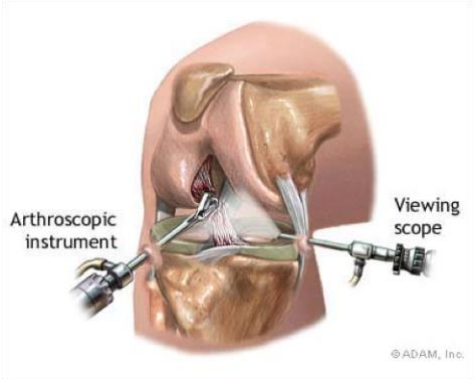
Options for your Arthritis

Overview: The goal of treatment for your arthritis is to reduce pain and restore function to that joint. There are two basic pathways we can take to achieve these goals, these are:

1. Surgical treatments
2. Non-surgical treatments

We will review each option with a brief description of how each treatment works including how it is administered and who is the ideal candidate. We will also review the efficacy, safety; amount of time and effort involved (convenience) ; and the expected costs associated with each treatment. We rate each of the latter sections on a scale of 0-4 + with + indicating more pain, more inconvenience, less safety and less efficacy. A maximum score of 4 ++++ indicates that this procedure has LESS pain, is more convenient, has better safety and better efficacy. So, in summary, the more + next each segment, the improved rating.

Surgical Treatments



Arthroscopy

What is it?

This is a minimally invasive surgery where a small digital camera is inserted into your knee joint through a small 3-4 mm incision. Another 3-4 mm incision is made for a small tool used to remove and or repair tears of the cartilage rings in your knee called a meniscus or to remove small floating pieces of cartilage or loose pieces peeling off your knee. This is all done as an outpatient (meaning you return home the same day).

How does it work?

The arthroscopy is used to treat instability or locking of the knee. Sometimes, the feeling of "giving away", locking or catching to your knee is caused by something that is loose, torn or floating in your knee. This procedure is designed to remove something that is causing a mechanical symptom to your knee. It is not specifically used to treat or cure arthritis of your knee. However, special conditions related to inflamed bone next to your cartilage may benefit from a special arthroscopic procedure.

Ideal Candidate

Although this is not a complete list, it is a general guideline to help you understand whom may be the ideal candidate for this procedure. You, and your surgeon will always find exceptions since not all patients respond the same to each treatment.

- Mechanical symptoms such as locking, catching or giving-away at least 2 or more times per week.
- Evidence of inflamed bone found only on an MRI.
- Positive MRI for a meniscal or ligament tear, loose bodies, or loose cartilage. (not always required)
- Medically stable to undergo an anesthesia and the surgery.

Safety of this Procedure: Score: +++
Overall, this is a safe procedure. Complications can occur such as blood clots, infections, pain, and skin damage. However, others not mentioned can also occur. In a recent study entitled "*Complications after arthroscopic knee surgery*"[1] , the authors reviewed 2,623 cases of arthroscopic knee surgery. The overall complication rate was 0.27% (less than 1%) with the most common complication being infection. Another safety review entitled "*Quantifying the excess cost and resource utilization for patients with complications associated with elective knee arthroscopy: a retrospective cohort study*by Bohensky, MA , reviewed 166,700 elective knee arthroscopies and found a total of 976(0.6%) complications, including 573 patients who had a venous thromboembolism (VTE) (0.3%), 227 patients with a joint complication (0.1%) and 141 patients with infections (0.1%).[2] So, we can see that the overall complication rates are normally under 1%.

Efficacy of this Procedure: Score: ++
Knee arthroscopy for degenerative meniscal tears can help to relieve the symptoms of instability and pain associated with this instability. However, it will not relieve the pain associated with arthritis. In a study called "*Is arthroscopic surgery beneficial in treating non-traumatic, degenerative medial meniscus tears? A five year follow-up* [3] the authors designed a prospective, randomized trial comparing exercise alone to knee arthroscopy and exercise. Both groups improved, but the exercise group alone had 1/3rd of the patients still experiencing disabling pain at the end of the study.
Another interesting study entitled *"Arthroscopic debridement compared to intra-articular steroids in treating degenerative meniscal tears"* [4]randomized 120 patients with MRI confirmed medial meniscal tears into treatment with steroid injections vs. arthroscopy. At one year, the arthroscopic group still had improvement in 79% of the patients while 61% of the steroid treated patients noted improvement. Thus, we can understand that arthroscopy for a mechanical problem such as a meniscus tear can offer

---

[1] Hagino, T et al *Complications after arthroscopic knee surgery*. Achieves of Orthopedic Trauma Surgery , 2014 November; 134(11):1561-4
[2] Bohensky, MA et al. *Quantifying the excess cost and resource utilization for patients with complications associated with elective knee arthroscopy: a retrospective cohort study2* Knee, 2014 Mar;21(2):491-6
[3] Herrlin, SV et al *Is arthroscopic surgery beneficial in treating non-traumatic, degenerative medial meniscus tears? A five year follow-up* . Journal of Knee Surgery, Sports, Traumatology and Arthroscopy 2013 Feb;21(2):358-64
[4] Vermesan, D et al. *Arthroscopic debridement compared to intra-articular steroids in treating degenerative meniscal tears* The European Review of Medical Pharmacology Science, 2013 Dec;17(23):3192-6

some relief of symptoms associated with a mechanical problem of the knee superior to injections or physical therapy alone.

Convenience of this procedure: Score: ++
You will be required to report back to the office for a pre-operative evaluation called a history and physical. Some patients with pre-existing medical conditions such as coronary artery disease may also require an evaluation by their primary care physician or a cardiologist. Sometimes, this means some extra testing such as an EKG or even a cardiac stress test. You will need someone to come with you to the surgery center to drive you home, and stay with you at least the night of the procedure. You may require assistive aids such as crutches or a walker for anywhere from 1 day to 2 weeks. You will also need to report back to our office for at least one post-operative visit. Some patients will be prescribed physical therapy, but most can follow a simple home exercise program.

Pain Associated with this procedure: **Score: +++**
Most patients have pain that is well controlled with some over the counter or prescription medications and most only use these medications for approximately one week after the surgery. However, every patient responds differently to treatment.

Cost: Score: ++
Although most insurance plans cover surgery, there are many plans with deductibles, co-pays, co-insurance and out of network charges. The average charge from a surgical center for a knee arthroscopy in the Detroit area is $11,800 according a survey of surgical centers at: http://www.newchoicehealth.com/procedures/arthroscopic-knee-surgery
Remember, that charge and cost have very little relationship to each other. The charge is what the hospital or surgical center hopes to be paid. Normally, they receive one half to one third of what they charge.
Consumer Reports published the national average cost of simple knee arthroscopy (CPT 29981) to be $3,792 in the *2017 Healthcare Blue Book*. When calculating your expenses, you should also factor in the time lost from work as an opportunity cost. Most patients are off work an average of 7-10 days with an arthroscopy. These expenses **may be** reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details.

Knee or Hip Replacement

What is it?
Joint replacement is a resurfacing and re-alignment procedure for your arthritic joint. A angled joint is straightened and a new surface is placed on either end of the joint. The joint is opened through an incision and the arthritic portions of the joint are removed with specially designed instruments and tools to place a new surface on either end of the joint while the surgeon balances the joint through normal range of motion.

How does this work?
You are admitted to a hospital or surgery center the day or your surgery. Incisions are made over the joint in a manner designed to preserve the normal function of the joint. Special cuts are made on the bones of your joint to allow proper placement of the new joint and to restore normal mechanical alignment of the joint. These joint replacements are made of metal such as titanium and cobalt chrome and they articulate with a high density and durable plastic liner. Most knee replacements are glued to your bones with a special bone cement. Most hip replacements are designed to wedge within your current bone after reaming the bone to a specific geometry. Your own bone grows into this replacement to further stabilize the fixation. Most patients stay in a hospital or surgery center for 1-2 days, however, a few select patients may leave the day of surgery. You will require constant 24 hours a day care 7 days a week care for up to 3 weeks after the surgery. You will be ambulatory the day of your surgery, but you will require someone to help you with simple activities such as dressing, meal preparation and bathing.

Ideal Candidate
Although this is not a complete list, it is a general guideline to help you understand whom may be the ideal candidate for this procedure. You and your surgeon will always find exceptions since not every patient responds the same to each treatment:

- Documented arthritis on x-ray or MRI
- Deformed or angulated joints
- Severe loss of motion of the joint
- Failure of multiple treatments such as injections, therapy and weight loss.
- Loss of activities of daily living such as shopping, dressing and walking
- Medically stable to undergo anesthesia, the surgery, and rehabilitation
- Lack of any active infections

- Able to have someone take care of you at home 24hours a day, seven days a week for at least 2 weeks and ideally 3 weeks.
- Willing to participate in the pre-operative preparation classes and appointments
- Willing to participate in physical therapy for 6-8 weeks.

Safety of this Procedure: Score: ++

We take steps to help identify and reduce complications, but there are complications that can occur. Luckily, most of these complications can be treated successfully. In a recent study entitled *"Complications Following Outpatient Total Joint Arthroplasty: An Analysis of a National Database."* by Courtney, PM[5] the author performed a retrospective review of 169,406 patients receiving either a total knee or total hip replacement. The overall complication rate was 16% for inpatient joint replacement. Patient age over 70; malnutrition, cardiac history; smoking history; and diabetes; increased the risk.

Another very large study looking at the trends of adverse outcomes after total hip replacement entitled "*Adverse outcomes in hip arthroplasty: Long term trends."* by Brian Wolf[6] found that between 1991 and 2008, 1,405,379 total hips were performed with a decreasing trend of adverse outcomes from 4% to 3.4%, however, of the 337, 874 revision (re-do) hip replacements, there was a trend towards an increase in adverse outcomes from 7% to 10.9%.

Efficacy of the Treatment Score: ++++

Overall, many patients are very happy that they had the procedure performed. The knee and hip society reports that most patients have 95% pain relief and that over 80% of these joint replacements will last over 20 yrs. (http://www.aahks.org/care-for-hips-and-knees/do-i-need-a-joint-replacement/total-hip-replacement/) Another study entitled " *Patient-level clinically meaningful improvements in activities of daily living and pain after total hip arthroplasty: data from a large US institutional registry"* [7]looked at 6168 total hips from 2 to 5 years after their surgery. Clinically meaningful reduction in pain was reported in 94% of patients with moderate pain and 91% of patients with severe pain. Only 4% of patients with moderate limitations and 17% with severe limitations reported severe limitations on their activities at 2 years after the surgery. Thus, these procedures can be reliable, reproducible and durable. However, recent studies such as "*A Review of the Clinical Approach to Persistent Pain Following Total Hip Replacement"* by Lam, YF et al. (Hong Kong Med J, 2016 Dec: 22(6): 600-7)[8] reviewed that 27% of total hip patients had persistent pain after their hip replacement. In addition, Wylde et al. also

---

[5] Courtney, PM et al. Complications Following Outpatient Total Joint Arthroplasty: An Analysis of a National Database. JArthroplasty, 2016 Dec 14

[6] Wolf, B et al, *Adverse outcomes in hip arthroplasty: Long term trends.* Journal of Bone and Joint Surgery, 2012, July 18, 94(14) 8.

[7] Jasvinda A. Singh et al, *Patient-level clinically meaningful improvements in activities of daily living and pain after total hip arthroplasty: data from a large US institutional registry"* , Journal of Rheumatology (Oxford), 2013, June 52 (6), 1109-1118

reviewed similar findings in total knee patients. (*Total Knee Replacement: Is it Really and Effective Procedure for All?*; Knee, 2007, Dec 14 (6): 417-23)[9]. ***In summary, total joint replacement is a standard of care for severe arthritis with good track record of relieving pain, but with some potential for complications and some persistent symptoms***.

Conveniences of the procedure Score: +

You must visit your primary care physician for a checkup. Some patients with pre-existing medical issues, such as heart or lung disease, may need to visit a specialist and undergo special testing. There is a mandatory pre-operative orientation meeting you must attend with the person appointed as your coach. This is a half-day event reviewing the entire procedure. You will have a history and physical exam, informative lectures and a chance to ask questions. You will be admitted to the hospital for 1-3 days with most patients leaving in 24 to 48 hrs. A few select patients will be able to leave the day of surgery. You will have physical therapy if you are not progressing and this may last for up to 8 weeks. You must have someone who can help you get up from a chair and into your bed or bathroom as well as help you with dressing, bathing and preparing foods for approximately 2 to 3 weeks after your surgery. This person (s) must be with you 24 hrs a day, 7 days a week. Some people heal faster than others, and they may be independent in these critical activities of daily living sooner, but count on 3 weeks. Some people can return to a sedentary job within 2- 3 weeks, however it may take up to 3 months for a return to a physically demanding occupation. If you have the procedure performed on your right leg, it is recommended that you not drive for 6 weeks. If you have the procedure on your left leg, this may be reduced to 2 weeks if you are not currently taking narcotics.

Pain associated with the procedure. Score : +

Joint replacement surgery is still a major surgical procedure and may require some sort of pain control for up to 3 months. However, we have made tremendous improvements in pain management that allow easier recovery in more rapidly. We use a multi-modal strategy to help relieve pain. This means we use numerous different methods to reduce and/or block your pain. This also normally results in a reduction of the complications that can occur with these treatments. This multimodal approach uses a mixture of numbing nerve blocks, combined with anti-inflammatories, anti-nausea, anti-anxiety, and cryo-therapy (ice). Most patients are discharged from the hospital with a narcotic medication that is used for 3 to 6 weeks after the surgery.

Costs Score: +

Although most insurance plans cover the cost of a joint replacement, many plans have deductibles, co-insurance, co-pays and other uncovered services. The average charge by a hospital for a joint replacement is approximately $35,000 and the average out of pocket cost for Medicare recipients in Lebanon New Hampshire was $4,275 in a survey conducted in 2011. (http://health.costhelper.com/knee-replacement.html) . The charge and cost are not related to each other. The charge is what the hospital hopes to receive from an insurance carrier. Normally, they receive one half to one third this charge. Consumers Report published the average fair cost as $21,626 for a total knee replacement

(CPT code 27447) and $21,698 for a total hip replacement (CPT code 27130) in their 2017 Healthcare Blue Book. When calculating your expenses, you should also factor in the time lost from work as an opportunity cost. Most patients are off work an average of 2 to 3 weeks for a sedentary job and up to 3 months for a physically demanding job. These expenses **may be** reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details.

---

[8] Lam, YF et al, *A Review of the Clinical Approach to Persistent Pain Following Total Hip Replacement,* HongKongMedJ , 2016 Dec: 22(6): 600-7

[9] Wylde, V et al, *Total Knee Replacement: Is it Really and Effective Procedure for All?*; Knee, 2007, Dec 14 (6): 417-23

Non-operative treatments

Non-operative treatments for arthritis focus on the ancient concept of ***homeostasis***. This is a concept where your own body tries to maintain a constant state of stability. Everyday our joints are subject to damage and everyday our joints try to repair this damage. However, our joints have a limited ability to repair themselves especially as we age. The goal of a physician trying to restore homeostasis is to do two things. The first is to determine factors that are causing joint destruction and attempt to eliminate or modify these. The second is to find ways to stimulate and aide the body to repair the joint. When you have more destruction than repair this means you have pain and reduced function of the joint. When repair is equal or sometimes greater than destruction, you have reduced pain and increased function.

We attempt to reduce the damage through a comprehensive approach including goal setting, weight control, nutrition, shoe wear modification, bracing, medications, vitamin and herb supplements and constant encouragement. These steps can be found and followed using our *10 Steps to Healthy Joints* handout. However, we can also improve your outcome by encouraging your body to up-regulate your reparative process. We will review some of the more common options.

Steroid Injections

What are they?
Corticosteroids have been used since the 1940's to help reduce an interrupt the process of inflammation in your joint. The type of steroids we use for joint pain works mainly within the joint they are injected. However, there is always some systemic effect of injected steroids that can also help reduce inflammation in other areas. The reduction in inflammatory chemicals in your joint help reduce pain.

How does this work?
A dose of the steroid is mixed with a local anesthetic such as lidocaine. After your joint is cleansed to prevent infection, the cocktail is injected directly into the joint. There is immediate relief of pain within 3-5 minutes in most patients due to the injection of the anesthetic. However, this will wear off in approximately 30 to 60 minutes. The steroid portion of the injection requires anywhere from 48 hrs to one week to take effect. These steroids work on the chemicals producing inflammation in your joint and help reduce

their activity. The result is a temporary reduction of pain, and an increase in your activity levels. The peak effect of the steroids is normally in the first 2 weeks, and most patients notice a relief of pain for an average of 6-8 weeks. Although there are no hard-set rules on the number and interval of repeat injections, a generally accepted rule is one injection every 3 months or 4 times per year.

Ideal Candidate:

Although this is not a complete list, it is a general guideline to help you understand whom may be the ideal candidate for this procedure. You and your surgeon will always find exceptions since not every patient responds the same to each treatment:

- Looking for short term pain relief for 2-8 weeks.
- Stable diabetes since these injections can increase blood sugars for short periods of time.
- Willing to participate in additional therapies to improve the health of the joint.

Safety of this Procedure: Score: +++

Steroid injections are normally safe. The risk of complications such as infections is very low. However, other side effects such as an increase in your blood sugar for 1 to 5 days, vision changes, heart palpitations, insomnia, hyperactivity and skin color changes can occur. Despite what you may have been told, repetitive steroid injections into a joint does not lead to further progression of the arthritic disease as found in the study conducted by Raynauld JP named "*Safety and efficacy of long-term intra-articular steroid injections in osteoarthritis of the knee: A randomized double-blinded, placebo-controlled trial*."[8] The chance of systemic effects on your bone density, weight gain and facial changes have not been reported with the proper use of joint injections.

Efficacy of this Procedure: Score: ++

Approximately 80% of patients will report reduction of their joint pain with this treatment. This will last anywhere from 2 weeks to 2 months with most receiving pain relief for 6 weeks. A review of all the current evidence of use for corticosteroids for arthritis is found in an article entitled "*Corticosteroid injections for osteoarthritis of the knee: meta-analysis*" by Arrol, B et al.[9]concluded: "*Evidence supports short term (i.e. two weeks) improvement in symptoms of osteoarthritis of the knee after intra-articular corticosteroid injection.*" Improvement was also shown in some studies addressing longer-term response (16-24 weeks). So, in conclusion, steroid injections can provide short-term pain relief for arthritis. However, many patients in our practice notice that the period of pain relief shortens and the amount of pain relief reduces over years of these injections. Thus, this is not intended as a long-term solution for arthritis.

---

[8] Raynauld JPet al. *Safety and efficacy of long-term intra-articular steroid injections in osteoarthritis of the knee: A randomized double-blinded, placebo-controlled trial*. Arthritis and Rheumatology 2003 Feb; 48(2): 370-377

[9] Arrol, B et al . *Corticosteroid injections for osteoarthritis of the knee: meta-analysis*" British Medical Journal 2004, April 10 328 (7444):869.

Convenience of this Procedure: **Score: ++++**.
Steroid injections are normally very convenient. This is normally done during your normal physician visit. Most patients are asked to rest and ice the joint for the first 24 hrs. You can resume normal activities the next day.

Pain of this Procedure: **Score: +++**
Most joint injections are very tolerable. The area of the injection is sprayed with a cooling spray called ethyl chloride. This reduces the pain and distracts your pain fibers. The injection is over in 10 to 15 seconds. We normally use a numbing type of medication in the injection called lidocaine. This helps reduce the pain of the injection. Most patients come back frequently and request these injections indicating that the temporary pain associated with this injection is minimal compared to the relief they receive.

Cost: **Score: ++++**
Most insurance plans cover the cost of steroid injections. However, many plans have deductibles, co-pays, co-insurance and other un-covered services. The average cost for a steroid injection is between $120-140. These expenses may be reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details.

Hyaluronic Injections

What are they?
Hyaluronic acid is a normal, natural component of collagen in your body. It is also a natural component of the fluid in your joint called synovial fluid. As you age, your body slowly loses this vital component. The result is a failure of these structures. For example, the loss of hyaluronic acid found in the skin on your face results in wrinkles. Loss of hyaluronic acid found in your eyes, results in cataracts and the loss of hyaluronic acid in your joint can lead to arthritis. This is not the only cause of your arthritis; it is just one of the many biochemical processes which begin to fail. Hyaluronic acid is found in numerous components of your joint including the synovial fluid, the menisci and the articular cartilage. Luckily, we can replace this hyaluronic acid with a substitute found most readily in the combs of roosters.

How Does this Work?
You are given a series of 3 or 5 injections about one week apart into the joint. The hyaluronic acid in these injections attaches to the lining of your joint called the synovium. The receptors of this lining are stimulated to produce more of your natural hyaluronic acid. This can increase the viscosity (thickness) of your joint fluid. This

increase in viscosity helps the native cartilage cells metabolize and function like a healthier joint. The result is a reduction in pain and an increase in function.

Ideal Candidate:
Although this is not a complete list, it is a general guideline to help you understand whom may be the ideal candidate for this procedure. You and your surgeon will always find exceptions since not every patient responds the same to each treatment:

- Patients looking for midterm pain relief of 3 -12 months.
- No or limited instability symptoms to the joint (less than 2 x per week)
- Able to return for 5 injections given one week apart.
- Willing to participate in additional therapies to improve the health of the joint.

Safety of this Procedure: Score: +++
These injections have a good safety record. Some patients with allergies to poultry or feathers may have swelling and pain with these injections. Thus, it is important to make us aware of these allergies. We can easily use a non-avian (non-bird) formula. Infections and persistent joint pain or swelling is extremely rare with these injections. A review of multiple studies using hyaluronic acid revealed that the only adverse effects of significance are transient local reactions in the injected joint observed at a rate of 2% to 4%[10]

Efficacy of this treatment Score: ++
A double blinded, placebo controlled study of 495 patients revealed 56% of patients receiving had pain relief for 6 months & improved function with less side effects (2% vs. 9%) as compared to Naprosyn (a common anti-inflammatory) .[11] Another study by Wadell et al. presented at the American Academy of Orthopedic Surgeons convention 2005 showed that they could delay the need for a knee replacement. They injected 11187 patients and over 75% of patients with severe arthritic changes had not undergone a knee replacement at 3.8 yrs.

Convenience of this Procedure: Score: +++
There are 3 to 5 injections at about one week apart meaning you would come in to the office 3 to 5 times. The maximum effect of the injections peaks normally at 3 months and thus, some patients require patience to reach maximum benefit. You can drive yourself home. There is no need for a driver. Normally patients are asked to rest for the first 24 hrs after each injection.

---

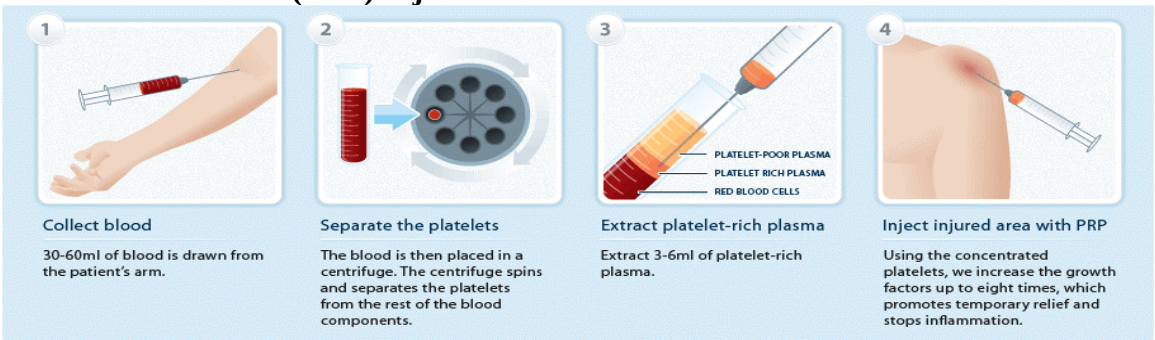
[10] Peyron, JG, *Intraarticular hyaluronan injections in the treatment of osteoarthritis: state-of-the-art review*, Journal of Rheumatology, 1993, Aug 39;10-5

[11] Altman RD, Intraarticular sodium hyaluronate (Hyalgan) in the treatment of patients with osteoarthritis of the knee: a randomized clinical trial. Hyalgan Study Group. J Rheumatology. 1998 Nov; 25(11):2203-12

Pain of the Procedure: Score +++
We numb the skin with a cooling spray to reduce any pain. Occasionally, some patients will have pain during the injection which may last for anywhere from 5 minutes to a day. Resting and icing the knee will help.

Cost: Score: +++
Most health insurance plans cover hyaluronic injections to the knee but not any other joint (i.e. hips or ankles). There has been a trend of many insurance companies to not cover these injections, but many plans including Medicare still cover them. Many plans have deductibles, co-pays, co-insurance and un-covered services. The average cost of a hyaluronic acid injection is approximately $200 each (5 injections = $1000 3 = $600). These expenses **may be** reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details.

Platelet Rich Plasma (PRP) Injections



What are They?

This is a therapy based on your own cells and thus is in a class called ***Cell Based Therapies.*** Any cell taken from your own body used to treat an ailment in the same body is called a cell based therapy.

Platelets are normally found in your own body. When you have a cut or scratch, the scabs that forms are filled with platelets. These platelets are special cells of your blood that causes the blood to clot. This clot helps heal an injury by releasing special growth factors (insulin-like growth factor, transforming growth factor b-I, platelet derived growth factor). In addition, the platelets can also help reduce some harmful chemicals released by a trauma (i.e. Matrix Metalloproteinase). Your joint or injured tissue can benefit by the release of these growth factors in a concentrated form.

Ideal Candidate:

Although this is not a complete list, it is a general guideline to help you understand whom may be the ideal candidate for this procedure. You and your physician will always find exceptions since not every patient responds the same to each treatment:

- Patients looking for midterm pain relief of 3 months up to 2 years.
- Patients searching for improved pain relief and improved function above and beyond what is found in hyaluronic acid injections.
- No or limited instability symptoms of the joint (Not more than 2 events per week).
- Not currently taking blood thinners such as warfarin, Plavix™ or Pradaxa™.
- Ability to stop anti-inflammatory medications (i.e. Motrin™) for 2 weeks prior and 2 weeks after the procedure.
- Willing to participate in additional therapies to improve the health of the joint.

How Does this Work?

A small amount of your own blood (anywhere from 10 to 60cc) is drawn and then centrifuged (spun at a very high speed) to separate out your blood cells from your plasma and platelets. A concentration of anywhere from 3 to 9 times your normal number of platelets is than formed into a solution called platelet rich plasma (PRP). This is packed with growth factors as well as cytokines, chemokines, arachidonic acid metabolites, extracellular matrix proteins, nucleotides, and even ascorbic acid which help heal

damaged tissue. This is all done in our office setting within 20 to 30 minutes. There are different protocols for these injections, but we normally recommend one injection. Some patients require more, but most respond to one injection lasting anywhere from 3 months to 2 years. Most people start to notice improvement in approximately 2 weeks. Our experience is that about 80% of our patients improve for about 1 year. This treatment can be repeated if requested.

Safety of This Procedure: Score: ++++

In clinical studies to date, PRP is safe, with no serious complications reported. Minor adverse events associated with repeated injections have been moderate pain, swelling and mild effusion that lasted a few days. In a double blinded randomized study conducted by Sanchez12 of PRP vs. Hyaluronic Acid injections, the PRP group had a PRP 14.1% greater improvement with no increased reports of adverse reactions. In another study entitled "*Treatment with platelet-rich plasma is more effective than placebo for knee osteoarthritis: a prospective, double-blind, randomized trial.*"[12]the authors evaluated the use of a single PRP injection vs. two injections of PRP vs. a simple saline injection. The result revealed that a single injection could provide similar results compared to 2 injections. Complications were very transient including brief experiences of dizziness, and nausea noted in the treatment groups. However, in a study conducted by Sampson et al. in the American Journal of Physical Medicine and Rehabilitation in 2010 there were no adverse reactions reported.[13] Our experience is that there are little to no adverse reactions and we have been using this technology since 2005 in over 4,000 patients.

Efficacy of the Treatment: Score: +++

There have been numerous studies evaluating the positive effects of this treatment for arthritis of the knee. A few worth reviewing include "*Platelet-rich plasma: intra-articular knee injections produced favorable results on degenerative cartilage lesions*." by Kon and colleagues[14] They looked at 115 patients treated with 3 PRP injections and followed up at 6 and 12 months. A statistically significant improvement of all clinical scores was obtained from the base line evaluation to the end of the therapy and at 6-12 months follow-up ($P < 0.0005$). They concluded *" The preliminary results indicate that the treatment with PRP injections is safe and has the potential to reduce pain and improve knee function and quality of live in younger patients with low degree of articular*

---

[12] Patel et al. *Treatment with platelet-rich plasma is more effective than placebo for knee osteoarthritis: a prospective, double-blind, randomized trial.* American Journal of Sports Medicine 2013 Feb;41(2):356-64.

[13] Sampson S et al. *Injection of platelet-rich-plasma in patients with primary and secondary knee arthritis: a pilot study*. American Journal of Physical Medicine and Rehabiliation (2010 Dec;89(12):961-9.

[14] Kon et al. *Platelet-rich plasma: intra-articular knee injections produced favorable results on degenerative cartilage lesions*. Knee Surgery Sports Traumatology and Arthroscopy, 2010, April; 18(4):472-9.

degeneration." One other study by Filardo[15] was a retrospective study of 90 patients treated with three injections of PRP into arthritic knees at 24 month follow up. All of the parameters at the 24-month period improved including the IKDC subjective and objective parameters for a median length of improvement for over 9 months. If we compare PRP to hyaluronic injections (ie Supartz), PRP patients tend to have better pain and function scores. A great review article entitled "*The effects of platelet rich plasma in the treatment of large-joint osteoarthritis: a systemic review.*"[16] compared 13 studies of hyaluronic acid to PRP. Twelve of these were for knee arthritis. All the studies revealed that PRP had statistically significant benefit in knee osteoarthritis compared to hyaluronic acid. Although most of these studies utilized 3 separate PRP injections, a few have shown that one injection is effective. One study conducted by Torreo in 2012 found that one injection of PRP was effective in reducing pain.[17]

Convenience of this procedure: Score: ++++
This is all done in one simple 30 minute or less office visit. The blood is drawn and processed within 15 minutes and injected into the affected area. You can resume your normal activities the day of the injections within reason. Nobody is needed to drive you home or stay with you during this treatment.

Pain Associated with this Procedure: Score: +++
Sometimes you can experience some pain with the drawing of the blood but not usually more than another other blood draw. The injection into the joint is not any more painful than other injections and if pain occurs, it is normally for just a few minutes.

Cost: Score: +++
Most insurance plans do not cover these injections and the cost for these on a national average is between $600 and $1000 per injection. Advanced Orthopedic Specialists offer these starting at **$500/injection**. Many patients chose the PRP Plus option which provides a higher concentration of important plasma proteins resulting in improved results. These expenses may be reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details.

---

[15] Filardo G et al. *Platelet-rich plasma intra-articular knee injections for the treatment of degenerative cartilage lesions and osteoart*hritis; Knee Surgery, Sports, Traumatology, and Arthroscopy; 2010 Aug 26

[16] Teitze DC et al *The effects of platelet rich plasma in the treatment of large-joint osteoarthritis: a systemic review. Physiology and Sports Medicine 2014, May; 42(2) 27-37.*

[17] Torrel JL. *Treatment of knee chondropathy with platelet rich plasma. Preliminary results at 6 month follow up with only one injection*. J Biolo Regul Homeost agents. 2012 June 26 (2 Suppl) 71s-78s.

Bone Marrow Concentrate Stem Cell Injections
What are they?

Our body stores cells required for repair within specific areas of our body. One such area is within your bone marrow. This is the space within the middle of your bone rich in cells used to regenerate damaged cells. Some of the stem cells found in this space are progenitor cells. These are matured stem cells used to repair damaged tissue such as bone and cartilage. **Progenitor stem cells** may be more efficient than normal stem cells found in your blood at repairing bone and cartilage but have lost some of their ability to form all different types of tissue. [18] Think of progenitor cells as stem cells that are more mature and like a young man in college majoring in biochemistry. They are bigger, smarter and more efficient than their younger stem cell cousins in elementary school. These younger cousin cells have the potential to mature into different cell lines, but we only need them to mature into bone and or cartilage cells. Thus, these progenitor stem cells are perfect for orthopedic conditions. Although other tissues in our body may have a higher number of stem cells, they are less likely to form the cells and tissue we need.[19] Many of the same growth factors found in **platelet rich plasma** are found abundantly in your bone marrow. Specific stem cells called **pericytes** which support our vascular system are found within our bone marrow and they become important in the **paracrine cell to cell communication**.[20] When our joints become diseased, this cell to cell communication breaks down and bone marrow derived stem cells as well as other factors help restore this normal communication. Finally, very important **plasma proteins** are found within your bone marrow including Intrluleukin-1 Receptor Antagonist Protein (IRAP) and Alpha 2 Macroglobulin (A2M).[21] These plasma proteins are extremely important in reducing the destruction of your bone and joint.[22] These very important

---

[18] Levesque JP et al, Mobilization of Bone Marrow Derived Progenitors, Bone Marrow Derived Progenitors, Springer Berlin, 2007, p 4-28.
[19] Danisovic L et al, Comparison of in Vitro Chondrogenesis Potential of Human Mesenchymal Stem Cells Derived from Bone Marrow and Adipose Tissue, Gen Physiol Biophys, 2009 March, 28 (1) 56-62.
[20] Caporali A et al, Contribution of Pericyte Paracrine Regulation of the Endothelium Angiogenesis, Parmacol Ther. 2016, Oct 11, 30179-6.
[21] Weng S et al, Identification of a2-macroglobulin as a master inhibitor of cartilage-degrading factors that attenuates the progression of post traumatic osteoarthritis, Arthritis Rheumatol. 2014 Jul: 66(7) 1843-53
[22] Dinarello, CA et al, Treating inflammation by blocking interleukin-1 in humans; Semin Immunol. 2013 Dec 15 25(6) 469-84.

proteins can be filtered and concentrated to help reduce damaging chemical reactions in your joint which cause destruction and pain.

Bone Marrow Concentrate Stem Cell treatments can provide the following:

- Source of stem cells such as pericytes, and progenitor cells to help repair damaged tissues especially bone and cartilage cells and help cells communicate with each other.
- Platelet Rich Plasma (PRP) which provides important growth factors to help in the repair process.
- Plasma Proteins found in your bone marrow to reduce harmful chemicals in your joint.

How Does this Work?

You will have the area over the front or back of your pelvis numbed with a local anesthetic like what you receive at the dentist. In addition, we provide you with medications to relax you. A specially designed needle is than used to enter the middle of your pelvic bone to remove the bone marrow concentrate. This concentrate is than processed in a sterile manner to further concentrate the progenitor, stem and pericyte cells as well as the platelet rich plasma into a fibrin material that is injected directly into the area of concern. These regenerative cells work on numerous biochemical pathways in your joint to help reduce pain and inflammation as well as increase cell-to-cell communication (paracrine signaling) resulting in improved function of the joint over a 3-4 month period. The pathways and mechanism of how this occurs is still debated, and very complex, but one possible theory could be:

- **Restorative Phase**- The bad, destructive chemicals within the joint are reduced. Interleukins and cytokines causing chronic destruction to the joint are reduced to restore a normal balance.
- **Communicative Phase-** Cells that have lost their ability to communicate with each other are now restored and this cell to cell communication causes a paracrine event. The cell function is restored so the joint can function in a more normal manner.
- **Regenerative Phase-** Once the chronic destructive phase is reduced to a manageable level, and the cells begin to talk with each other and restore normal lines of communication, the joint can begin to function like a normal organ just like a kidney, brain or heart. Once these necessities for growth are established, the cells can start to regenerate. However, the actual number of cells regenerated may be minimal in comparison to the changes occurring with the restorative and communicative phase.

Ideal Candidate:

Although this is not a complete list, it is a general guideline to help you understand whom may be the ideal candidate for this procedure. You and your surgeon will always find exceptions since not every patient responds the same to each treatment:

- Patients looking for longer term pain relief of 4 or more years.
- Diagnosed osteoarthritis of the joint.

- Stable joint with giving away, locking or instability not occurring more than 2 times per week.
- Lack of severe bowing of the joint (less than 8-10 degrees of bowing)
- Lack of frequent severe joint swelling requiring needle aspirations (removing water from the knee)
- Lack of severe stiffness of the joint with range of motion within 20 degrees of normal motion.
- Willing to participate in additional therapies to improve the health of the joint

Safety of this procedure: **Score: ++++**
This procedure has been used for many years with a very good safety record. Laula MM and colleagues reviewed all the clinical trials using intravascular stem cell therapy in humans through the national database, and found that in over 1012 participants, they did not detect any association between acute toxicity, organ system complications, infection, death or malignancy and the only adverse event was transient fever.[23]

Another researcher reviewed over 1873 patients from 1990 to 2006 who received autologous bone marrow stem cell therapy at the University of Paris and concluded that there was no risk of cancer or cancer formation. In fact, he found that the normal rate of cancer in this patient population reduced from an expected number of 97 to 108 cases down to 58 cases. Thus, the actual rate of cancer in these treated patients was lower than expected.[24]

A long term, retrospective study conducted by Mendoca[25] injecting Bone Marrow Concentrate (BMC) into 14 patients with spinal cord injury. All subjects displayed variable improvements in tactile sensitivity, and eight subjects developed lower limbs motor functional gains, principally in the hip flexors. Seven subjects presented sacral sparing and improved American spinal injury association impairment scale (AIS) grades to B or C - incomplete injury. Nine subjects had improvements in urologic function. Statistically significant correlations between the improvements in neurological function and both injury size and level were found. Most importantly, *no adverse events occurred in this sensitive procedure.* In another meta-analysis (a review of numerous studies) of 78 studies using bone marrow derived stem cell therapy for cirrhosis of the liver

---

[23] Lalu MM et al, Safety of Cell Therapy with Mesenchymal Stromal Cells (SafeCell): A systemic Review and Metanalysis of Clinical Trials. PLoS One. 2012 Oct 25 7(10) e47559.
[24] Herniguo P et al, Cancer risk is not increased in patients treated for orthopedic disesases with autologous bone marrow concentrate. J Bone Joint Surg Am, 2013 Dec 18: 95(24) 2215-21.
[25] Mendoca et al *Safety and neurological assessments after autologous transplantation of bone marrow mesenchymal stem cells in subjects with chronic spinal cord injury*. Stem Cell Research and Therapy, 2014 Nov 17;5(6):126.

concluded that there were no adverse events or complications.[26]Thus, we can see from this short review that there have been little to no adverse events with this treatment and it is a very safe procedure.

Efficacy of Treatment: Score: +++

Overall, most of the studies evaluating the use of this treatment have been encouraging but not conclusive. One such study is the use of bone marrow concentrate (BMC) injection compared to an orthopedic surgery used to grow cartilage cells in a culture and re-implant these into a surgically created pouch in the damaged joint called Autologous Chondrocyte Implantation (ACI). The ACI procedure requires two invasive surgical treatments and prolonged rehabilitation. On the other hand the bone marrow concentrate only required the simple injection to the knee without any significant pain or rehabilitation. Seventy-two (72) patients were in each group and both groups improved in all parameters. Interesting enough, only patients younger than the age of 45 improved with the ACI surgery. However, **age did not alter results in patients receiving the bone marrow concentration**.[27]Another study evaluating the use of bone marrow concentrate in combination with a procedure that straightens the knee (called a high tibial osteotomy or HTO) revealed some encouraging results. Seventy-six (76) patients were split into two groups. The first group received the standard joint straightening procedure (HTO) along with a micro-fracture technique (holes placed in the bone to stimulate cartilage-like formation) to help repair the damaged cartilage. The second group had the same HTO procedure but they added culture expanded bone marrow cells to the knee. They were followed for 2 years and had a follow up MRI. The bone marrow group had statistically significant improvements in all the measurement scores including improvements of the cartilage as seen on the MRI scans.[28] Another orthopedic surgeon in Colorado has used a technique of culture expanded bone marrow cells (meaning these were grown in a lab) and then re-injected into the knee. In a single case study report, the researcher could show an improvement in clinical outcome with improvements seen on follow up MRI of the knee.[29] Further *in-vitro* studies (Latin for "in glass") which is

---

[26] Pan XW. *Bone Marrow-derived mesenchymal stem cell therapy for decompensated liver cirrhosis: a metal-analysis.* World Journal of Gastroenterology, 2014 Oct 14;20(38):14051-7.

[27] Nejadnik H. et al *Autologous bone marrow-derived mesenchymal stem cells versus autologous chondrocyte implantation: an observational cohort study*. American Journal of Sports Medicine 2010 Jun;38(6):1110-6

[28] Wong, KL. et al *Injectable cultured bone marrow-derived mesenchymal stem cells in varus knees with cartilage defects undergoing high tibial osteotomy: a prospective, randomized controlled clinical trial with 2 years' follow-up*. Arthroscopy 2013 Dec;29(12):2020-8

[29] Centeno CJ *Increased knee cartilage volume in degenerative joint disease using percutaneously implanted, autologous mesenchymal stem cells*. Pain Physicians, 2008 May-Jun;11(3):343-53

studying cells outside their environment revealed that bone marrow cells can differentiate into cartilage cells better than adipose derived cells.[30]

Convenience of this Procedure: Score: ++++
This procedure is done in the office setting within 30-60 minutes. You may require someone to drive you home if you choose to use an oral sedative for the procedure. You can resume all your normal activities within reason the day of the procedure. There is no need for time off work and there are limited follow up visits. We do ask most patients to perform simple home exercises to help heal the joint. Other patients are encouraged to use a brace for 3 months. Patients who require conscious sedation or a general anesthetic in a surgical center for a more extensive procedure such as an arthroscopic treatment of a meniscus tear or placement of stem cells within the bone next to the cartilage, may require the use of a walker or crutches for one week. To help expedite your recovery, we also provide you with a special pre-conditioning treatment. This helps to increase the number of active stem cells in your bone marrow and prevent the sequestration (trapping) of stem cells within your spleen. Finally, we offer the option of using an antibiotic called doxycycline to help prevent damage to the growing cells. The pain relief from this procedure may not occur until 3 months, and patients with severe arthritis may take 4 or more months.

Pain of this Procedure: Score: ++
There is minimal pain associated with this procedure. Some people may have some soreness around their pelvis along with some bruising for up to a week. You are provided with pain medication if needed for the procedure. There is minimal if any swelling or pain to the joint injected.

Cost: Score: ++
No insurance plans currently cover this procedure. There are no procedure codes which can be reported to your insurance carrier. Thus, you will be presented with an Advanced Beneficiary Notice of Noncoverage otherwise known as an ABN. This means that we cannot and will not bill your insurance carrier for the non covered procedure. We cannot contact your insurance company about coverage since there are no known procedure codes. However, these expenses **may be** reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). The current complete cost of this procedure can start at $2,750 for one joint and prices can change. Comparison to other centers throughout the country reveals that price varies between $2,000 to $4,500 for a single joint and $5,000 to $6,000 for two joints. The cost of this procedure covers the harvesting, processing and delivery of the cells. This does not include normal office visits including x-rays, co-pays, or additional therapies. When considering price comparisons, please realize the following:

---

[30] Dansovic L, *Comparison of in vitro chondrogenic potential of human mesenchymal stem cells derived from bone marrow and adipose tissue*. Gen Physiol Biophys 2009 Mar;28(1):56-62.

- *To ensure a positive outcome, our procedure includes an additional single PRP injection **if needed** with our more advanced treatment package. Many of the other centers charge an additional $500 to $1500 for just one PRP. This is provided at no extra cost with our more advanced packages.*
- Our advanced stem cell packages also include plasma proteins such as A2M and Interleukin 1 receptor antagonist (IL-1ra) which many centers do not offer, or they are a hidden charge. These are very important in reducing the destructive process in your joint. Many other centers discard these proteins into the trash, but we have found that they are very important to the success of your treatment. This is normally an additional charge of $600 to $1200 at many other centers.
- We have the most experience in recognizing the most appropriate patients for these treatments as well as the most advanced harvesting, processing and delivery of these cells with over 12 years of experience and over 4,000 patients treated with all forms of cell-based therapies.
- The process we use can increase the number of harvested cells by over 300% from normal harvesting techniques, and we can capture over 90% of the important cells where many other systems capture a maximum of 50%.
- We provide a comprehensive evaluation and treatment for your arthritis including our **Ten Steps to Healthy Joints**.
- We have developed easy to follow pre-and post procedure protocols which help ensure a positive outcome.
- These expenses **may be** reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details. Deferred payment plans are available is you are interested. Our surgical scheduler can provide you with the details of this simple plan.

How long will these treatments last?

Patients rightfully ask this question. Here is some evidence to show that this is not a short-term solution, but hopefully a long-term solution. First, many of the studies above show results at 2 years and some as short as 6 months. However, this does not mean that the treatment stopped working at this interval. This merely means that the study was designed to stop at this point. If you look at some of these studies, there are some promising results showing positive structural reversal of the arthritic disease. For example, Koh et al in his arthroscopic second look study revealed reversal of the arthritic changes on visual inspection of the knee through arthroscopy. This finding was confirmed by the South Korean dosing study.[31] In addition, Khanh Hong-Thien Bui and colleagues found positive structural changes on serial MRI's. [32] Thus, we can conclude

---

[31] Koh YG et al, Mesenchymal stem cell injections improve symptoms of knee osteoarthritis. Arthroscopy, 2013 Apr; 29(4) 748-55.

[32] Khanh Hong-Thien Bui et al , *Symptomatic knee osteoarthritis treatment using autologous adipose derived stem cells and platelet-rich plasma: a clinical study*, Biomedical Research and Therapy, 2014 (1):02-08

that this is not just a band aide type of treatment, but this evidence helps point us in the direction of positive reversal of the underlying destructive process of arthritis. This is unlike many other current treatments available in orthopedics.

Some more recent studies from Iran show further long term success. Eighteen patients were treated with a bone marrow concentrate in multiple joints including knee, ankle and hip and followed for **30 months** with careful laboratory, radiographic and MRI studies. The research team reported that "All" patients received therapeutic benefits confirmed by pain and function scores and were confirmed by MRI.[33] Researchers at the University of Paris followed 534 patients up to **18 years** after a bone marrow stem cell treatment for avascular necrosis of the hip which is an arthritis caused by the lack of blood supply to the hip. This long-term study revealed that only 15.7% of the patients went on to receive a total hip after this treatment and many of the x-rays and MRI's of the hip stabilized.[34]

Phillipe Hernigou, MD from the University of Paris recognized the shortcomings of joint replacement as well as the benefits of bone marrow derived stem cell therapy and decided to compare the two treatments in some well-designed long term studies. He first looked at using this treatment for young patients who traditionally required joint replacement for a devastating type of arthritis of the knee called avascular necrosis. This is a condition where the blood supply to the bone around the knee is diminished and the result is death of the bone and cartilage. This normally occurs in younger patients during the third and fourth decades of life. The thought of replacing a knee in such a young group is concerning since most joint replacements have a limited life expectancy and younger patients will have multiple joint surgeries in the future. Thus, his research team decided to evaluate the use of autologous bone marrow derived stem cell therapy injected into the diseased bone near the joint to treat this condition and compare it to traditional joint replacement in the same patient. Thirty patients with an average age of 28 were randomized to receive a stem cell replacement to one knee and a joint replacement to the other knee. The randomization process eliminated bias in selecting the less severe knee for one specific treatment. All the patients were followed for an amazing **12 years of average follow up (range 8-16 years)**. MRI's were performed prior to the surgery and at 24 months, 5 years and at the last follow up visit. X-rays were also reviewed and compared to the initial study. Samples of bone marrow were taken at specific sites in the arthritic knee as well as the pelvis where the bone marrow was harvested. The surgical procedure to replace the knee took an average 1.5 times longer than the entire stem cell procedure on the other knee. After the surgery, patients reported a higher rate of blood clots on the side which received the knee replacement (15% vs. 0%). At last follow up, six of the thirty knees (20%) with the knee replacement required another surgery while only three of the stem cell knees (10%) required a knee replacement but at longer periods

---

[33] Emadedin M., et al, Long-Term Follow up of Intra-articular Injection of Autologous Mesenchymal Stem Cells in Patients with Knee, Ankle or Hip Osteoarthritis, Arch Iran Med. 2015, Jun;18(6): 336-44

[34] Hernigou, P, et al, Cell Therapy of hip necrosis with autologous marrow grafting , Indian J Orthop.2009 Jan-Mar; 43(1): 40-45

out of 6, 8 and 12 years from the stem cell procedure. The patients recorded their satisfaction with each knee. The knee replacement group had 8 of 30 (26%) reporting excellent pain relief and the stem cell side reported 4 of 30 (13.3%), but there were a much higher number of patients in the poor pain relief after the knee replacement with 4 out of 30 (13.3%) and only 1 out of 30 (3%) from the stem cell side. **Most importantly though when patients were asked to point to the knee they preferred more, 21 of 30 (70%) pointed to the stem cell side!** When Dr. Hernigou evaluated the sequential MRIs of the stem cell treated knee, they found that there was an increase in cartilage volume as well as a significant decrease in the size of the bone marrow lesion (BML) which is a marker of pain. Even when some of the stem cell knees required a joint replacement, sampling of the bone and cartilage revealed that the patients who had a poor response still had an average 45% increase in bone mass and required a less invasive type of knee replacement than the other side. In addition, none of the stem cell knees that required a knee replacement required further surgeries. [35]

Dr. Hernigou's team also looked at treating the very elderly with the same treatment. We have a "white paper" result from a very interesting long term study comparing bone marrow stem cell therapy to our traditional total knee replacement in elderly male patients. A white paper is a study which is not yet published and thus it has not been peer reviewed and one must be careful in using this data because it has not yet been validated. However, this same researcher has published hundreds of peer reviewed studies and is a very respectable source. This study took 60 elderly male patients all 80 years old or older. Group A was treated with the standard total knee replacement for both knees. Group B was treated with the bone marrow stem cells to both knees injected directly into the bony part of the knee next to the joint. Group C had one knee injected with the stem cells and the other knee replaced. After an average of 6 yrs. (ranging from 2 to 15 yrs.), the patients in Group B (stem cell group) had the following:

- **Improved knee function scores (Knee Society Scores)-** 16.3-point improvement for the stem cell group vs. only an 8.9-point improvement for total knee group.
- **Faster Functional Recovery**- At 9 months, the stem cell group had faster recovery than the total knee group.
- **Lower Complication Rates**- Blood clots occurred in only 2% of the stem cell group compared to 12% in the knee replacement group. None of the stem cell patients required a blood transfusion, and 29.3% of the total knee group required blood transfusions. Higher use of analgesic medications such as narcotics were used in the total knee group.
- **Lower Re-operation Rate**- Only one of the stem cell patients required further surgery or conversion to a total knee. However, 5% of the total knee patients required further surgery.
- **Higher Overall Satisfaction**- In Group C, when patients were asked to point to

[35] Hernigou P, Auregan JC, Dubory A, Flouzat-Lachaniette CH, Chevallier N, Rouard H. Subchondral stem cell therapy versus contralateral total knee arthroplasty for osteoarthritis following secondary osteonecrosis of the knee. Int Orthop. 2018 Mar 27. doi: 10.1007/s00264-018-3916-9. PubMed [citation] PMID: 29589086

the knee which they preferred, 70% of the patients pointed to the stem cell therapy knee.

So, it is very interesting that Dr. Hernigou has been able to demonstrate that cell based treatments help the two most vulnerable populations affected by arthritis of the knee. Both the very young and the very old may benefit from this treatment with superior safety, efficiency and patient satisfaction.

A large multi-national, multi-center study evaluating patients of all ages with all levels of severity gives us some further evidence that this is a longer term treatment for arthritis. In the study by Michalek J, et al. entitiled "*Autologous adipose tissue-derived stromal vascular fraction cells in patients with osteoarthritis*,"(Cell Transplant, 2015 Jan 20. doi: 10.3727)[36] followed 1128 patients for up to 54 months (over 4 yrs). A majority of these patients (63%) had at least 75% improvement of pain and function and 91% had at least 50% improvement. However, obese patents and patients with more severe arthritis took longer to respond. This is one of the largest and longest term study showing promising positive results in the longer term. Our own experience confirms this result. Our own unpublished evaluation of pain and function using a visual analog scale and the WOMAC on hundreds of patients receiving a similar procedure for over 4 years reveals similar results with an excellent safety profile and no serious adverse events.

Most of these studies are not controlled, blinded, or randomized, but they do show a common pattern of:

- This is a safe procedure with very low rates of complications
- Consistent reduction of pain.
- Consistent restoration of function.
- High rate of patient satisfaction.
- Improved MRI or physical findings (microscopic or arthroscopic).

Is there one single solution for my arthritis?

Every patient is a unique individual with special and specific conditions. Thus, one single treatment does not fit every patient. A clear majority of patients require a combination of the options presented above. So, don't feel you must pick just one.

For example, many patients present with mechanical symptoms of their joint such as giving away, locking and catching more than 2 times per week. This indicates a symptomatic meniscus or ligament tear in addition to their underlying arthritis. Thus, both conditions need to be addressed. Normally, this may require an MRI to evaluate the joint for this condition and possibly a simple, outpatient arthroscopic surgery to remove the damaged tissue causing these symptoms. At the time of this procedure, a cell based therapy can be performed to also address the underlying arthritis of the joint. In addition,

---

[36] Michalek J et al., *Autologous adipose tissue-derived stromal vascular fraction cells in patients with osteoarthritis*, Cell Transplant, 2015 Jan 20. doi: 10.3727

some patients have severe inflammation of the joint which is now penetrated in the bone adjacent to the cartilage. Ignoring this condition, may lead to persistent pain and swelling to the joint. A simple arthroscopic and fluoroscopic (meaning placed by x-ray of the joint) placement of the stem cells into this area of the bone may be required.

In addition, we strongly encourage and coach you through our **Ten Steps to Healthy Joints** program which emphasizes a comprehensive and holistic approach to your joint pain. This normally starts out with some goal setting exercises followed by weight control strategies; proper and health exercise, nutrition, shoe wear, bracing and continual monitoring and coaching.

Although this plan may be overwhelming, we have attached an **Arthritis Decision Sheet** to help you understand what we found and what plans may work the best for you.

To help you make your decision, we have put together two simple charts. Chart 1 compares all the components discussed above. Chart 2 compares some of the most common concerns of patients such as number of office visits, recovery time, need for therapy. pain and cost. We rate each section on a scale of 0-4 + under each column. More + indicate more pain, more inconvenience, less safety and less efficacy. A maximum score of 4 ++++ indicates that this procedure has LESS pain, more convenient, better safety and better efficacy. So, in summary, the more + next each segment, the improved rating.

Treatment	Safety	Efficacy	Convenience	Pain	Cost
Arthroscopy	+++	++	++	+++	++
Joint Replacement	++	++++	+	+	++
Steroid Injections	+++	++	++++	+++	++++
Hyaluronic Injections	+++	++	+++	+++	+++
PRP Injections	++++	+++	++++	++++	+++
Bone Marrow Concentrate	++++	++++	++++	+++	++

Treatment	Office visits	Recovery	Therapy	Pain	Cost
Arthroscopy	**3 visits**	**7-10 days**	**Home Exercise**	**Narcotics 3-7 days**	**$3,675 ***
Joint Replacement	**8 visits, 3 pre-op , 5 post op**	**3 wks to 3 mo**	**6 – 8 weeks (12 to 24 visits)**	**Narcotics 3 - 6 weeks**	**$35,000 ***
Steroid Injections	**1**	**1 day**	**None**	**None needed**	**$120-140***
Hyaluronic Injections	**3 to 5**	**1 day**	**None**	**None needed**	**$100 to $325/ea***
PRP Injections	**1**	**1 day**	**None**	**None needed**	**$500 ** **
Bone Marrow Concentrate	**1**	**1 day**	**Home exercise**	**Tylenol or narcotics 1-2 days**	**$3,995 ** **

*denotes- this a normally covered benefit in most insurance plans. However, this does not include co-payments, co-insurance, deductibles, and other services not covered, but provided with the procedure such as medications, anesthesia, and durable medical equipment.

-denotes-these expenses **may be reimbursable through qualified Health Spending Accounts (HSA), Flexible Spending Account (FSA), Medical Savings Account (MSA), or Health Reimbursement Arrangement (HRA). Please contact your plan administrator for details. The cost quoted includes the cost of the procedure only. This does not cover follow up visits, x-rays, therapy and the need for further treatments.

revised egl 5-24-18

Arthritis Decision Sheet

Based on the information you provided and the information we obtained during your examination and review of your studies, we have suggested the following treatments. The priority of our suggestions is numbered next to each option. For example, a #1 in the box next to stem cell procedure means we feel this is your best option. The list of reasons does not mean that you have each reason, this only gives the most common reasons. Each patient is unique and special and thus, not every patient will fit within each recommended treatment. This is not a final decision since every patient may change and new symptoms or findings may occur in the future:

- **Joint Replacement**- due to the following issues, your joint should be replaced:
  - Angle of your joint on x-rays is severe
  - Subluxation of your joint on x-rays
  - Dysplasia or Chronic Impingement (deformed or pinching joint)
  - More than 20 degrees loss of motion
  - Severe swelling of the joint more than 4 x year
  - Giving away more than 2 x week
  - MRI findings :
    - Avascular necrosis with collapse
    - Large Meniscal, Ligament or Labral tears
- **Arthroscopy Followed by Bone Marrow Stem Cell or other treatments:** This is used to treat issues related to instability or inflammation under the bone first as well as treating the arthritis.
  - Angle of joint under 8º to 10º from normal alignment of the joint.
  - Range of motion within 20º of normal
  - No Subluxations noted on standing x-rays
  - Giving away more than 2 times/week
  - Reproducible symptoms of meniscus tear or mechanical issues
  - Tight knee cap with tilting.
  - MRI:
    - Meniscal tear or loose body
    - Signs of bone swelling and inflammation without collapse of the joint.
- **Bone Marrow Stem Cell –** This is an in-office treatment.
  - Angle of joint under 8º to 10º from normal alignment of the joint.
  - No subluxations noted on x-ray.
  - Limited or no giving away (less than 2 x week)
  - Stable joint on exam
  - Range of motion within 20º of normal
  - MRI reveals arthritis with only small, asymptomatic, tears and/or bone marrow swelling.
  - High Risks for surgical treatment
    - Bone or Joint infections
    - Blood clot history
    - Overweight (BMI above 40)

        - Chronic pain with use of narcotics
        - Treated Diabetes
        - Depression
        - Hepatitis or Liver Dz.
        - Kidney dz.
    - Unable to take off at least 2 weeks from work
    - Unable to have family or friends provide 2 weeks of care
    - Unwilling to accept risks and required therapy of surgical treatments
- **Platelet Rich Plasma (PRP) or PRP Plus**
    - Angle of joint under 8º to 10º from normal alignment of the joint.
    - Mild to Moderate arthritis on x-rays.
    - Stable joint on exam and history
    - Range of motion within 20º of normal
    - High Risks for surgical treatment
    - No MRI Evidence of large meniscal/ligament tears, loose bodies, avascular necrosis or bone marrow swelling.
    - Not using or can stop using Coumadin or Plavix or other blood thinners
    - Able to stop anti-inflammatories for 2 weeks.
    - Failure of other conservative measures.
- **Hyaluronic Acid (i.e. Supartz™) injections**
    - Stable joint on exam and history
    - High risk for surgical treatment
    - Unwilling or unable to have surgical treatment
    - Able to report back for 5 injections one week apart.

Obviously, this is only a suggestion. Symptoms and findings can change over time. This is also a team decision and if you or your family decide on a choice different than these suggestions, we can always re-evaluate your condition.

In addition, we strongly encourage and coach you through our "Ten Steps to Healthy Joints" program which emphasizes a comprehensive and holistic approach to your joint pain. This normally starts out with some goal setting exercises followed by weight control strategies; proper and health exercise, nutrition, shoe wear, bracing and continual monitoring and coaching.