Steven F. Harwin, MD, FACS: Informed Consent for Surgery - Risks and Complications

PRIMARY REVISION LEFT RIGHT TOTAL HIP REPLACEMENT TOTAL KNEE REPLACEMENT

OTHER PROCDURE:

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 and your family 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.

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.

Disorders of the kidneys, urinary tract and bladder, leading to disturbed function or abnormal urination and/or infection can occur. 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 flair up of gout and prostate problems. Disturbances of the heart, including abnormal beat and function can occur, as well as heart attack, with serious and rarely, even fatal consequences. 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. Changes in mental function, confusion and even a stroke can occur. Mental changes and confusion usually improves, or clears completely after some time, but some mental and physical deficits can be permanent.

Nerve and blood vessel damage may result as a consequence of mobilization of joint structures and operating near a nerve or blood vessel. Nerves and blood vessels may be stretched, compressed, damaged or cut in the process, which may result in excess bleeding, paralysis or loss of blood supply to the leg especially when contractures, 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 the nerve supplies. Numbness, tingling, burning and pain may occur. The recovery process may be prolonged and may require surgery, depending on the extent of damage and the nerve involved. If a blood vessel is damaged another surgical procedure to repair it may be needed. During the procedure there could also be damage to muscles, tendons and adjacent and remote structures. To gain access to the joint, some structures, including muscles, tendons and ligaments are detached and/or released. As part of the closure of the wound, some of these structures are repaired. After surgery, the repair could disrupt, especially if post-operative physical therapy instructions are not followed. This could necessitate another surgery to repair the structures.

Wound, joint and bone infection as well as poor or delayed wound healing may occur. Blood may collect in the wound after surgery and may leak through the skin, requiring evacuation. If superficial infection occurs re-operation may be needed to clean the wound, bone and joint. If deep infection occurs, the prosthesis may need to be removed for an extended period of time or even permanently, to allow the infection to heal. This can result in a stiff and painful joint. In most cases, if the infection is successfully treated with antibiotics and surgery, a prosthesis can then be re-implanted. 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. Even a successfully treated infection can result in permanent pain, stiffness and weakness.

Blood clots in an artery or vein may cause a block in circulation. 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. Blood clots in the vein may cause pain and swelling and they may travel to the lungs (pulmonary embolus) or brain causing chest pain, shortness of breath, stroke and rarely death. 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. Other complications include reflex sympathetic dystrophy, a condition that causes pain, swelling and stiffness after surgery. While these effects usually disappear, they can be permanent. Rarely a compartment syndrome can occur. This condition is a result of swelling of the thigh or calf that compromises the viability of the nerves and muscles and other structures. This condition requires surgery to alleviate the pressure and can result in permanent damage to the nerves and muscles.

As part of my effort to perform less invasive surgery, if the bone condition is felt to be satisfactory, I use implants that provide a biological fixation to the bone rather than using cement. Cementless implants offer the possibility of long lasting biological fixation but in some cases initial fixation is not achieved and reoperation is necessary. Similar loss of fixation can occur with cemented implants as well. While the survivorship of many cemented and cementless implant designs are comparable, with over 90% of implants lasting 15 years or longer, any joint replacement can fail to cure all symptoms and any implant can fail due to mechanical reasons. The parts can loosen, break, dislocate, wear out, become unstable or generate plastic or metal debris that damages the bone and adjacent soft tissues. The soft tissues can become stretched or damaged. Noises such as clicks and squeaks in the new joint may occur. 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. While all efforts are made to achieve optimal outcomes, there can be no assurance that all pre-operative symptoms will be relieved and that all pre-operative expectations will be achieved. There could be residual pain, stiffness, weakness and limp.

Joint replacement surgery is a combined effort. In order to achieve success you must follow our post-operative instructions. After total knee replacement, you must perform exercises and attend physical therapy to regain a satisfactory range of motion within 6 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. If you had a hip replacement you must use a cane or crutches for 6 weeks after surgery to allow the muscles to heal properly. No abduction exercises should be done until your first post-operative visit or the repair could be disrupted. At 6 weeks it is not unusual to have a limp. It will improve and most likely disappear after completing your physical therapy as directed.

Complications related to anesthesia can occur. If you have specific questions regarding your anesthesia, you may ask them when you meet our anesthesiologist at the time of your surgery. 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, a complication 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 the rarest 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. Patients with a history of serious medical problems and those with an elevated Body Mass Index and obesity will be at increased risk for all complications.

I use a team approach in the surgical treatment of hip and knee disorders. My team includes physicians, nurses, operating room technicians, physician assistants, anesthesiologists, physical therapists, social workers and other specialists who are trained to provide orthopaedic care. Most of us 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 primary and revision joint replacements every year. While I perform the operation for you 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 exposing the joint, the preparation and implantation of all joint replacements and closure of the deep structures. 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 I am a designer of total hip and total knee implants, orthopaedic instruments, and author of many surgical technique manuals and videos, 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, watching video, or by being scrubbed in the sterile operative field. If scrubbed, they only observe, and do not touch you or participate in the surgery. Representatives of the company making the implants I use are often present in the operating room, not scrubbed, in order to make sure we have proper inventory. As a designer and inventor of implants and instruments, I do have a financial relationship with the manufacturer of some of the devices I use. However, by law, I receive no financial benefit or incentive from any implant that I personally use or those used by any other surgeon at our institution.

If you have any questions regarding the benefits, risks, alternatives and possible complications of your operation 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.

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 benefits, risks and alternatives of various treatment options were discussed, I have decided to proceed with surgery. I also acknowledge that I have been given my pre-operative instruction packet for the operation indicated above and advised to read in detail. 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.

_____ (12-16)

Signature of Patient or Legal Guardian

Witness_____ **Date**_____