



**Oklahoma Joint
Reconstruction Institute**
Paul B. Jacob, DO

Informed Consent Packet

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Board Certified and Fellowship Trained Orthopedic Surgeon
Specializing in Advanced Reconstruction of the Hip and Knee*

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Oklahoma Joint Reconstruction Institute

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Dear Patient,

Welcome to Oklahoma Joint Reconstruction Institute. This informed consent packet of information is intended to help you understand your risks and to provide informed consent for your upcoming surgery. Please review all information and write down any questions you have. You may call, email, or bring them to your next visit, and we will discuss them.

You will receive information notifying you of the dates and times of your pre-admission testing and pre-operative clearance appointments. During your pre-operative routing, you may request an education visit where you can ask any and all questions that may arise after reviewing this packet. You will also have the opportunity to attend a joint replacement education class taught by our nurse educator. This class will provide you with detailed information with regards to your surgical experience. This education class is offered free to you and your family and friends. You may attend the class as many times as you would like. This class is also available to you online through my website.

You will be provided with a *written educational booklet* and will be offered the **Joint Coach** and **MotionSense apps** to assist you in your preparation for your upcoming surgery. This packet and the apps include itineraries which provide information about your pre-operative preparation, what to expect on the day of surgery, your hospital stays, and your post-operative recovery. You will be sent home with written discharge instructions in regard to your incision care, physical therapy, and my rapid recovery program.

We realize this is a great deal of information to obtain at one time and a significant decision to make. Please do not hesitate to contact the office any time if you need assistance.

The following information is included in this Document:

- 1) **Informed Consent for Surgery**
- 2) **Informed Refusal for Surgery**
- 3) **Informed Consent for Patient Imaging**
- 4) **Informed Consent for COVID Risk**
- 5) **Informed Consent for Remote Patient Monitoring**
- 6) **Informed Consent for Telehealth**
- 7) **Informed Consent for Metal Allergy Testing**

Sincerely,

Dr. Paul B Jacob D.O., MSPT, FAAOS
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Informed Consent for Surgery

The surgical treatment of disorders of the hip and knee (including the related bones, joints, muscles, nerves and other structures) carries with it a degree of risk that you, your family, and / or parent or guardian should be aware of before you sign below. The following risks and complications are rare, but despite our best efforts to eliminate their occurrence, they can happen. In order to achieve the best possible outcome and to minimize these complications, I **urge you read this completely and to follow my recommendations**, including the prescribed pre- and post-operative instructions and physical therapy. The following is a description of some, **but not necessarily all**, of the possible complications of surgery and their effect on your outcome.

Risks of Anesthesia

You will meet with the anesthesia team prior to your procedure and they will review the risks of undergoing anesthesia, and the types of anesthesia that can be selected for your procedure. General or Regional anesthesia are the options for the procedure and local blocks will be added by your surgeon in addition to the main anesthesia, to reduce post-operative pain. All procedures small and large, can be complicated by heart, lung, neurologic, and/or vascular complications including death, despite the best planning and most meticulous surgery. Every effort will be made to reduce the risk of any complications for your procedure.

Alternatives to joint replacement surgery

Although you are a candidate for joint replacement, alternatives do exist that may help you manage your symptoms for as long as possible. These include but may not be limited to weight loss, activity modification, over the counter and prescription medications, physical therapy, exercise, injections, never ablations, bracing, less invasive surgical procedures, and the use of walking aides. If at any point you would like to discuss any of these alternatives, please let us know.

Allergic and other troublesome reactions and side effects to drugs and blood administration can occur.

These side effects and reactions to drugs, blood and other substances can develop in anyone. While usually minor and transient, they can be more serious, occasionally permanent, and rarely, even fatal. All medicines and substances prescribed for you are given only if the anticipated benefits are felt to outweigh the risks associated with taking them.

Bleeding/Bruising/Leg Swelling/Bursitis/Tendonitis

These findings can be the direct result of surgery and are not complications, but temporary effects of the nature of surgery. These findings are self-limiting if present and vary in amount from patient to patient. Some incisions will have bloody drainage in small amounts for a few days and should be monitored closely until this has stopped. Elevation of the operative leg to heart level for the first several weeks when not walking can reduce the swelling in your leg. The use of ice packs or cooling sleeves on the knee, isometric exercises, and lymph massage of the legs will also reduce swelling.

Renal and urinary tract complications

Disorders of the kidneys, urinary tract and bladder, leading to disturbed function or abnormal urination and/or infection can occur.

Internal organ complications

Disorders of the digestive system, including stomach and intestinal ulcers with bleeding, distention, obstruction and perforation, liver infections and inflammation (hepatitis), and stones in various organs and systems such as the kidney and gall bladder, have also been observed as well as flare up of gout and prostate problems.

Cardiac complications

Disturbances of the heart, including abnormal beat and function can occur, as well as heart attack, with serious and rarely, even fatal consequences.

Lung complications

Pneumonia (infection of the lung), collapse of all or part of the lung, with pulmonary edema (fluid in the lungs) may occur and can have serious and rarely, even fatal consequences. To avoid pneumonia and lung complications it is important to cough and take deep breaths after surgery to expand the lungs. You should perform deep breathing exercises a few times an hour while awake after surgery to reduce your risk of pneumonia. While at home, you need to consciously take good slow deep breaths to expand your lungs fully and follow the incentive spirometry instructions in your discharge instruction packet.

Changes in mental function, confusion and even a stroke can occur.

Mental changes and confusion usually improve, clearing completely after some time, but if a stroke occurs it is likely to have some permanent effects.

Blood Loss

Some blood loss is expected after surgery. The amount associated with this technique does not commonly require transfusion. In the unusual event of significant blood loss, your symptoms, medical conditions, and lab results would be evaluated to determine further treatment. Major blood vessel injury is extremely uncommon. In the event of such a situation, all appropriate treatments would be provided as would be medically necessary.

Nerve and blood vessel injury

Nerve and blood vessel damage may result as a consequence of mobilization of joint structures or operating near a nerve or blood vessel itself. Nerves may be stretched, compressed, damaged or even cut in the process, which may result in weakness or paralysis. This is more of a risk during revision surgery or when congenital deformities, contractures, other limb deformities and shortening of the limb are present. The damage may be transient with return of some or all function, but it could be long lasting or permanent. Paralysis may involve partial or complete loss of sensation, muscular function and movement of the part of the body that is involved. Numbness, tingling, burning and pain may occur. The recovery process may be prolonged depending on the extent of damage and the nerve involved.

Skin numbness

A common side effect but not a complication of any skin incision is that the skin just to the side of the incision will become numb, tingly, more sensitive, or feel different after surgery. The area affected commonly shrinks in size and stabilizes by 12-24 months.

Wound, joint and bone infection.

Blood may collect in the wound after surgery and may leak through the skin, requiring evacuation. Re-operation may be needed to clean the bone and joint. If a joint replacement was performed, the prosthesis may need to be removed for an extended period of time or even permanently, to allow the infection to heal. In most cases, after an infection is successfully treated with antibiotics and surgery, a prosthesis can then be re-implanted. This can result in a stiff and painful joint. If massive infection occurs and it cannot be treated successfully, the bones of the joint may need to be fused together, and in very rare circumstances even amputation may result.

The literature has reported some instances where, even years after a total joint replacement, a patient has developed an infection in the joint that has been replaced. This could occur as a spreading of infection from a source such as an infected tooth, an acute gallbladder attack, a urinary tract infection, or any other type of infection in your system. This is not typical, but you should be aware of this fact. If you should, even months or years after the operation, be affected by an infection, treatments as described previously may become necessary.

Poor and delayed wound healing may occur or rarely failure to heal.

Smokers, diabetics, patients with autoimmune disease, malnourished patients, obese patients, patients with a history of delayed wound healing, and people with other systemic diseases may be slow to heal or not heal at all. Failure to heal may result in continued pain or subsequent surgeries.

Blood clots in an artery or vein may cause a block in circulation.

The operation could result in blood clots forming. This is a potential complication following any surgery, particularly when the operation is done on the lower extremities. This could produce what is known as a deep vein thrombosis. In some cases, a clot may break off in the vein and be carried by the blood stream to the lung (pulmonary embolism), resulting in severe chest pains and shortness of breath. Surgery and anticoagulants (blood thinners) may then be required. In extremely rare cases, Blood clots in the vein may cause pain and swelling and they may travel to the lungs or brain causing chest pain, shortness of breath, stroke and rarely death; therefore, it is critical to follow directions on taking blood thinners after surgery. In the very rare circumstance that the blood vessel supplies the bulk of blood supply to the extremity and it cannot be repaired, gangrene or amputation may result.

Heterotopic Bone Formation (HBF)

This is bone growth that may occur beyond the normal edges of the bone after surgery that can cause pain or loss of motion. If HBF occurs, it may take up to 18 months to complete its process at which time decision on the need to treat can be discussed. If you have a known history of HBF and inform your surgeon, preventative measures can be taken. Extra bone may form in the muscles after surgery causing pain and limiting motion. Medication recommended for you during and after your hospitalization will help to minimize these complications. Failure to follow the prescribed medication and therapy protocol after surgery will put you at greater risk.

Excessive scar formation.

Some patients may be genetically predisposed to form excessive scar. This may limit your range of motion or provide an undesirable cosmetic outcome. These conditions, if correctable, may require further procedures or surgeries to partially or completely correct these issues. They may lead to permanent limitation in the patients range of motion.

Adhesions

The healing process requires collagen fibers to connect and seal the incisions. Tissues can sometimes rapidly form new tissue connections and too much tissue called "adhesions" are formed causing loss of motion and pain. It is important to move your knee after surgery and perform your exercises each day to allow these new tissues to heal and stretch properly. If you develop painful tissue adhesions that limits motion significantly or causes sharp pains in certain locations when bending or walking, you may require further surgery to remove the scarring tissue.

After total knee replacement, you must perform exercises and attend physical therapy to regain a satisfactory range of motion within 12 weeks.

If not, the joint may require manipulation. This requires another hospital procedure under anesthesia to move the knee and break up the scar tissue. Rarely, this can result in tearing of muscles and tendons and even fracture of bones requiring additional surgery.

Robotic procedures

If you are having a robotic-assisted procedure, you will have small pins placed in the iliac crest (for hip replacement) or leg above the knee and below the knee (for partial and total knee replacement) that will be removed at the end of the procedure. There is a very small chance of a fracture that could occur during or after the procedure that would require surgical fixation. There is an even smaller chance that some portion of the hardware could be retained after the procedure.

Fracture

Bone fracture is a very rare complication of knee replacement which can result in additional surgery, bracing, protected weight bearing or revision surgery. The navigation pins in the iliac crest, femur and tibia can cause fracture with overly aggressive early activity after surgery before the bone heals in these holes.

Over time, any implant can loosen, break, wear out, become unstable or generate debris that damages the bone. This may result in the need for further surgery or revision. Over time the implants may wear down or loosen requiring replacement or revision surgery. In rare cases, the interface used to hold the implants can either de-bond from the implant or bone and loosen, requiring re-operation. Increased activity levels and high impact exercises like running and jumping can potentially cause implants to loosen, wear down faster becoming painful. It is likewise possible that the parts which we have inserted into your hip or knee could, in the future, loosen up from excessive wear and use. Mechanical failure, breakage, loosening or wearing out of the implants or cement may occur at any time requiring early or late revision of the implants. This may require further surgery in order to replace part or all of the components. It is important that you maintain your ideal body weight as the artificial replacement surface is more likely to wear down faster or loosen in people who are overweight, requiring revision surgery.

Hip dislocation

It is possible that the total hip ball may pop out of the socket (dislocate) in the future. This is rare since the hip is thoroughly checked at the time of surgery, but excessive bending and twisting could force it out. This would require a relocation of the hip in the operating room.

Noises such as clicks and squeaks in the new joint may occur.

This is usually a benign occurrence and does not usually indicate that there is a problem.

Allergy to the implant

Allergic reactions to the implant can rarely occur. Reactions such as hives, redness, itching, and inflammation can occur. This can lead to dissatisfaction with your outcome, joint stiffness and pain, and systemic reactions. Occasionally revision surgery may be required to remove the implant causing the issue and replace it with an implant to which the patient is not allergic. If you are interested in getting metal testing done prior to surgery, please ask Dr. Jacob or a member of his staff.

Patients under 55

Patients under the age of 55 are more likely than patient's over the age of 55 to be dissatisfied with their outcomes. The most common reasons include poor *pain control, activity limitation, less pain control than expected, less improvement in functional status and stiffness.*

Pre-operative obesity

If your body mass index (BMI – a measure of the ratio between your height and weight) is 40 or greater your inter-operative and post-operative surgical risks are significantly increased. Your risks include but are not limited to an increased risk of anesthesia complication, increased operative times, delayed or poor wound healing, difficulty breathing, blood clots, pulmonary embolism, post-operative infection, and death. There is also an increased risk of implant complications such as implant loosening, implant breakage or failure, and dislocation post-operatively. You are also more likely to require early revision surgery and may require more frequent revisions. If you are interested in more information on weight loss, please ask Dr. Jacob or his staff for more details.

Leg length difference

All efforts are made to equalize leg lengths, but in some cases an undesirable change in the length of the operated leg may occur, with either shortening or lengthening. Your leg will feel heavy and may feel longer or shorter than the other leg after surgery for up to three months. This is normal and temporary. As you regain strength, this feeling will go away.

Off-label use of implants

Although every attempt is made to be prepared for every eventuality, there may be unexpected changes during the operation. "Off-label" uses of implants may occur as determined by the judgment of Dr. Jacob. Implants from different companies may be mixed.

Unforeseen complications

Occasionally, unforeseen conditions could arise during the course of the operation that, in your surgeon's judgment, may require an additional surgical procedure or procedures different from those that have been discussed. Your surgeon respectfully requests your authorization to allow such procedures to be performed should they become necessary under any circumstances.

Use of cadaveric graft

Autograft (from you), or Allograft (from a cadaver) bone graft may be required to reconstruct the joint.

Residual Pain

Some patients may have residual pain despite having a well installed implant. Most of these pains can be resolved with proper rehabilitation and muscle maintenance. In the rare case that the symptoms cannot be reduced or eliminated with medications, injections, muscle or bone stimulators, braces, protected weight bearing or therapy, further surgery may be necessary. Revision surgery may be required but does not always eliminate the residual pain.

Patients on pre-operative pain medication

In specific reference to an upcoming joint replacement, pre-op opioid medication use has demonstrated to *increase complications, the need for revision surgery, and even post-op pain.* A study in the [The Journal of Bone & Joint Surgery](#) looked at patients who had regularly used opioid medications for pain control prior to total knee arthroplasty. This group was compared to patients who had not used opioids before surgery. The study found that "patients who use opioid medications prior to joint replacement may be at a **substantially greater risk for complications and painful prolonged recoveries.**" Specifically, of the patients on opioid based pain medication prior to surgery, a significant number of them had revisions for persistent stiffness/pain. Comparatively, no one had a revision in the matched, opioid-free group.

Knee replacement patients

There will likely be a small area of numb skin on the outside part of the knee. The small skin nerve to this region must be cut in order to gain access to the knee. This numbness often diminishes or completely resolves with time and in no way will it affect the function of your knee replacement.

Resolution of symptoms

While all efforts are made to achieve optimal outcomes, there can be no assurance that all pre-operative symptoms will be relieved, and all pre-operative expectations will be achieved.

There are no guarantees or warranties provided with regards to the outcome of this procedure.

Injury during or after the surgery

Injuries sustained during or after the operation, such as fractures, burns, lacerations and injuries during transfer may occur.

Alternative Therapies

I understand that I have the option of treating my condition with therapies other than joint replacement. This includes further observation, weight loss, activity modification, over the counter and prescription medications, exercises or physical therapy, joint injections, bracing, walking aides, and possible alternative surgical procedures. ***I understand I may get a second opinion from another surgeon at any time.***

As described above, most complications have only temporary consequences and will not affect the ultimate outcome of the operation. However, to a greater or lesser extent, they tend to complicate, prolong and/or lead to the need for additional treatment and may require consultation or treatment by other specialists. Complications often increase the length and cost of hospitalization and convalescence. A minor complication may cause nothing more than some additional discomfort and inconvenience but may increase the period of disability and recovery. A major complication, however, may be much more serious and rarely, even devastating, leading to significant distress for you and your family. It may require the need for intensive care and/or additional surgery and cause a major prolongation of hospitalization and disability, and increased expense. Rarely, it could cause abandoning the original treatment plan or operation and have an adverse effect on the outcome of the procedure, causing permanent physical damage and impairment and in rare circumstance, even death.

Our surgical, anesthesia, and nursing staffs are aware of these possible complications and are trained to monitor your condition, recognize early signs of trouble, and treat complications when they arise, in order to try to minimize the consequences to you.

I use a team approach in the surgical treatment of hip and knee disorders. My team includes physicians from multiple specialties, nurses, operating room technicians, physician assistants, anesthesiologists, certified nurse anesthetists, physical therapists, social workers, nutritionists and other specialists who are trained to provide orthopedic care. In most circumstances, we have worked together on a regular basis for many years. It has been demonstrated that the quality of the outcome is directly related to the experience and volume of procedures performed by the surgeon. I perform a high volume of joint replacements and reconstructive procedures every year. While I perform each operation myself, I do have a team of surgical assistants in the operating room with me, who each have a specific task to perform during each type of procedure. I perform the most important parts of each operation including the preparation and implantation of all joint replacements and closure of the major muscles and tendons. My personally trained assistants, who have operated with me for many years, perform other parts of the procedure such as closure of the more superficial structures, including the layers beneath the skin and the skin itself. These are all highly skilled professionals. **We have no interns, residents or fellows.**

Since we perform cutting edge surgery, I often have visiting surgeons or observers in the operating room who are there to watch and learn my surgical techniques. They do this by either observing from afar and watching video.

Representatives of the company that produces the implants I use are often present in the operating room, however, they do not directly participate in the surgery. They are there in order to make sure we have proper inventory and to provide technical information with regard to the implant. Some representatives have special training in robotic procedures and assist me in preparation of the robotic procedures.

I understand that Dr. Jacob participates in clinical research and lectures on hip and knee replacement topics. As such, Dr. Jacob is a paid consultant for medical device companies (Stryker Orthopedics, and Pacira Pharmaceuticals) that supply materials used during your procedure.

If you have any questions regarding the risks, benefits, possible complications, and alternatives to your procedure or any questions about any of the above subjects, please ask and discuss it with me so that you will be completely and satisfactorily informed before giving your consent to the planned procedure.

Other: _____

For office use only:

Laterality:

- Left
- Right
- Bilateral

Procedure:

- Partial Knee vs Total Knee Replacement
- Patellofemoral vs Total Knee Replacement
- Total Knee Replacement
- Revision Knee Replacement
- Core Decompression
- Partial Hip Replacement
- Total Hip Replacement
- Revision Hip Replacement

Other: _____

1. I hereby authorize **Dr. Paul B. Jacob** to treat the illness(es) and/or condition(s), which appear indicated by the diagnostic studies already performed and the clinical judgement and opinion of the physician.
2. My physician has explained to me the general nature of my condition, the proposed treatment(s), procedure(s), examination, or test, the expected outcome, the potential risks, and the reasonable alternatives.
3. My physician has explained to me that during the course of the operation, unforeseen conditions may be revealed that necessitates an extension of the original procedure(s) or different procedure(s) than those set forth. I, therefore, authorize and request that the above-named physician, to perform such surgical, medical and/or other procedures as are desirable in the exercise of professional judgment. The authority granted shall extend to remedying all conditions that require treatment and/or were not known at the onset of the procedure including, but not limited to, blood transfusions, removal of tissue, administration of medications, and correcting the complications that may arise during the above-named procedure.
4. My physician has informed me that there are risks including, but not limited to the complications as described in the attached document.
5. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the results of the operation or procedure.
6. I hereby voluntarily authorize and consent to the observation of the procedure by third parties as may be necessary for the observer's education or as a consequence of my request or the request of my physician. I hereby release the Hospital, each of their directors, officers and employees and my physician and his employees from liability for any claim arising out of such observation, including any imaging, photographs, or video performed.
7. In the event my health care provider involved in my care is exposed to my blood or body fluids, I consent to having my blood drawn and tested for any and all communicable disease. I understand that the results of this blood test will be a part of my medical records and will be treated confidentially.
8. I understand that before prescribing controlled danger substances in the course of treatment for acute pain Dr. Jacob will perform a preliminary investigation utilize the Oklahoma Bureau of Narcotics Drug Tracking Program (OBN PMP) prior to prescribing opiates, synthetic opiates, semisynthetic opiates, benzodiazepine, or carisoprodol, or prior to authorizing a refill, or if 180 days have elapsed prior to the previous OBN PMP check. Dr. Jacob will continuously monitor the OBN PMP throughout my treatment. Dr. Jacob will document results in my medical record.
9. I have been informed by my doctor about narcotic effects, including the normal physiological effects of tolerance (where I might need to take more medication to obtain the same pain relief) and dependence (an uncomfortable withdrawal reaction which may occur if I stop taking medication abruptly), and the abnormal effects of addiction (psychological dependence leading to abnormal behavior), which is very rare in patients with genuine pain.
10. I understand that narcotics can adversely affect my judgment in making business decisions and in operating equipment such as an automobile.

By signing below, I acknowledge that I have read this document and completely and fully understand it. I am aware that I am entitled to ask questions regarding any aspect of this document and my medical care. After the risks, benefits, possible complications and alternatives of various treatment options were discussed, I have decided to proceed with surgery. I also acknowledge that I have been given and been advised to read in detail my pre-operative instruction packet for the operation indicated above. I acknowledge that I have read the section on medical imaging and I give my permission for these images to be used in a professional manner as described above. I understand that I must follow all pre and post-operative instructions in order to be best prepared for surgery and to obtain the most successful outcome possible.

Signature of Patient or Legal Representative

Print Name

Date

Witness Signature

Print Name

Date

Dr. Paul B. Jacob

Date

If not signed by the patient, please indicate which situation applies below:

- Patient is a minor (under 18)
- Other: _____

Informed Refusal for Surgery

Have you been told you need joint replacement surgery, but had hoped you could wait a little longer? Well, you're not alone. Many patients want to find relief from pain but are not ready to proceed with a major surgery. They may, therefore, choose to delay joint replacement and continue conservative treatments, including weight loss, activity modification, oral medications, injections, nerve ablations, use of walking aids, bracing, and physical therapy. But you may also worry...am I doing damage, or making surgery more difficult, by delaying a hip or knee replacement? In the short term, the answer is no. Seldom does surgery get more complicated or more difficult because of a delay in joint replacement surgery. Patients who are diagnosed with hip arthritis or knee arthritis should take time to determine the right course of treatment for their situation. This may include trying more simple treatments, getting another opinion, or taking some time to consider their options.

But there are some considerations patients should understand. While delaying surgery for months, or even a year or two, may not have significant consequences, a prolonged delay may complicate their situation. Here are some of the concerns about delaying joint replacement surgery.

Worsening of Joint Deformity

Most often arthritis progression is gradual and develops slowly over the course of months and years. Some people do have accelerated changes, but even in these situations, the changes don't occur overnight. As arthritis worsens, there can be increasing deformity of the joint. In patients with knee arthritis, this most commonly becomes an increasing knock-kneed or bow-legged deformity. In hip arthritis, the leg length can shorten as cartilage and bone wear away. Joint replacement can become more complicated with increasing deformity of the joint increasing your chances for complications. This may require your surgeon to use specialized implants or to perform more extensive surgery to correct the deformity.

Stiffness of Joint

In the same light, as joint arthritis progresses, the joint moves less. With less movement, soft-tissues surrounding the joint including muscle, ligaments and joint capsule may contract, causing stiffness. This is especially notable for patients having knee replacement, where mobility before surgery is one of the best indicators of expected motion after surgery.

Strength of Muscles

As arthritis progresses, muscles surrounding the joint are likely to weaken. People use the joint less and limit their physical exertion as a result of their pain. As the muscles weaken, rehabilitation after surgery may become more difficult, and perhaps the muscles may never regain their full strength.

Fall Risk

As you lose strength and flexibility, you increase your risk of falls. Fixing an arthritic joint around a fracture site is complex to say the least and has the potential to affect your long-term outcome. Often, we are forced to wait for a fracture to heal before we can proceed with correcting the arthritis which may take a significant amount of time.

Longer Recovery Time

Significant muscle loss associated with delayed hip replacement may result in a longer recovery time. Strong muscles help stabilize your thighbone within the newly replaced hip joint socket; strong muscles also help you power through physical therapy sessions to speed healing.

Compensatory Issues and Problems

This is probably the most controversial complication of delaying surgery, as there is a debate about the extent to which the body develops this type of compensatory problem. When you have pain in one limb, the natural tendency is to put more pressure on other joints. There is very little clinical data to support the theory of compensatory joint problems, but anecdotal evidence is commonly referenced. Many patients experience back problems and pain in other joints, as well as the affected joint. But it's reasonable to believe that people who favor one joint may place more of a burden on other parts of the body. People with severe arthritis often experience back pain, and people with knee arthritis often complain of pain in their opposite limb.

General Medical Health

Your surgeon can usually overcome the technical difficulty of performing joint replacement on someone who has delayed her surgery, but there can be patients who develop medical problems as a result of aging and decreased physical activity. Weight gain, decreased endurance, cardiac and pulmonary conditions are all concerns for people who put off joint replacement for too long. On rare occasions, these medical conditions prohibit you from ever becoming a candidate for hip or knee replacement.

These are some of the reasons that you may want to proceed with joint replacement surgery. As stated, seldom are any of these issues' acute emergencies, meaning you certainly have time to make a decision that works for you. I encourage you to think about the signs you're ready for knee replacement or hip replacement and use these as your guide for determining when to proceed with surgery.

Signature of Patient or Legal Representative

Print Name

Date

Witness Signature

Print Name

Date

Dr. Paul B. Jacob

Date

If not signed by the patient, please indicate which situation applies below:

- Patient is a minor (under 18)
 Other: _____

Informed Consent for Patient Imaging

Patient images (ex. pictures, videos, live recordings) are used for many purposes in medical practice. They are placed in the medical record as an adjunct to clinical care, displayed to colleagues, students and other audiences in educational settings, and published in medical journals or other media as part of medical research and education. In each case it is not only prudent, but necessary for the patients' protection and interest that appropriate consent be obtained. With the proliferation of published images on the Internet it has become particularly important to obtain permission for all uses that will be made of medical images, including worldwide distribution through various electronic media. Please read the following consent carefully and ask any questions prior to signing.

I hereby consent to be photographed while receiving treatment from Dr. Paul B. Jacob and Oklahoma Joint Reconstruction Institute. The term "photograph" includes video, still photography, or live broadcast in digital or any other format, and any other means of recording or reproducing images.

I hereby authorize the use or disclosure of the photograph(s) for the following uses or purposes: dissemination to hospital staff, implant manufacturer representatives, physicians, health professionals, and members of the public for educational, treatment, research, scientific, public relations, marketing, news media, and charitable purposes.

I understand that to the extent possible, any personally identifying information will be removed from the photograph prior to being used for the above listed purpose. However, due to the nature of photography, it is possible that I may still be identified in spite of efforts to the contrary.

I have no expectation of compensation for the use of the photography and relinquish any ownership of the photograph(s) to Dr. Paul B. Jacob and Oklahoma Joint Reconstruction Institute. Furthermore, I understand that because the photography is not used for the purpose of my medical treatment or service, the photograph(s) will not become part of my medical record and will not be maintained as such unless otherwise deemed appropriate by Dr. Jacob.

I understand that authorizing the taking or publication of photograph(s) or films, including videotape and television monitoring of this episode of care is voluntary. I can refuse to sign this consent and authorization. I need not sign this form in order to ensure treatment.

Other: _____

Signature of Patient or Legal Representative	Print Name	Date
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Witness Signature	Print Name	Date
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Dr. Paul B. Jacob	Date
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If not signed by the patient, please indicate which situation applies below:

- Patient is a minor (under 18)
- Other: _____

COVID-19 RISK INFORMED CONSENT

I understand that I am opting for an elective treatment/procedure/surgery that is not considered a medical emergency. I also understand that the novel coronavirus, COVID-19, has been declared a worldwide pandemic by the World Health Organization. I further understand that COVID-19 is extremely contagious and is believed to spread by person-to-person contact; and, as a result, federal and state health agencies recommend social distancing. I recognize that Dr. Paul B. Jacob and all the staff at Oklahoma Joint Reconstruction Institute and Community Hospital are closely monitoring this situation and have put in place reasonable preventative measures aimed to reduce the spread of COVID-19. Given the nature of the virus, I understand there is an inherent risk of becoming infected with COVID-19 by virtue of proceeding with this elective surgery. I hereby acknowledge and assume the risk of becoming infected with COVID-19 through this elective surgery, and I give my express permission for Dr. Paul B. Jacob and all the staff at Oklahoma Joint Reconstruction Institute and Community Hospital to proceed. I understand that, even if I have been tested for COVID and received a negative test result, the tests in some cases may fail to detect the virus. It is also possible that I may have contracted COVID after the test. I understand that, if I have a COVID-19 infection, and even if I do not have any symptoms for the same, proceeding with this elective surgery can lead to a higher chance of complication and/or death.

I understand that possible exposure to COVID-19 before, during or after my surgery may result in the following:

- A positive COVID-19 diagnosis
- Extended quarantine/self-isolation
- Additional testing
- Hospitalization that may require medical therapy
- Intensive Care treatment
- Possible need for intubation/ventilator support
- Short-term or long-term intubation
- Risk of death
- Other potential complications

In addition, after my elective surgery, I may need additional care that may require me to go to an emergency room or a hospital. I understand that COVID-19 may cause additional risks, some or many of which may not currently be known at this time, in addition to the risks described herein, as well as those risks for the surgery itself. I have been given the option to defer my surgery to a later date. However, I understand all the potential risks, including but not limited to the potential short-term and long-term complications related to COVID-19, and I would like to proceed with my surgery.

I may contract COVID-19 by any of the following methods:

- Breathing and droplets that are produced when an infected person coughs or sneezes.
- When an infected person, with or without symptoms, spreads COVID-19 by touching a surface that I then come in contact with.
- Through unknown ways that may become apparent during or after the procedure.

I understand that I can decrease my chances of contracting COVID-19 with the following methods:

- Frequent hand washing (minimum of 20 seconds) and practicing good hand hygiene.
- Use an alcohol-based hand sanitizer containing at least 60% alcohol.
- Avoid touching your eyes, nose, and mouth with unwashed hands.
- Social distancing (6 feet)
- Limiting contact with individuals (both symptomatic and asymptomatic individuals)
- Wearing a mask when in public places
- Clean and disinfect frequently touched objects and surfaces.

Patients with the following circumstances may be at higher risk for contracting COVID-19.

- Patients with advanced age
- Chronic medical conditions
- Patients with *diabetes, high blood pressure, and lung disease* are especially at risk for severe and life-threatening disease from COVID-19
- Patients who will need discharge to a long-term care facility (skilled nursing facilities)

Signature of Patient or Legal Representative **Print Name** **Date**

Witness Signature **Print Name** **Date**

Dr. Paul B. Jacob **Date**

Remote Patient Monitoring Informed Consent

MotionSense

What Is MotionSense Patient Engagement Application:

MotionSense is a digital companion, created by surgeons and physical therapists to support you through every step of your preparation and recovery from surgery. Our aim is to improve the experience of having surgery by informing, empowering and enabling people to engage with their own care and prepare for every stage of your road to recovery. From time to time you will be asked to complete surveys and daily pain scores along with information about your daily activity. This important information will generate patient specific reports that your surgeon will use to provide you with customized recommendations that will help you throughout your recovery process. The app will assist you in getting ready for surgery, planning your recovery and tracking progress towards your goals!

The MotionSense App will provide you with the following:

- Information about your surgery
- Pre-op and post-op check-lists
- Educational insights to help you prepare for your procedure.

The application enables surgeons to:

- Engage with patients outside of the clinic through customized educational videos.
- Provide information based on each surgeon's pre-hab and rehab protocols.
- Provide simple, straight forward, easy to understand answers to frequently asked questions.

Through the mobile app, your surgeon will actively engage in monitoring your progress through:

- Daily pain journals
- A personalized home exercise program
- Activity monitoring such as daily steps and weekly range of motion

The MotionSense App empowers you, the patient, and assists your healthcare professional to:

- Prepare for your procedure in an individualized manner
- Assess your daily pain scores and make recommendations to your recovery plan.
- Review your surveys post-op to evaluate your progress through your recovery journey.
- Monitor and review your total joint recovery progress.

MotionSense Key Features

- Step-by-step interactive videos to match the plan from your surgeon and physical therapist
- Real time access to written information curated by your surgeon and physical therapist
- Self-care tools to help you set goals and track your progress
- Customized exercise plans and exercise videos
- Reliable, accessible information, relevant to each stage of your preparation and recovery
- Integrates with the Apple Health app, enabling us to give you personalized targets and encouragement

To get started, download the free MotionSense app on the apple or android app store and enter the 6-digit pin code (sent to you by your surgeon's office) to unlock your unique app.

I hereby consent to receiving the MotionSense remote patient monitoring services from Dr. Paul B Jacob, Oklahoma Joint Reconstruction Institute ("Medical Practice"), and its providers as part of my health evaluation and treatment. I further give this Medical Practice and its providers permission to consult with relevant specialists as needed during the course of my treatment. I am providing the foregoing consents based on my understanding of the following:

During the MotionSense remote patient monitoring process, my provider and I will be in different physical locations and my medical and/or health information will be communicated to health care providers at those other physical locations. I may benefit from the use of the MotionSense app, but results cannot be guaranteed or assured.

I have the right to terminate the medical practice's remote patient monitoring services at any time without affecting my right to future care or treatment or risking the loss or withdrawal of any program benefits to which I would otherwise be entitled.

I understand that my medical insurance will be billed for these services however I am responsible for any applicable deductibles or copays for remote patient monitoring services. These amounts are determined by my insurance company and the terms of my health plan or health insurance agreement and not by the Dr Paul B. Jacob, Oklahoma Joint Reconstruction Institute, or the medical practice itself. If at any time these costs are not acceptable, I understand that I may terminate the agreement and no charges will be issued to me except for services already provided.

The information and data disclosed by me (the patient) during the course of my participation in Medical Practice's remote monitoring services may be integrated into my medical record and will generally be protected and confidential. However, I understand that there is a risk that data security protocols could fail, which could result in the unintended disclosure of my information.

Only one practitioner or facility may provide, and be paid for, remote monitoring services during a calendar month. I hereby attest that, to the best of my knowledge, I am not participating in remote monitoring services with any of my other medical providers.

In some states, including California, remote patient monitoring may be considered a type of "telehealth." My consent is therefore intended to satisfy any and all legal requirements that apply to the use of telehealth, including and without limitation, Section 2290.5(b) of the Cal. Bus. & Prof. Code.

I hereby authorize **Dr. Paul B. Jacob and the Oklahoma Joint Reconstruction Institute** to remotely monitor my condition through the **MotionSense app** and bill my insurance company for these services.

I understand that I can opt out at any time by contacting the medical practice and terminating this agreement.

I have discussed the foregoing information with my provider and all of my questions have been answered to my satisfaction.

- I elect to proceed with remote monitoring.*
- I DO NOT elect to proceed with the MotionSense app and remote monitoring.*

By signing below, I acknowledge that I have read this document and completely and fully understand it. I am aware that I am entitled to ask questions regarding any aspect of this document and / or my medical care.

Signature of Patient or Legal Representative **Print Name** **Date**

Witness Signature **Print Name** **Date**

Dr. Paul B. Jacob **Date**

INFORMED CONSENT FOR TELEHEALTH

Prior to your telehealth visit, please read the below consent for telehealth treatment.

I hereby consent to receiving treatment through telehealth from Dr. Paul B. Jacob or a qualified member of his care team. I understand that "telehealth" is the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care. I understand that telehealth also involves the communication of my medical information, both orally and visually, to health care providers located at affiliated facilities or elsewhere. I understand that I have the following rights with respect to telehealth:

1. I retain the option to withhold or withdraw consent at any time without affecting my right to future care or treatment or risking the loss or withdrawal of any program benefits to which I would otherwise be entitled. I understand that receiving treatment through telehealth does not mean I cannot receive in-person health care services, either today or in the future. I understand that there are limitations to the types of treatment that can be appropriately provided via telehealth, and that my provider determines whether or not it is appropriate for me to receive treatment via telehealth.
2. The laws that protect the confidentiality of my medical information also apply to telehealth. The information disclosed by me during the course of my treatment is generally confidential.

Exceptions to confidentiality laws include the requirements to: *Protect me or the public from serious harm; report abuse or neglect of children, the elderly, or people with disabilities; and respond to an order from a court or other valid legal process such as a subpoena.*

3. I understand that I may benefit from telehealth, but that results cannot be guaranteed or assured. I also understand that there are risks involved in receiving treatment via telehealth, such as the possibility that transmission of my medical information could be disrupted or distorted by technical failures; delays in receiving medical treatment could occur because of technological failures; the transmission of my medical information could be interrupted by unauthorized persons; and/or misunderstandings between me and my provider can more easily occur.
4. Telehealth-based services and care may not yield the same results as a face-to-face service. If I or my provider believes I would be better served by face-to-face service, I may be asked to schedule a face-to-face visit or be referred to a provider in my area to receive such service, as applicable.
5. There are potential risks associated with any form of mental or physical treatment for medical conditions, and despite my efforts and the efforts of my provider, my condition may not improve, and in some cases may even get worse.
6. The benefits of telehealth may include removing transportation and travel barriers, minimizing time constraints, and providing greater opportunity to prepare in advance for treatment sessions.
7. All existing laws regarding access to my medical information and copies of medical records apply.
8. I agree not to record or share the content of my telehealth visit.
9. I agree to conduct the visit in a private space without any unwanted attendee's present, or able to hear or see my visit, unless an alternative arrangement is agreed to by me and my provider.
10. If an unauthorized individual comes into the room during my visit, I agree to pause my phone call and restart only after they have left.

Signature of Patient or Legal Representative **Print Name** **Date**

Witness Signature **Print Name** **Date**

Dr. Paul B. Jacob **Date**

Metal Allergy Informed Consent

Metal Sensitivity or Metal Allergy

Metal Sensitivity (also called metal hypersensitivity or metal allergy) is a form of an allergic reaction and can be caused by exposure to metals in jewelry, dental implants and **orthopedic implants**.

Implants Contain Metal

The metal hip or knee implants themselves will not likely be the cause of a reaction. In older, poorly functioning "metal-on-metal" joint implants, where the metal ends of the implants are in contact, large quantities of metal could be released inside the joint. If you have a metal allergy, and metal particles are present in your joint, then that may play a role in failure of the joint replacement. In implants with plastic parts, wear of the plastic may over time lead to unintended wear of metal against metal. This happens in poorly-functioning joint replacements and generally takes several years to occur. **Typically, well-functioning joint replacements do not lead to deterioration of the implants and generation of metal particles.**

Testing for Metal Allergy

In the past, skin patch testing was used to help diagnose a metal allergy; however, research has shown a skin test that is positive for metal allergy does not necessarily mean you will have complications with your joint replacement. Blood tests are available to check for metal sensitivity, but these tests also **are not** the best predictors of whether or not your joint replacement will have complications. Metal-LTT is a blood test which tests immune cell responses to different metals. Metal-LTT testing can identify which people are susceptible to metal sensitivity. Metal-LTT testing can also identify which specific metals cause sensitivity responses and which specific metals do not cause excessive immune reactions. Determining the right kind of metal implant for a metal sensitivity person can only be accomplished when the specific metals an individual is reactive to can be diagnosed. **It is important to remember that routine skin or blood tests to check for metal allergy/sensitivity is not recommended by the American Academy of Hip and Knee Surgeons or the American Academy of Orthopedic Surgeons since there is still not enough evidence to suggest these are helpful.**

Signs of Metal Sensitivity Before Surgery

Common symptoms of a metal allergy conditions are skin hives, rashes, local skin redness, swelling, and itching. Other symptoms include inflammation and pain associated with a metal orthopedic or dental implant where infection and other causes of inflammation **have been ruled out**. If you have had skin reactions to jewelry (rings, necklaces, earrings, etc.) or eyeglasses, this may be an indication to obtain metal sensitivity testing but often **does not** correlate with positive results. In addition, patients who work with or around metals can develop a sensitivity. Let your surgeon know before you schedule your surgery if your work with metals frequently or if you have had reactions to jewelry or metals that come in contact with your skin.

Allergic or Sensitive to Metal

Generally, the amounts of metal exposure to cause allergic responses are below the concentrations that cause toxicity. Metal ions that are released from metal implants can produce sensitivity responses by attaching to circulating proteins and changing them enough to activate the immune system. Metals that are common sensitizers include **nickel, cobalt and chromium**, where **10-15% of people** are allergic to one or more of those three metals. If you think you are allergic or sensitive to metal, then it is important to alert your surgeon prior to having joint replacement surgery. While 10-15% of people will have some reaction to certain metal allergy tests, **metal allergy is a very rare cause of failure in knee replacements.**

Signs of Metal Allergy after Surgery

The diagnosis of a metal allergy after surgery is very challenging. The symptoms may include skin rash, itching and discoloration in the area around the artificial joint. Other symptoms such as joint pain, swelling, and joint stiffness can have numerous causes and not necessarily be because of a metal allergy/sensitivity. If you develop a skin reaction near the location of your hip or knee implants, steroids or topical creams can be used for mild symptoms.

Revision Surgery

A second surgery, called "revision," to non-allergenic implants is generally not needed and should be considered only as a last resort. Because diagnosing metal allergy after surgery cannot be done with 100% certainty, the outcomes of a revision surgery are **unpredictable at best**. It is exceedingly rare to have a hip or knee replacement fail because of metal sensitivity or allergy.

Ortho Analysis LLC

Oklahoma Joint Reconstruction Institute and Dr. Paul B. Jacob use **Orthopedic Analysis** to perform metal allergy testing on patients.

Ortho Analysis LLC has been in operation since 2005, founded by Dr Nadim James Hallab (CEO), a Professor in the Department of Orthopedics, Department of Cell Biology/Anatomy and Department of Immunology at Rush University Medical Center in Chicago.

This company was formed after the utility of metal-LTT testing was demonstrated in over 10 years of scientific study and publication in top ranked peer-reviewed US journals. And the subsequent request of orthopedic surgeons from around the USA to conduct this testing for them.

The chief scientist Dr Marco Steve Caicedo (COO) is a well published Immunologist with nationally known expertise in immune reactivity to non-biological materials. Orthopedic Analysis aims to provide diagnostic services both nationally and internationally.

Payment

Orthopedic Analysis does not bill insurance companies and payment in full is required once the sample arrives at their facility. **The cost of the test is \$573.00** paid directly to Orthopedic analysis. Payment can be made by attaching a check, money order or credit card information on the requisition form included in the kit. You can also pay online with a credit card. It is important to know that Oklahoma Joint Reconstruction Institute does not affiliate in any way with orthopedic analysis. Nor, does Oklahoma Joint Reconstruction Institute receive any reimbursement for this testing. This is a direct interaction between the patient and the lab itself. Orthopedic Analysis will provide you with a copy of your results and an itemized paid invoice (including their procedure code) that you can submit to your insurance company and seek reimbursement for the test

Private insurance reimbursement for the testing varies greatly depending upon the individual's healthcare plan. It is also based on medical necessity. While some patients are routinely fully reimbursed, others have received partial reimbursement or no reimbursement at all.

Metal Allergy Testing Informed Consent

I _____ have read the aforementioned documentation of metal allergy and confirm understanding.

The general nature and purpose of the testing has been explained to me as well as the proposed treatment(s), procedure(s), as well as the potential risks, and the reasonable alternatives.

I understand that if I choose to waive metal allergy testing offered by OJRI at this time, I am taking the risk that I may have unforeseen issues with my joint replacement postoperatively due to possible metal allergy.

I choose to do the following:

- Waive undergoing metal allergy testing offered by OJRI
- Submit to metal allergy testing offered by OJRI

Signature Patient Printed Name Date

Staff Witness Printed Name Date

Dr. Paul Jacob Date

Understanding Your Metal Testing Results

How will your results be reported?

Your results will be reported in three categories:

- 1) **Normal** - Anything below a stimulation index of 2.
- 2) **Mild (Mild reaction)** – A Stimulation Index between 2 and 4. This is considered a sub-clinical reaction that is unlikely to affect your short term or long term outcome. You will receive *standard cobalt chrome and/or titanium implants*.
- 3) **Reactive (moderate reaction)** – A Stimulation Index between 4 and 8. This is considered a clinically relevant reaction that has a low potential to affect your short term and/or long term outcome. You will receive an *implant that avoids the use of the substances you were reactive to*.
- 4) **Highly Reactive (severe reaction)** - A Stimulation index above 8. This is considered a clinically relevant reaction that has the potential to affect your short term and/or long term outcome. *You will receive an implant that avoids the use of the substances you were reactive to*.

What is the Known Stimulant (PHA)?

The **Known Stimulant (PHA)** is the measurement of the reaction to a substance that will strongly stimulate your immune system. It is the standard to which your responses (mild, reactive, and highly reactive) are measured for clinical relevance. A proliferation index (or stimulation index) is a number measurement of how much proliferation happens when immune cells are exposed to each metal. The proliferation index (or stimulation index) is simply a measure of how many more times metal-treated immune cells (lymphocytes) have proliferated when compared to that same person's immune cells that were not treated with anything (non-challenged).

How are the results sent to me?

An example of the results sent out are shown in figure below. The amount of each person's immune reactivity (stimulation index) to each of the metals tested for are calculated and put in graphical form, like the one below, and the results are sent out to whomever the patient has indicated (self and / or physician).

Are these results private?

Privacy is our top priority. No one has the right to see your results except you and whoever you want to see them. Your results are only sent to whomever you (the person tested) wants them sent to and in the way they want them sent (email, fax or regular mail).

What is and is not reactive?

Although anything above 2 is generally considered a mild response, if the reactivity is between 2 and 4 (not statistically significant) then the reaction is considered sub-clinical and does not limit your choices. Thus, the amount of reactivity has been broken down into 3 ranges, mild, reactive, and highly reactive. If you are in the **reactive or highly reactive** ranges then I would recommend avoiding that material in your construct.

References

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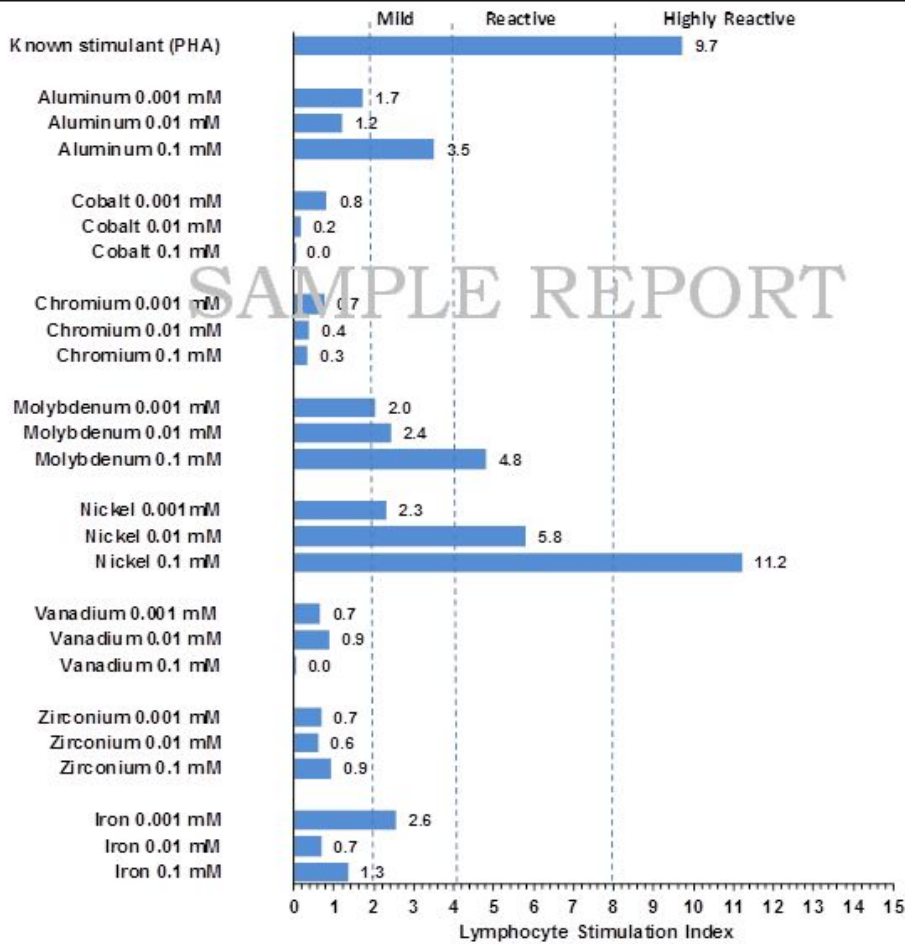


Metal-LTT Analysis Report

Panel 1

Report Date	1/1/2011	Sample Collected	1/1/2011
Report Time	12:00 AM	Sample Received	1/1/2011 10:00 AM
Patient ID	1234	DOB	xxx/xx/xx
Report For	Doe, John		
Attending Physician	Dr. X		

Control cpm 3122.0
Positive control (PHA) cpm 30358.3



Mildly Reactive 2 to 4
 Reactive 4 to 8
 Highly Reactive above 8

2201 W. Campbell Park Drive, Suite 211 Chicago, IL 60612
 www.orthopedicanalysis.com

Results by: MC
 p: (312) 733-7121

Page-1 of 2

RESULTS

Operating Principle: Metal-induced immune response = Increased Lymphocyte Proliferation

OPIOID THERAPY INFORMED CONSENT FOR TREATMENT

The purpose of this agreement is to give you information about the medications you will be taking for pain management and to assure that you and your physician comply with all state and federal regulations concerning the prescribing of controlled substances. It is also meant to prevent misunderstandings about certain medicines the patient will be taking for pain management. This is to help both the patients and their provider comply with the law regarding post-surgery pain management. Please read this contract thoroughly as it is a condition of any treatment requiring narcotic pain medication or other controlled substances. Your signature will also be required prior to initiating any treatment involving controlled substances.

Our goal is to provide you with the best quality treatment of your pain. To accomplish this goal, your physician will customize your treatment plan to best fit your healthcare needs. Your pain management treatment plan may include, but is not limited to, injection therapy, physical therapy, medication therapy, psychological counseling, relaxation therapy and exercise and weight loss programs. When opioids and other controlled medications are the best option, it is important to review and follow the policies to ensure your safety and our continued ability to treat you in the most effective way possible.

Please read this carefully, as these policies will be enforced. If you do not understand any of the information below or require additional clarification on the policies of this practice regarding prescribed medication, please ask prior to signing the agreement. You are required to sign this agreement stating your understanding and compliance before receiving any pain medication.

Dr. Jacob and his physician assistants ***do not*** prescribe pre-operative opioid based pain medication. If you require pre-operative opioid based pain medication prior to your surgery, this needs to come from your pain management provider or your primary care physician. We will provide you with prescriptions for your pain medications per the rules set forth on your pain contract for a **maximum** of 90 days post-operatively. This does not guarantee that you will receive pain medication for 90 days. If you require pain medication beyond the allotted time frame you will be referred to back to your primary care physician or a pain management physician for ongoing pain management needs.

You understand that opioids and other controlled medications are prescribed to increase your function, activity level and quality of life. These medications may reduce your pain but may not provide complete relief. Your treatment plan will be evaluated, at least, every three months. You agree to fully communicate your pain level, functional ability and any side effects of the medication to the best of your ability. If these aspects do not improve with these medications, the risks of the medication outweigh the benefits or there is the potential of negative effects related to another medical condition or medication, your provider may reduce or eliminate the medications from your treatment plan.

You agree to inform your physician of all medications you are taking, including herbal remedies, since Opioid medications can interact with over-the-counter medications and other prescribed medications. This is especially true of cough syrup that contains alcohol, codeine or hydrocodone.

To ensure your safety, **it is your obligation and responsibility to take medications exactly as prescribed by your physician** (dose and frequency). You understand that these medications can lead to physical dependence and/or addiction, and can be associated with other risks including, but not limited to, decreased effectiveness, physical and psychological dependence, confusion, itching, difficulty urinating, constipation, allergic reactions, decreased sex drive, drowsiness, nausea or vomiting, trouble driving and/or operating machinery. Taking more opioids than prescribed or mixing sedatives, benzodiazepines, sleep medications, or alcohol with opioids can result in fatal respiratory depression.

You agree **to only take pain medications prescribed by Dr. Jacob or his covering physicians and/or partners**. Do not take any pain medication given to you by another person or provider (health, dental, clinic or emergency department) or increase your dosage without authorization from this physician. You understand that taking more medication than prescribed or taking pain medication from another source may lead to **overdose** that could result in slowed or stopped breathing, brain injury from lack of oxygen, coma, or death.

You understand that there is an increased risk of overdose associated with the use of opioids in combination with medications used to treat anxiety disorders, panic attacks, insomnia or seizures (benzodiazepines), alcohol and other central nervous system depressants. If you are prescribed these medications by another provider at any time during your pain management treatment, you must inform your physician immediately. You must also inform all other treating healthcare providers of the medications being prescribed as a part of your pain management treatment plan.

You understand this clinic has a policy of limiting dosing to a maximum of ***100mg of Morphine or equivalent maximum doses as outlined in the CDC Opioid Treatment Guidelines and Oklahoma state law***. You agree to comply with such policies and dosing limitations.

You understand addiction is a primary, chronic neurobiological disease with genetic, psychosocial and environmental factors influencing its development and manifestation. It is characterized by behavior that includes one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and cravings. If you have a history of alcohol or drug misuse/addiction, you must notify the physician of such history.

You understand your medications are required to last for the duration prescribed. You must safeguard and protect your prescription medications, including keeping them in a safe place and away from children. It is recommended you keep them in a locked safe or cabinet. You must not share, sell or otherwise permit others to have access to these medications. If you fail to meet this prescribed timeline, your medication is lost, misplaced, destroyed or stolen, **early prescription refills will not be permitted**. This physician reserves the right to choose to taper or discontinue medications that are lost or stolen.

If you intend to stop taking your medications, have a negative reaction, or fail to submit your prescription refill request according to the policies below, you must discuss this discontinuation of medications with your physician prior to doing so. Sudden discontinuation of medications may result in withdrawal, including nausea, shakiness, sweating, rapid heart rate, diarrhea, high blood pressure, pain or severe nervousness. If your physician discontinues your medications as a part of the treatment plan, non-compliance or dismissal from the practice, you will be provided with a weaning or tapering dose to avoid negative withdrawal effects.

All prescriptions will be obtained at **one pharmacy**, when possible. Should the need to change pharmacies arise, you must inform our office immediately.

In the event of a new injury or significant change in your condition, please call our office to make an appointment. In the case of a true medical emergency, please go directly to the ER or call 911. Patients are responsible for notifying any other doctor they see that they obtain narcotics from this office. Patients are responsible for notifying this office of any treatment received by the ER or another physician. If you see another doctor who gives you a controlled substance medicine (a dentist, a doctor from the Emergency Room, another doctor, etc.), you must notify your doctor. I am not to seek or accept medications from other providers without my doctor's permission, except in the event of a true medical emergency in which case, I must notify my doctor as soon as possible.

The prescribing physician and staff have permission to discuss history, diagnosis and treatment details with dispensing pharmacists or other professionals who provide you healthcare.

This clinic and/or physician retains the right to discuss your treatment with law enforcement officials during any official investigation.

You agree to read the package inserts and prescription bottle labels for any prescribed medications. You will discuss any questions or concerns regarding contraindications or reactions with your physician. You will inform this clinic, immediately, if you have a reaction or are allergic to any prescribed medication.

You will be asked to obtain a Narcan or opioid "overdose kit", available from local pharmacies without a prescription. Failure to comply may result in discontinuation of medication.

(Female Patients Only) To the best of your knowledge, you are NOT pregnant. You agree to use appropriate contraceptive during your course of treatment. **If you do become pregnant or suspect pregnancy, you will notify your physician IMMEDIATELY.** You understand there are potential risks associated with pregnancy and chronic opioid therapy. You or your unborn child may experience significant or serious side effects related to the medications you are prescribed.

***(Patients Currently Pregnant) The short-term use of opioids for acute pain can be safe when prescribed by your physician. Long-term use of opioids can be harmful for your unborn baby. There is also a risk of neonatal abstinence syndrome with use of opioids that can require in-hospital treatment of the baby after birth. You should discuss alternatives to opioids for pain control, but non-steroidal anti-inflammatory drugs should not be used in the third trimester of pregnancy.**

You must keep your scheduled appointments. If you are unable to make it to an appointment, please provide 24-hour notice to cancel. **If you fail to appear or give the requested notice of cancellation, your medications may not be refilled.** If you fail to appear for more than 2 appointments, you may be dismissed from our practice.

You understand that if anytime, your provider has reason to believe that you are not in compliance with the terms of this agreement or your treatment plan, the provider may terminate this agreement and medications with a proper weaning dose. If you wish to terminate this agreement, please contact our office for guidance.

Your health care team is dedicated to your safety and the control of your pain, and we must have your cooperation to achieve these goals. The agreement is designed to ensure your safety and to help us and you comply with the standards of good medical care, as well as, state and federal laws related to chronic opioid therapy. Please sign below.

SUMMARY OF INFORMED CONSENT:

- All prescriptions must be sent electronically per state law. No paper prescriptions will be issued.
- Pain medication will only be prescribed for a maximum of 90 days post-operatively.
- **You are not guaranteed pain medication during this time period**
- If continued pain management is needed after this time, you will be referred for further care.
- You may not share, sell, or trade my medicine.
- I agree not to take any medicine not prescribed to me.
- Forging or altering a narcotic prescription or distributing medications to others is a crime.
- Excessive phone calls requesting increased dosages or frequency is viewed as drug-seeking behavior.
- Changes in medication will not be made without an office visit.
- You will not increase your medicine without speaking with Dr. Jacob or one of his physician assistants.
- Your medicine will not be replaced if it is lost, stolen, or used up sooner than prescribed.
- You will keep all appointments set up by your doctor.
- You will notify your doctor's office at least 24 hours prior to your scheduled appointment if you must cancel.
- Multiple cancellations, no-shows, or rescheduled appointments is considered non-compliance and may result in dismissal.
- You will bring the pill bottles with any remaining pills of this medicine to each clinic visit if requested.
- You agree to come to the office for a pill count at any time if asked by my doctor.
- You agree that you will not use any illegal substances.
- You understand that your doctor's office will use the Oklahoma Bureau of Narcotics Drug Tracking Program as required by law.
- You have been informed by your doctor about narcotic effects, including the normal physiological effects of tolerance (where you might need to take more medication to obtain the same pain relief) and dependence (an uncomfortable withdrawal reaction which may occur if you stop taking medication abruptly), and the abnormal effects of addiction (psychological dependence leading to abnormal behavior).
- You understand that narcotics can adversely affect your judgment in making business decisions and in operating equipment such as an automobile.
- You understand that refills of narcotic medication will be given only during my regularly scheduled appointments or, when appropriate, by telephone if the current prescription has been correctly used.
- You will only use one pharmacy to get your medicine. Your doctor may talk with the pharmacist about your medicines.

Signature of Patient or Legal Representative **Print Name** **Date**

Witness Signature **Print Name** **Date**

Dr. Paul B. Jacob **Date**