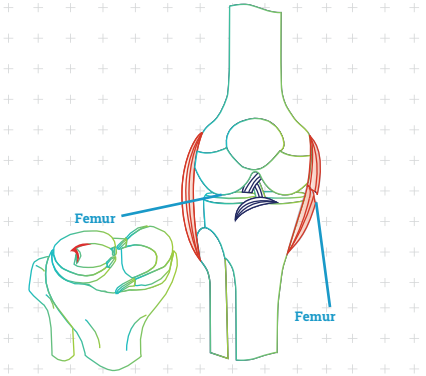
Cartilage Defects and Tears



Any sprain, stretch or tear in cartilages is associated with cartilage defects. Typically, when someone refers to a tear in the cartilage, they are referring an injury to the meniscus cartilage, the rubbery knee cartilage cushioning the shin bone from thigh bone.

Cartilage defects or meniscus tears are associated with poor blood supply and won't heal on its own thereby resulting in knee replacement.

Risk factors for Cartilage Defects and Tears

Conventional Treatment Practices

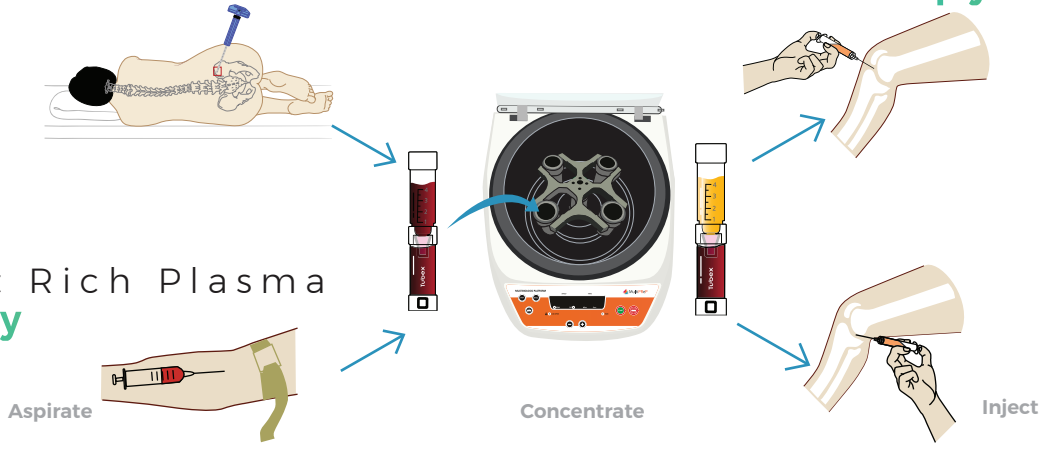
- Pain Medication such as ibuprofen or aspirin
- Physical Therapy
- Braces or Crutches
- Arthroscopic Surgery or Meniscus Repair
- Severe Cartilage defects
  - o Microfracture Surgery
  - o Autologous Cartilage Transfer

How does **Orthobiologics help?**

Arthroscopic meniscus repair is an outpatient surgical procedure done to repair torn knee cartilage. A meniscus tear normally requires external stimulation of blood supply to heal. It involves drilling holes into tear areas to create new blood vessels, thereby stimulate blood circulation and nourish the affected areas to aid in bone rebuilding. Surgeons also fill these holes with a cocktail mixture of Platelets and Stem cells derived from Bone Marrow Concentrate facilitating accelerated healing and bone regeneration. During this procedure, Bone Marrow Aspirate drawn from Iliac Crest is processed with our **TriPReP™ BMC kit** to produce an enhanced concentrate of platelets, stem and progenitor cells, and injected to defect area encouraging cartilage regeneration and avoid knee replacement. If the damage is extensive, then a new cartilage graft can be inserted to replace the damaged cartilage. The use of stem cells for the treatment of cartilage defects is increasing. Methods of delivery of stem cells to the cartilage vary from direct injection to implantation with scaffolds.

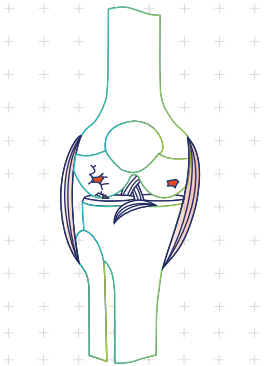
Autologous Bone Marrow Concentrate **Therapy**

Platelet Rich Plasma **Therapy**



Anderson, J. A., Little, D., Toth, A. P. et.al (2014). Stem cell therapies for knee cartilage repair: the current status of preclinical and clinical studies. The American journal of sports medicine, 42(9), 2253-2261.

Osteochondral Lesions



An Osteochondral lesion is a defect in the cartilage of a joint and the bone underneath. Any break, tear, separation, or disruption of the cartilage that covers the bones between joints is referred to as Osteochondral Lesion. In severe cases, the bone right underneath the cartilage will also be injured. The knee, ankle, and elbow joints are common places where this defect occurs. It is caused due to degenerative or traumatic injury and is characterized by pain, stiffness, instability, or a 'locked' feeling.

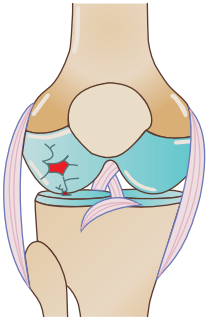
Risk factors for Avascular Necrosis

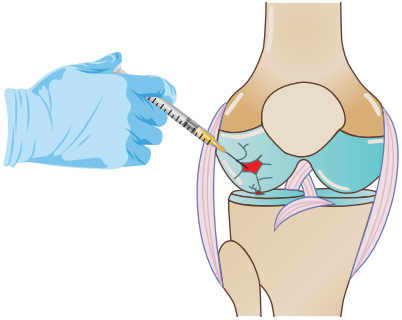
Conventional Treatment Practices

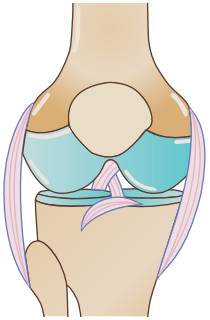
- Physical or Occupational therapy
- Braces or Assistive Devices
- Surgery
    - o Microfracture
    - o Osteochondral Allograft Transplantation (OATS)

How does **Orthobiologics help?**

Microfracture is a surgical procedure performed to promote the healing of damaged cartilage with the use of Stem Cells (progenitor cells of the body). It is usually performed as an arthroscopic procedure. The surgeon will remove loose or unstable cartilage and insert a sharp tool to make several holes in the defect area. These holes penetrate the Subchondral Bone (underlying the cartilage) and open up new blood supply from within the Bone Marrow that supplies the damaged joint surface with new Stem Cells, which fills the damaged area and promotes the formation of new tissue. Similarly, Osteochondral Autograft Transplantation Surgery (OATS), is a Bone/Cartilage transplant procedure used for the treatment of varying degrees of Osteochondral Lesions. This procedure involves inserting new Bone/Cartilage grafts to help regenerate damaged tissue, rather than replacing the joint with an implant. Surgeons typically incorporate Stems Cells or PRP into these holes or grafts to promote faster healing and reconstruction of the injured tissue.

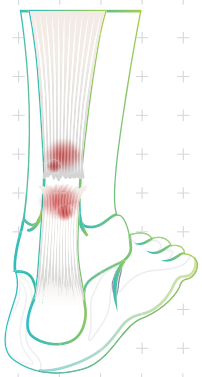






Nam, Y., Rim, Y. A., Lee, J., & Ju, J. H. (2018). Current therapeutic strategies for stem cell-based cartilage regeneration. Stem cells international, 2018.

Traumatic Bone Loss



A fracture is a broken bone. A bone may be completely fractured or partially fractured in any number of ways. Trauma may cause irreversible bone tissue damage and loss of function. Additionally, trauma activates the immune system, alters stem cell behavior, and impairs healing partially or completely.

Risk factors for Traumatic Bone Loss

Trauma or Accidents

Osteoporosis

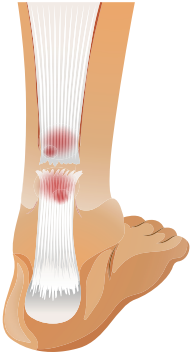
Stress or Overuse

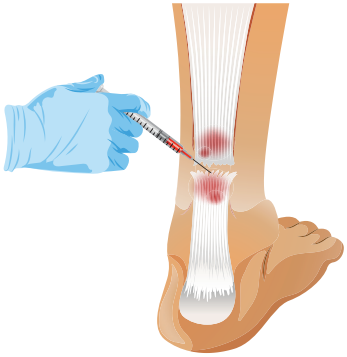
Conventional Treatment Practices

- Plaster Cast Immobilization
- Functional Braces
- External and Internal Fixation
- Traction

How does **Orthobiologics help?**

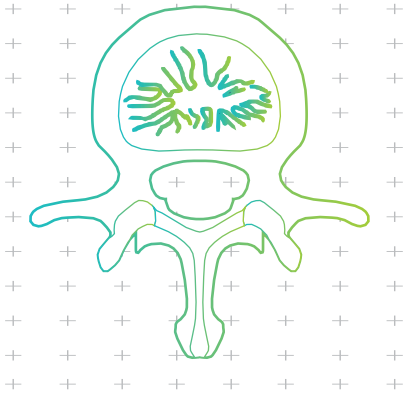
Patients with Non-Unions or Bone Fractures exhibit a decreased pool of Bone Marrow-Derived Stem Cells (BMSCs) and Growth Factors necessary for proliferation and bone regeneration. Several clinical studies have shown that employment of stem cells, either alone or with other biological scaffold materials can stimulate healing at the fracture site. Moreover, stem cells are an easy source of osteoblast (bone) progenitors and secrete bioactive molecules that regulate cell differentiation and tissue regeneration. Bone Marrow Aspirate drawn from Iliac Crest and processed with our **TriPReP™ BMC kit** can produce an enhanced concentrate of platelets, stem, and progenitor cells to encourage non-union healing with minimal complications.





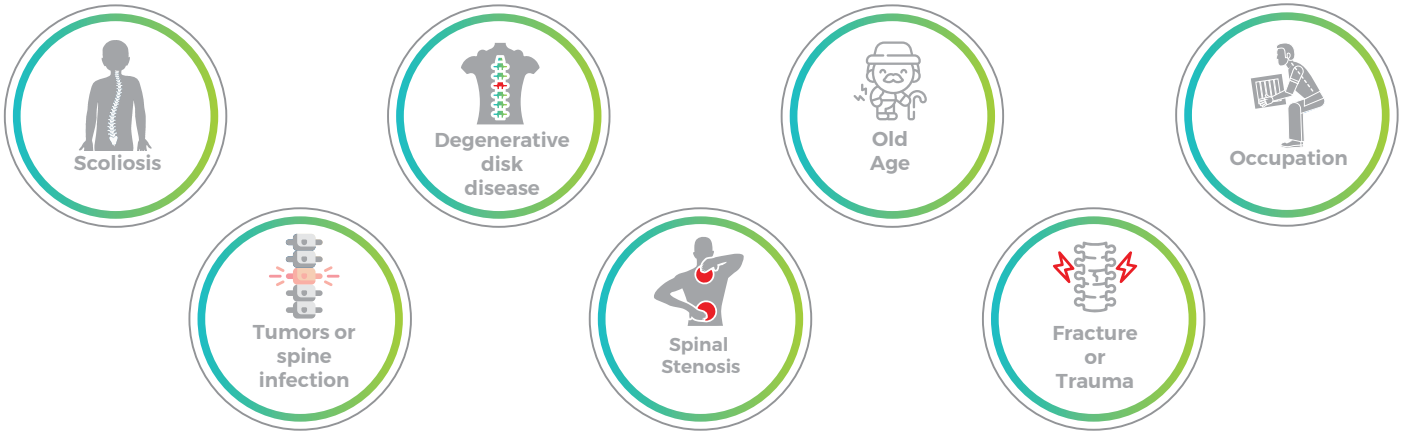
Perez, J. R., Kouroupis, D., Li, et al (2018). Tissue engineering and cell-based therapies for fractures and bone defects. Frontiers in bioengineering and biotechnology, 6, 105.

Spinal Fusion



Spinal deformity is an abnormal alignment or curve of the bony vertebral column. Spinal deformities also can interfere with the spinal cord or nerve roots causing permanent changes in strength, sensation and other body functions Spinal fusion is a surgery designed to join two or more vertebrae to stimulate the normal healing process of broken bones. Metal plates, screws, and rods may be used to hold the vertebrae together, so they can heal into one solid unit during spinal fusion. The surgeon places bone grafts or a bonelike material within the space between spinal vertebrae to facilitate accelerated bone regeneration.

Risk factors for Spinal Fusion



How does **Orthobiologics help?**

All spinal fusions use some type of bone material, called a bone graft, to help promote the fusion. Generally, small pieces of bone are placed into the space between the vertebrae to stimulate bone healing. It enhances bone formation and helps the vertebrae heal together into a solid bone. Moreover, it provides structural support and shape to the spine. However, even after 10 years, there is still a high chance that grafts may fail to integrate leading to nonunion and late graft fractures. Hence, surgeons usually incorporate a cocktail mixture of Platelets and Stem cells derived from Bone marrow concentrate on graft materials to enhance the effects of grafts by facilitating accelerated healing and bone regeneration. Bone Marrow-Derived Stem Cells (BMSCs) are rich sources of adult mesenchymal stem cells with high proliferative capacity and established osteogenic and regenerative potential. During this procedure, the Bone Marrow Concentrate processed with our **TriPReP™ BMC kit** is implanted into the defect area to encourage the longevity of grafts and treatment benefits.

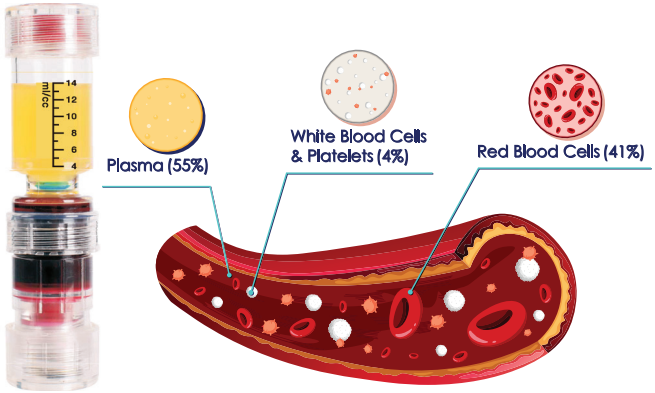
Perez, J. R., Kouroupis, D., Li, et al (2018). Tissue engineering and cell-based therapies for fractures and bone defects. Frontiers in bioengineering and biotechnology, 6, 105.

What is **PRP Therapy?**

- The body's first response to soft tissue injury is to deliver platelets, packed with growth factors and stem cell markers vital for tissue regeneration and repair.

- PRP contains high concentration of these platelets which act as the directors of healing cascade.

- PRP therapy uses injections - to accelerate the healing of injured tendons, ligaments, muscles and joint using patient's own healing system to improve musculoskeletal problems.



Benefits of **PRP Therapy?**

Treat Unresponsive and Unresolved Chronic Issues

Limited Side Effects

Minimally-Invasive

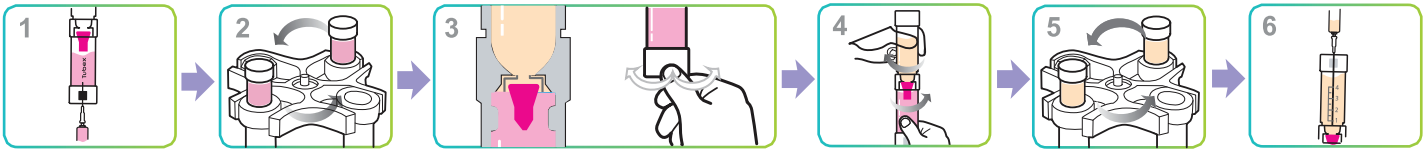
Why choose **PRP Therapy?**

Safe

Quick Recovery

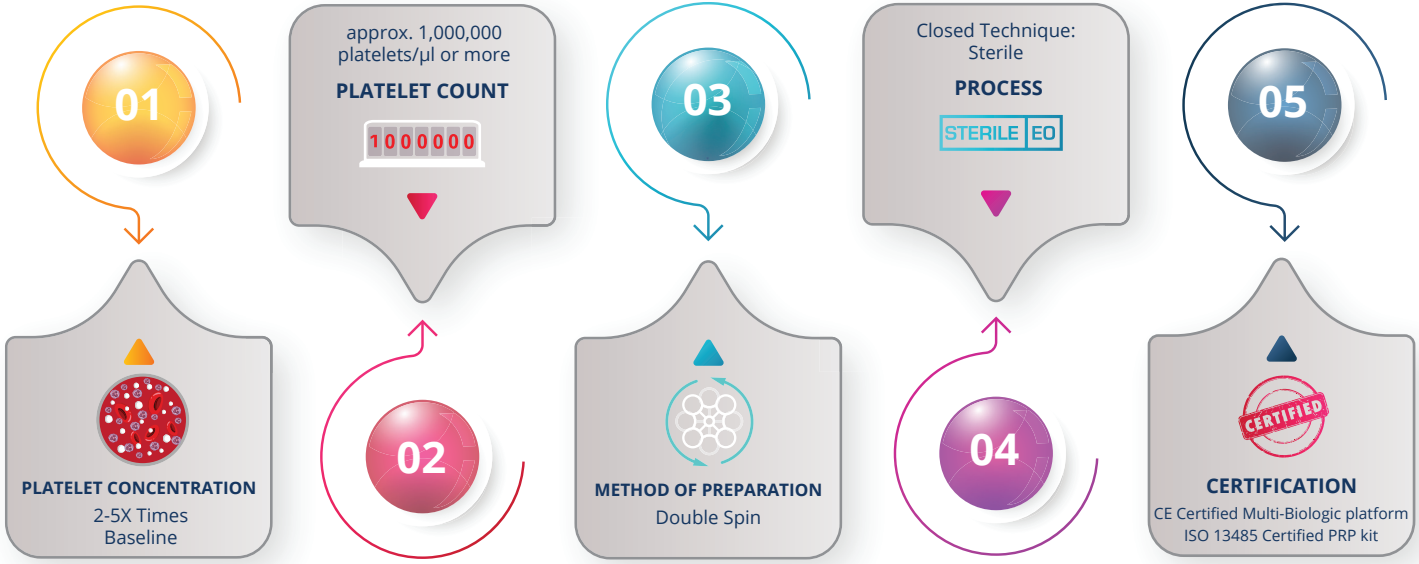
Natural Healing

TriPReP™ PRP - How is it prepared?

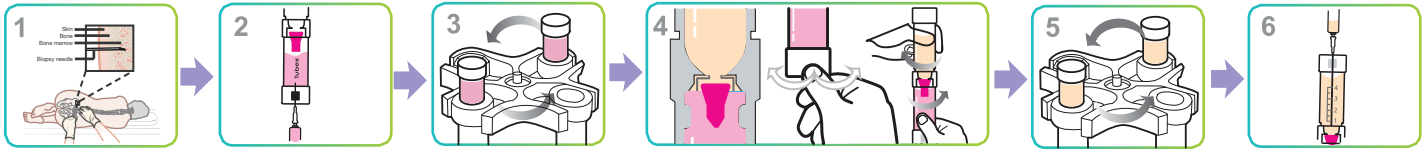


1. Inject blood/BM into Tubex
2. Adjust RCF value and time for 1st centrifugal separation
3. Turn the bottom cork to adjust red-blood-cell level to meet blue line (left : down, Right : up)
4. Not to mix the red-blood cell and plasma, lock the middle valve. (Hold the lower chamber and turn the upper chamber to the left side)
5. Adjust RCF value and time for 2nd centrifugal concentration
6. Extract PP above 2mm first, and then extract PRP/BMC under 2mm

What makes us unique?



TriPReP™ BMC - How is it prepared?



1. Bone Marrow Aspiration
2. Inject blood/BM into Tubex
3. Adjust RCF value and time for 1st centrifugal separation
4. Turn the bottom cork to adjust red-blood-cell level to meet blue line (left : down, Right : up) Not to mix the red-blood cell and plasma, lock the middle valve. (Hold the lower chamber and turn the upper chamber to the left side)
5. Adjust RCF value and time for 2nd centrifugal concentration
6. Extract PP above 2mm first, and then extract PRP/BMC under 2mm

What makes us unique?

01 — 4-5x times increased Cell Load from Baseline

02 — Customizable Bone Marrow Concentrate

03 — Adjustable Buffy Coat and Cell Load

04 — 100 % Sterile with In-Built Filter System

STERILE EO

05 — ISO 13485 Certified Cell Concentration Kit

CERTIFIED

Our Products

TriPReP™ BMC
Stem Cell Therapy

TriPReP™ PRP
Platelet Rich Plasma Therapy

Coltrix
Scaffold for tissue regeneration

ORTHOBIOLOGICS BOOKLET - MARCH 2020

TriCell™ BIOLOGICS

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