Patient Consent for Posterior Lumbar Fusion Surgery

(Transforminal interbody fusion / Posterior lumbar interbody fusion / Posterolateral fusion/ Facet sparing Transforminal interbody fusion)

DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT AND FULLY UNDERSTOOD ITS CONTENTS

Name: _____Date of Birth: _____

Physician: ***Dr. Amit Bhandarkar*** Facility: _____

The planned procedure: _____

Diagnosis: _____

After careful consideration, I have decided to undergo surgery to try to lessen my pain and disability. I authorize Dr. Bhandarkar and any assistants as may be selected and supervised by him to perform my surgery. I understand that Amit W Bhandarkar, M.D., is my doctor and will participate in and supervise my hospital and surgical care. I understand that, in his absence, other designated physicians and/or assistants might be involved in my follow-up care. I acknowledge and understand that the above procedure or treatment has been explained to me (sometimes referred to as the patient) in layman's terms. This information is given to me so that I can make an informed decision about having a lumbar spinal fusion procedure to treat my spine-related pain, instability, and or stenosis. I also acknowledge that I had the opportunity to ask for clarifications, and all my questions have been answered to my utmost satisfaction.

Lumbar Fusion surgery is a procedure used to treat instability and disc degeneration in the spine, leading to persistent back pain and, in some cases, numbness and pain in the legs caused by pinched nerves. It is only performed when non-surgical therapies haven't improved symptoms.

Surgical Approach

General anesthesia is used to keep you asleep and comfortable during the procedure. An optimal incision is made to the posterior aspect of the back on at the level identified to be causing the problem. The incisions may be made in the midline or in the paraspinal area. The surgeon may make 1, 2, or 3 incisions, depending on the technique used to approach the spine for decompression and instrumentation. Stab incisions can be placed in addition to insert the screws.

Endoscopic/Minimally invasive techniques

We will attempt to achieve all objectives through small incisions with endoscopic or microscopic assistance. If this fails, an open incision will be performed to meet the goals or in case of complications such as a dural tear

Decompression: *An* optimal portion of the bone/facet joint over the nerve root (where the nerve exits the spinal cord) and/or disc material from under the nerve root is removed to give the nerve root more space and provide a better healing environment. Indirect decompression may be achieved by reducing the slip and increasing the disc height.

Discectomy: The offending disc is maximally removed. The endplates of the discs will be made raw for a good healing surface.

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Spacer–cage insertion may be introduced into the disc space after disc removal to promote fusion. The type and material of the cage to be inserted will be determined based on the specific needs and characteristics of the disc space. Usually, titanium/PEEK /optimesh (bag of bones) are used.

Instrumentation Screws and rods will be inserted in the back to give it stability.

The purpose of the spinal instrumentation
(Metal hardware) is to hold the spacer in the disc space and prevent its extrusion at the same time
Temporarily make the segments of the spine stiff until the bone fusion heals.
Reduction of the slip may be attempted, limited by the stretch on the nerve roots. Complete Reduction of the slip of the vertebrae is usually not needed.

Bone grafting will be performed in the spine joints and disc space to achieve fusion and create a single bone. Bone from the bone bank is used to form the fusion. This bone may be supplemented with a bone graft or bone marrow harvested from the iliac crest (pelvis- the flat bone on each side). The purpose of the bone graft harvest is to obtain bone to pack around the spine so that the vertebrae heal together. The risk of infectious disease transmission from cadaveric bone is very minimal.
Other bone-forming agents, such as bone morphogenetic proteins or stem cell products, may be used (BMP). These agents sometimes have their own specific sets of complications

Expected outcomes
Fusion involves make the segment of the spine permanently stiff. It results in some permanent loss of motion of the spine.

The goal of decompression and fusion surgery is to improve or eliminate symptoms caused by pressure on the nerve root(s) and to provide stability to the back. Some patients have immediate pain relief, and patients wake up after the surgery feeling significant relief from their leg pain. Symptoms such as weakness and /or numbness can sometimes take time to improve, depending on how much damage the pressure caused to the nerve. Sometimes symptoms may improve, but do not ever go away completely. This procedure is more likely to help with leg pain than with back pain. Some patients may take longer to get relief from back pain.
Supplemental Procedures that may be required

- Urinary catheterization
- Neuromonitoring equipment and needle electrode placement
- C- arm – X-ray imaging
- Drains
- local anesthetic infiltration at the incision site
- Bone marrow aspiration
- Bone graft harvesting – separate incision
- Intercoastal Drain placement
- ***Staged Surgery***
- A combination of anterior and posterior approaches may be indicated. This may be done:
- On the same day under one anesthetic
- Five to seven days apart
- Eight to twelve weeks apart

Risks/Complications
The following are some, but not all the risks associated with this procedure.
General anesthesia: Risks of cardiac arrest/failure, pulmonary failure and/or death.

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Nerve, spinal cord complications: Nerve root injury, which could result in numbness/tingling/pain in one or both legs, weakness in one or both legs, loss of bowel, bladder, and/or sexual function. Scarring around nerve roots (epidural fibrosis/arachnoiditis), which could result in intractable and untreatable leg pain/ numbness.

Dural tear (cerebral spinal fluid leak), which, if unrecognized or persistent despite repair, could result in headaches and/or the need for further surgical care.

Wound complications:

Superficial (skin) infection, which could result in the need for additional antibiotics or possibly further surgery.

Deep (below the skin) infection, which could result in abscess formation, bone infection, or infection of the spinal cord or nerve roots that could result in paralysis and/or death. *Deep infection would result in the need for additional surgery(s) and might seriously jeopardize the expected result of the surgery. There may be a need for prolonged IV antibiotics.

Dehiscence or re-opening of the wound after closure. Can increase the risk for infection and will need to be examined for treatment, including repeat surgical closure.

Pseudoarthrosis:

This means the bone fusion doesn't heal. This could result in continued pain, hardware loosening or breakage, and require additional surgery. (Smokers are at four times the risk of non-smokers).

Adjacent Segment Disease:

There is a chance that the segments of the spine near the fusion may degenerate and cause pain, which may need surgery to fix it. The chances of they going bad with time is 3% per year.

Instrumentation failure: The instrumentation inserted to fix the spine may become loose or even break if the fusion does not heal in time, requiring further surgery. Patients with osteoporosis may need bone cement augmentation to increase the strength of the instrumentation to increase the pullout strength of the screws. Bone cages in the disc space may subside in patients with osteoporosis.

Risks to the nearby structures:

Important viscera in close proximity to the area to be instrumented or operated upon are always at risk of iatrogenic injury during the procedure. This may include, but is not limited to, injury to major blood vessels, ureter, and colon. Injuries to these structures, if recognized intraoperatively, are repaired immediately, but the injury is catastrophic and may even cause death.

Blood Loss & replacement

Blood loss during or after surgery can result in the need for blood transfusion or replacement. Blood from the blood bank would be used, and although rare, it can expose you to the risk of blood-borne disease such as hepatitis and AIDS.

General surgical complications:

Atelectasis - mechanical pneumonia.

Pulmonary embolus (a blood clot in the lungs), which can lead to death.

Deep vein thrombophlebitis (blood clot in the leg).

Complications related to a urinary catheter.

Urinary tract infection, sepsis/death.

Continued pain after surgery due to failure of the procedure to relieve pre-operative complaints of pain.

Progression of spinal stenosis at the same or other levels.

A heart attack is due to strain on the heart.

Stroke or transient ischemic episodes (TIAs).

Other potential complications:

Erectile dysfunction

Swelling

Gastrointestinal bleeding from the stress of surgery

Prone position related complications include swelling of the face. Even blindness has been reported although very rare.

* There are many more complications that could occur, but they occur so infrequently that are not listed or discussed.

Complication prevention:

It is important for you to follow all the instructions provided to you by your surgeon and other care providers. Instructions are provided to assist you in your recovery and reduce the risks of surgical complications. Knowing the complications to be aware of and the signs of potential complications helps you to identify any problems early. Early discovery and intervention can potentially reduce the severity of complications if they do occur.

General complication prevention strategies:

Pre-op

Reduce pre-operative anemia by taking oral iron supplements. This can reduce the need for blood transfusions/replacement.

Maintain good blood sugar control if you are diabetic. Elevated blood sugar can increase your risks for infection. Impair your wound healing. Increase the risk of organ failure, such as kidney failure.

Maintain good nutritional status before your surgery. This will help your immune system to aid in healing after surgery.

Stop smoking. Smoking can increase your risk of infection. Smoking can increase your risk of blood clots. Smoking can increase your risk of pneumonia. Smoking can impair oxygen to your wound, causing delayed or poor healing of the incision. Smoking can increase the risk of surgical failure

Alternatives to Proposed Surgical Care:

Rest and anti-inflammatory medications

Exercise/physical therapy/re-conditioning

Spinal Bracing

I understand that alternative methods of treating my condition(s) exist. They have been considered and discussed, but at the present time, my choice is to proceed with the surgical lumbar neuro-decompression. If I choose not to have the procedure, I have been informed that my prognosis (my future medical condition) is still fair.

Implants, devices, and/or pharmacologic agents may be used in a manner considered to be an “off-label use” by the FDA. “Off-label use” refers to using a drug, implant or device for a reason not specifically approved by the FDA. The decision of whether to use an implant, device or pharmacologic agent for an off-label use is a matter of medical judgment.

I understand that the practice of medicine is not an exact science and that no guarantees or assurances have been made to me concerning the results of this procedure or treatment.

I understand that during the procedure or treatment described above it may be necessary or appropriate to perform additional procedures or treatments that are unforeseen or not known to be needed at the time this consent was given. It may also be necessary or appropriate to have diagnostic studies, tests, anesthesia, x-ray examinations, and other procedures performed during my treatment. I consent to and authorize the persons described herein to perform such additional procedures and treatments as they deem necessary or appropriate.

I consent to the taking of photographs or the use of video recording equipment during the procedure for medical education purposes.

For women only: I represent to my physician that I am not pregnant nor am I breastfeeding currently, and understand that there are risks of sedation or of the procedure to an unborn child.

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I have been counseled regarding the nature of the condition for which surgery is proposed. I understand the alternative(s) to surgery. The basic steps of the proposed procedure, the advantages, disadvantages, risks, possible complications, and alternative treatments have been explained and discussed with me by **Dr. Amit Bhandarkar**. I understand that there can be no guarantees on a surgical outcome or that a surgical complication will not occur. I understand that the proposed surgical procedure may not completely relieve all the pain I am experiencing and that the possibility exists that the pain I currently have could be the same or worse after the surgery.

_____ _____

Patient or Authorized person Signature

Date

_____

Relationship to patient if authorized person signature