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What is "regenerative medicine"?

Your body has the ability to heal itself from certain injuries or conditions. Think about this simple example: a paper cut. Within a day or so, most people get a scab at the site of the cut. That scab is the body working to heal the skin and the tissue beneath it.

Regenerative medicine relies on the body's ability to heal itself. The goal is to replace, or restore, human cells, tissues or organs. The hope is that over time your injured tissue will work normally again.

Regenerative medicine may help your body:

- Health injuries faster
- Have less pain
- Repair damaged tissues
- Function better

Regenerative medicine has been used to treat a variety of injuries and condition, such as:

- Tendon injuries, including Achilles tendonitis, rotator cuff injuries, and "tennis elbow."
- Arthritis and cartilage injuries
- Plantar fasciitis (heel pain)
- Muscle strains
- Ligament sprains
- Degenerative disc disease
- Facet joint arthritis

Is this treatment right for you?

Regenerative medicine does not work for everyone. For some people, it is the last treatment tried. Some studies have shown regenerative medicine to be a helpful treatment. However, when this information was written, the U.S. Food and Drug Administration (FDA) had not approved the use of regenerative medicine as treatment for musculoskeletal and spine conditions. In addition, this treatment has possible side effects and complications.



Finally, this treatment is typically not paid for by insurance plans. It can be a very expensive treatment. If you have questions about the cost(s) and how to pay for this, ask a member of your care team who you can talk to.

Two types of products used

Many bodily products may be considered useful for regenerative medicine. But the two most commonly used are:

- Platelet-rich plasma (PRP)
- *Bone marrow aspirate concentrate* (BMAC)

Platelet-rich Plasma (PRP)

Blood has many different types of cells, including:

- Red blood cells that carry oxygen in the body.
- White blood cells that fight infection.
- Platelet cells that help blood clot and help the body heal from injury.

Platelet-rich plasma is a solution made from our own blood. Plasma holds many platelets. Platelets have a lot of proteins including growth factors. These proteins help control inflammation and heal the body from injury.

How does PRP work?

When you are sick or injured, your body quickly sends platelets to the area. Platelets act like "first responder" cells. They form a clot to help prevent more bleeding. Platelets also help create a foundation for new tissue to grow. In addition, they release growth factors and other proteins. These proteins attract stem cells and other cells to the area. Each of these cells is needed to help the area heal.

How is PRP made?

The first step is creating PRP is to draw blood from a vein. The blood is placed into a machine called a centrifuge. It spins the blood. Spinning separates the platelets from the other blood cells. That step also increases the platelet concentration.



Your PRP injection

The following steps are taken before a PRP injection:

- 1 Blood is taken from your arm. This is done the same way as a blood donation is done.
- 2 The blood is placed into a centrifuge and PRP is made. The process usually takes about 20-30 minutes. The time depends on how much blood was drawn from your arm.
- 3 Ultrasound or fluoroscopy (X-ray) is used to look at the injured area.
- 4 Your skin is cleansed and numbed using a local anesthetic.
- 5 Using ultrasound or fluoroscopy, a needle is gently guided to the damaged tissue or joint.
- 6 The PRP is injected into the damaged tissue or joint.

It takes 60-90 minutes to make and inject PRP.

For tendon or ligament conditions

For tendon or ligament conditions, in addition to the PRP injection, the needle may be used to break up scar tissue and adhesions. This is called tenotomy or fasciotomy. This step helps stimulate healing. After the scar tissue is broken up, the needle is used to inject the PRP directly to the treated area. Ultrasound or fluoroscopy is used to target the abnormal tissue.

For joint conditions

For joint conditions, such as arthritis, the PRP is injected into the joint. Ultrasound or fluoroscopy guides this injection.

Bone Marrow Aspirate Concentrate (BMAC)

Stem cells are powerful cells. They can:

- Copy, or replicate, themselves
- Secrete, or ooze, anti-inflammatory proteins
- Turn into different types of cells, such as cartilage, bone and tendon.

When you are sick or injured, stem cells help tissue heal and regenerate. They also help control any nearby inflammation. Your bone marrow has stem cells and many other cells that help in healing. Bone marrow is the tissue inside your bones.

Blood cells are made in the bone marrow. Cells found in bone marrow can be used to treat damaged tissue, improve function and help control pain.

The process described below creates a concentrated form of bone marrow. It is called BMAC. Compared to typical bone marrow, BMAC has more regenerative cells, including stem cells. It also has platelets and growth factors like those found in PRP.

BMAC has been injected into injured joints, tendons, ligaments, muscles, intervertebral discs, and other areas.

How is BMAC made?

Bone marrow is most commonly taken from the back of your pelvic bone While you lie on your side or stomach, a member of your health care team:

- 1 Locates your pelvic bone either by touch, an ultrasound machine, or a fluoroscope.
- 2 Cleans your skin and the tissues down to the bone using a disinfectant.
- 3 Numbs your skin and the tissues down to the bone using a local anesthetic.
- 4 Uses a special needle to enter the bone.
- 5 Withdraws, or aspirates, the marrow from your bone.
- 6 Places the bone marrow in the centrifuge. Spinning the marrow removes much of the fluid and the unwanted components. And it concentrates the bone marrow cells. The result is BMAC.

Injecting BMAC into the injured area

To inject the BMAC, your health care provider:

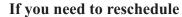
- 1 Ultrasound or fluoroscopy will identify the injection site.
- 2 Cleans your skin and numbs it using a local anesthetic.
- 3 Uses ultrasound or fluoroscopy to gently guide the needle to the diseased tissue or damaged joint.
- 4 Injects the BMAC into the target area.

It takes about 2 hours to make BMAC and inject BMAC.

Getting ready for your procedure

Tell your health care provider if you:

- Have had any changes to your health in the weeks or days before your scheduled procedure. It is very important that you be as healthy as possible for this treatment.
- If you are pregnant or think you may be pregnant.
- Are taking blood thinners, have bleeding tendencies, or have ever had difficulty with a blood draw.
- Have had a flu shot in the past 30 days. I you can avoid it, do not get a flu shot within 30 days before your scheduled procedure.



If you need to reschedule your procedure for any reason, call the health care provider who ordered the procedure as soon as possible.

Infection

You cannot have this procedure if:

- You are taking antibiotics on the day of the procedure. Or
- You have signs of infection during the 7 days before the procedure.

If you have any of the following problems, tell a member of your health care team right away:

- A temperature of 100.4 degrees Fahrenheit (38 degrees Celsius) or greater.
- Chills and aches.
- New or worsening cough.
- A burning sensation when urinating.

See also "Possible Side Effects and Complications—When to Get Help"

About your medications

Tell your health care provider about all medications you take. Include over-the-counter and prescription medications, vitamins, and any supplements.



On the day of the procedure:

- Take any prescribed medications as usual unless you were told specifically to do something different.
- Do not take vitamins or supplements. Some of these products may affect blood clotting and blood pressure.

Blood-thinning medications

Before your procedure, your blood-thinning medication routine may need to change. Talk with your health care provider who manages these medications as soon as you can. Blood-thinning medications affect clotting and bleeding both the healthcare provider who manages these medications and the provider doing your procedure decide whether your medications need to be changed before the procedure. They also decide together when you should restart the medication after the procedure. If you aren't sure whether you take medication that affects your blood this way, contact your health care provider or pharmacist.

Corticosteroid medications, such as cortisone, steroids, and prednisone

Talk to your health provider about whether you should continue using corticosteroid medications during the 30 days before your procedure. Corticosteroid medications can interfere with platelet and stem cell function. They also can affect how well you heal.

Most people are told to stop corticosteroid medications 30 days before the procedure. If you cannot stop taking corticosteroid medications, talk to your regenerative medicine health care provider.

Pain medications

Avoid anti-inflammatory products such as aspirin, ibuprofen and naproxen for one week before your procedure. Examples of ibuprofen are Advil and Motrin. Examples of naproxen are Aleve and Naprosyn. These medications may affect your platelets. Acetaminophen, such as Tylenol or a generic brand, usually is okay to take. But be sure to ask your health care



provider about what you can take for pain.

Drinking and eating

- Avoid alcohol for at least 1 week before the procedure.
- Unless you have been told to limit your fluid intake due to a medical condition, drink extra water in the days before your procedure.
- It is okay to eat before your procedure but try and stick to a light and gentle diet. Some patients might get nauseas during the procedure and it's best to have an empty stomach.

If you will have a spine procedure, see "Special Instructions—if you will get BMAC in your spine."

Smoking

If you smoke, stop. Smoking and inhaling second-hand smoke interfere with healing after a regenerative medicine treatment. If you'd like help to stop smoking, talk to a member of your care team. He or she will tell you about people who can help you quit.

Special instructions

Be sure to read your patient appointment instructions. Follow those instructions and any other instructions your care team gives you. If you do not follow the instructions, your procedure may be rescheduled.

If you do not get a copy of your patient appointment instructions from a staff member, in the mail or by email, contact your health care team a few days before your procedure.

See also, "After Your Procedure—Care following sedation, anesthesia and relaxant medication."

If you will get BMAC in your spine

 Read your patient appointment instructions and look for information about what to eat and drink in the hours before your procedure. If you do not follow those instructions, your procedure may be rescheduled.

- You likely will have sedation to help you relax during the procedure. For that reason:
 - a You must have a responsible adult drive you to and from the appointment.
 - b You cannot drive due to the sedative medication.
 - c You need a responsible adult with you for 24 hours after the procedure.
 - d If you do not have someone with you, your procedure may be rescheduled.
 - e If you are alone staying at a local hotel, ask whether they offer transportation.
 - f If needed, also talk to the hotel or your care team about hiring someone to stay with you for 24 hours after the procedure.

See also, "After Your Procedure—Care following sedation, anesthesia and relaxant medication."

If you will get BMAC in an area other than your spine Your health care provider may give you medication to take before your procedure. This helps reduce anxiety and discomfort. It allows most people to relax during the procedure. If you get this medication, be aware of these warnings:

- You must have a responsible adult drive you to and from the appointment.
- You need a responsible adult with you for 24 hours after the procedure.
- If you do not have someone with you, your procedure may be rescheduled.

Possible side effects and complications

When to get help

Medical problems, called complications, typically do not happen after these procedures. Every person and each procedure are different. Possible complications may include, but are not limited to the following:

Get emergency care

If you have any of the following signs of an allergic reaction, call 911 or have someone take you to the nearest emergency care center right away. An allergic reaction may be a lifethreatening problem.

- Rash
- Swollen throat
- Difficulty swallowing
- · Wheezing or difficulty breathing

If you seek emergency care, call your regenerative medicine care team the next business day to tell them about this.



If you have any of the following complications, contact your health care team to learn what you should do next:

- Bleeding from the aspiration or injection site. Minor bleeding is common. If the site does not stop after you hold ice on it for 10 minutes, contact your care team.
- Infection. Signs of infection are:
 - a Temperature or 100.4 degrees Fahrenheit (38 degrees Celsius) or greater.
 - b Increasing tenderness, redness or swelling at the site of your aspiration or injection.
 - c Increasing pain or pain not relieved by pain medications.
 - d Drainage, bleeding, or bad smelling odor coming from the site of your aspiration or injection
- Injury to a nerve. This may happen during an injection. It could cause pain, numbness, or muscle weakness. These symptoms are usually temporary.

Side effects

- After an injection into a joint: It is normal to have some pain and mild swelling in the area for several days.
- After an injection into soft tissue (such as a tendon): It is normal to have some pain and mild swelling in the area for several weeks.



After your procedure

Care following sedation, anesthesia, and relaxant medication

Sedation, anesthesia and medications that help you relax have side effects. They can cause you to have lapses in memory, slowed reaction time, and impaired judgement. You must have someone drive you home and stay with you on the day of the procedure.

For the rest of the day after the procedure:

- Stay home and rest. Do not return to work or school.
- Do not drive or operate motorized vehicles or equipment.
- Do not take on responsibility for children or anyone who depends on your care.
- Do not use exercise equipment or take part in rough play or sports.
- Do not drink alcoholic beverages.

Your activity limits

Ask you heal care team member about your specific activity limits. This information is a general guideline.

- If you had a PRP joint injection. Rest the joint for 2 days after the injection.
- If you had a BMAC joint injection: Rest the join for a week after the injection.
- If you had a PRP or BMAC injection into soft tissues (such as a tendon or ligament): Rest the area for 2 weeks after the injection. After that time, take about 4-6 weeks to slowly return to normal activities.
- If you had PRP or BMAC injection into your spine: Rest in bed as much as possible for 2 days. Get up only to use the bathroom and eat meals. Slowly, over about 2 weeks, return to your usual activities.

Bathing and water activities

The collection and injections sites should not sit under water until after your skin has healed.

For 72 hours after your procedure:

• Use a shower when you bathe.

• Do not swim. Do not use a bathtub, hot tub, or whirlpool.

Managing you pain

*If you had a PRP procedure*You may have mild discomfort at the injection site.

If you had a BMAC procedure

The site where the bone marrow was collected may be fairly sore for a few days after the procedure. You may use ice over the bone marrow collection site or over the injection site. This should be limited to 3 times per day for 15 to 20 minutes maximum each time. Do not use heating pad or any form of heat on the site for 2 days.

Pain medication

Do not use anti-inflammatory products for at least 2 weeks after your procedure. Examples of anti-inflammatories are aspirin, ibuprofen or naproxen. Examples of ibuprofen are Advil and Motrin. Examples of naproxen are Aleve and Naprosyn. These medications may affect your platelets. Acetaminophen, such as Tylenol or a generic brand, usually is okay to take. But be sure to ask your health care provider about what you can take for pain.

Blood thinning medication

Before your procedure, your blood-thinning medication routine may need to change. Talk with your health care provider who manages these medications as soon as you can. Blood-thinning medications affect clotting and bleeding both the healthcare provider who manages these medications and the provider doing your procedure decide whether your medications need to be changed before the procedure. They also decide together when you should restart the medication after the procedure.

Avoid corticosteroid medication, such as cortisone, steroids and prednisone

Talk to your health provider about whether you should continue using corticosteroid medications during the 30 days before your procedure. Corticosteroid medications can interfere



with platelet and stem cell function. They also can affect how well you heal.

Most people are told to stop corticosteroid medications 30 days before the procedure. If you cannot stop taking corticosteroid medications, talk to your regenerative medicine health care provider. Following the procedure, if possible, do not take corticosteroid medication for at least 30 days. Corticosteroid medication may affect your stem cells and their ability to help you. They can also affect your healing. If you stopped taking corticosteroid medication before your procedure, talk to your health care team about how and when you can begin them again.

If there are medical reasons why you may need corticosteroid medication from the 30 days after your procedure, ask your health care provider how to manage corticosteroid medication use after the procedure.

