

Welcome to the General spine surgery Consent section of the SAG Website.

Dear Patient,

Welcome and it's our (all members of spine association of Gujarat) pleasure and honor to have you here for all your spine need and care. It is our aim to make your surgery and recovery full of comfort (with as much low anxiety possible, lowest possible physical /mental discomfort, at most understanding of your disease and possible treatments: albeit some part will always remain in spite of yours and mine best effort). We wish you success as much as possible and pray in thought of god to make best possible efforts.

Spinal surgery takes its toll on patient and on their families. This all information is designed to help you become a well-informed participant in your health care before and after surgery. Please feel free to contact the surgeon if you have any questions or require additional information.

Please note that this information is not designed to frighten you or put you off the surgery. It is very important that you are fully informed about the risks of any surgical procedure. All surgical procedures carry risks in the same way that of driving, for example carries risks regardless of how skilled the operator (driver) is. It also varies with what you are driving, whether its a kids wave-board or an plane or a military artillery tank. They are not the same but necessary in that particular context and need of person/human or society. It is also a requirement of **quality regulatory authorities (Indian Government-NABH etc.), Insurance companies and Indemnifiers** that surgeons inform patients of as many risks as possible before undertaking any surgery in order to provide insurance cover for them. Below you will find current information related to spinal surgeries and answer to common queries as well as consent information as authorised and published by SAG.

Why do I need spinal surgery?

Degeneration this is the most common reason for having spinal surgery. It is wear and tear of your spine that causes one or more of your spinal nerves to become trapped. Symptoms of a trapped spinal nerve include: • sciatica • leg or foot pain • pins and needles • numbness. Sometimes you have back pain in one specific part of your spine and you may need surgery. These all symptoms have varying grades and may be not at all be severe or very serious. Its grading and quantifying of the disease is by the specialist spine surgeon.

In **Spinal stenosis** you usually get this in the lumbar (lower), Thoracic (middle) or Cervical (upper) part of your spine. The space for the nerves in your spine becomes narrow. This 'traps' the nerves as they are in traversing or while leaving or after leaving your spinal column.

Disc prolapse you have discs between each of the spinal bones which act as shock absorbers when you move around and carry things. They provide movements and flexibility to the back and

neck. At the same time any thing which has got movement or flexibility will show wear and tear. These may be a slow process or a sudden process of giving away. Usually, it happens as you get older or because you have lifted heavy objects or any abnormal sudden strain-movement or jerk.

Instability is a structural failure of vertebral body, leading to mechanical back pain or nerve compression. So, it is loss of the stable structure and function of spinal column (bone disc joints) which may affect directly the nerves.

Deformity (Kyphosis-scoliosis) is a loss of natural structure and or function of spine with or without **instability**.

What are my surgical options?

Here is a brief insight of about your surgical options based on condition. Decompression is usually the component of all types of surgeries. This means making space for neural tissue.

Laminectomy or laminotomy or fenestrations: This involves removing the arches of bone partly or completely at the back of your spine to make more room for your trapped spinal nerves. You usually have this operation if you have spinal stenosis.

Discectomy: Involves removing the part of the disc that is pressing on your nerve root. If you have a discectomy, the damaged disc is removed through a smaller incision (cut) or moderate incision or larger incision depending upon the need. This is in combination with laminectomy, laminotomy or fenestration.

Spinal fusion: This is complex surgery. We stop certain spinal bones from moving (immobilise) using cages or metal screws or wires or tapes. You have this only if your spine needs to be kept steady (stabilised). This is usually with some form of bone graft, natural , processed or artificial.

Mobility preserving devices: In some context when used it gives some stability and preserves mobility.

Goals and benefits:

Your consultant thinks that you will benefit from one of the surgical options we explain here to repair-stabilise- optimally correct the damage to your spine to have a functional improvement or stabilisation of the disease and reduction of pain and or disability. They will discuss with you which procedure is the best for you and explain it in more detail. The curative effects are less and improvements are usual the norm with some residuals expected. The long term outcomes depends not just on the surgery as believed by layman but more on the disease, genetics, habits of patient and life style modifications done by the patient. Moreover, there is a very big role of personality, psychology, family and social environment as well. Benefits are more than the risks and patient should be aware of them as well.

Complication and risks associated with spinal surgeries:

Any operation has the potential for complications or adverse effects whether it is a minor or major procedure. More major procedures do have higher chances of these complications or untoward side effects and this is even more so if you already have other pre-existing medical conditions such as heart disease, diabetes etc.; The risks of the operation are also higher in people whom are having a repeat or second time spinal operation. All spinal operations are regarded as major surgery. Every possible precaution is taken to prevent any complication from occurring. One cannot outline each and every complication that could occur, but the more common complications are discussed here.

1. Infection - The risk of infection is less than 1%. All precautions are taken to prevent a wound infection. All patients receive a dose of intravenous antibiotics at the time of surgery. If you develop an infection it is most likely to be a superficial wound infection that will resolve with a short course of oral antibiotics. Occasionally patients develop a deep spinal infection. This is much more serious and may require a prolonged course of intravenous antibiotics or additional surgery and protracted recovery including overall cost.

Risk factors like diabetes, obesity, smoking, immuno-compromised states increase the chances of infection up to 5%.

2. Deep Vein Thrombosis or DVT (developing clots in the legs) and Pulmonary Embolism or PE (these clots moving from your legs to your lungs) are potential life-threatening complication, but the incidence is less when compared to hip and knee surgeries. Many spinal surgeons prefer not to give DVT preventative medication (Warfarin or Heparin like medication – “blood thinners”) because they can cause bleeding around the spinal cord leading to weakness or even paralysis in the legs as well as permanent bowel and bladder incontinence. You will be shown exercises and will be mobilised early to try and minimize the chances of blood clots forming in your legs. Special stockings (TEDS) if needed also be given to you to help to try and prevent them from forming. These are to be worn for 6 weeks after the operation. The balancing of DVT prophylaxis or no prophylaxis should be done on as per the risk benefit ratio as per operating surgeon and physician.

Risk factors for clotting disorders are bed ridden patients, diabetes, obesity, old age, prior use of blood thinners.

3. With any major surgery there is always a chance that you may need a blood transfusion. We try to avoid giving blood transfusions but sometimes this is unavoidable. With today’s available modern tests, the chances that you acquire one of the transmissible diseases through a blood transfusion are exceptionally small though can occur. Also transfusion reactions can occur which may be minor like rash to chills/fever or even multiple organ failure.

4. If you have a spinal fusion operation, instrumentation is sometimes used (screws and rods or plate and screws placed into your vertebrae or bones of the spine). The aim of the

instrumentation is to hold the spine firmly together in position while waiting for the bone graft to fuse together. There are recognized possible (but rare) complications related to using the instrumentation in spine. These include cracking or breaking of the metal screws etc.; due to metal fatigue. Normally the screws or implants are left in your spine and not removed. If you are having a spinal fusion operation, we most often will use bone from the right or left side of your pelvis as part of the “bone graft”. You will most likely experience some numbness in this area. This should improve somewhat but will probably never return to being completely normal. Many time surgical site bone itself is morselised and used as bone graft. Bone graft non-union or lack of a solid fusion (pseudarthrosis) – this can affect up to 5% of fusion operations, and may necessitate further surgery. Please note that the aim for spinal fusion operations is to “Stiffen your Back” so please don’t be disappointed if your back feels very stiff afterwards!

Risk factors for pseudarthrosis (non-union) are smoking, diabetes/other chronic illness, obesity, malnutrition, osteoporosis and long term steroid use.

5. Dural tear – occasionally in spite of precision in surgery inevitable tear of the spinal cord is caused leading to leakage of the fluid that surrounds the spinal cord (the cerebro-spinal fluid). Some tears are managed conservatively, whilst others require surgical repair then itself or later on if any problems develop. Patients who have had a dural tear may be asked to lie flat in bed for a short period of time following their operation. Occasionally a persistent leakage of spinal fluid occurs which may require further surgical intervention like bypass tubing/drainage etc.

6. Nerve injury – As surgery involves critical and necessary handling of nerves, sometimes the nerves may get damaged partially/fully, temporary/ permanent in decompression or instrumentation surgeries. The spinal instrumentation is inserted very close to the spinal nerves. This can lead to loss of nerve function with persisting pain, weakness, and numbness in the area of that nerve. This complication can occur in up to 5% of patients. It is possible that a nerve injury could also affect your bladder and bowel function, as well as erectile function in men. Although further surgery may be undertaken to remove or adjust the spinal screw, the loss of function and pain from a damaged nerve may be permanent.

7. Scar tissue – Scar tissue occasionally forms around the nerve and can cause persisting neurological symptoms. This would usually be treated with steroid injections rather than further surgery.

8. Back pain – Even if a successful fusion is achieved, it does not guarantee 100 percent relief of back pain.

9. Adjacent level issues – as a fusion surgery stops part of your back from moving, there is a risk of aggravating wear and tear at the adjacent level or naturally as part of the ongoing degeneration which first presented at the index level and now going to engulf other joint levels. There is a 10-15% risk of requiring further fusion surgery as a consequence of this.

Will the anaesthetic doctor see me?

Do not be worried about your anaesthesia. Before your operation the anaesthetist will come and see you – this is the time to ask any questions that you may have. They will ask lots of questions about your general health. They will ask about medications you are currently taking and if you have any allergies any previous history of surgeries.

What are the risks of a an aesthetic medicines?

Serious complications following a general anaesthetic are uncommon; however, risks cannot be removed completely. The risks to you as an individual will depend on various factors: whether you have any other illness, personal factors (such as being a chronic smoker or overweight), or whether your surgery was more complex.

Very common side effects (1 in 10 patients): Feeling sick and/or vomiting, sore throat, dizziness, blurred vision, headache, itching, and pain during injection of drugs, bruising and soreness, confusion and/or memory loss.

Uncommon side effects and complications (1 in 1000 patients): Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious) during the operation.

Rare or very rare complications (1 in 10,000 or 1 in 100,000 patients): Damage to the eyes, serious allergy to drugs, nerve damage, death and equipment failure.

It is important that you are aware of these potential downsides or possible complications and side effects when having a back-neck surgery. The chances of them occurring are however very small but definitely not zero.

As mentioned, we will do absolutely everything we can to try and prevent and reduce the chances of problems related to your operation however any operation, even the smallest procedure, has the potential for experiencing some unpredictable complications. Other forms of anaesthesia like spinal anaesthesia/ epidural anaesthesia /local can be used where patient completely does not lose consciousness. They are given with injections in back.

Staying in bed after the operation and discharge time?

Generally, patients are encouraged to get out of the bed as soon as possible after surgery to prevent complications from lying in bed in same position for long time.

Patient may be in hospital for between one to five nights after surgery where some patients will be able to go home the day after their operation. You may need to stay longer, particularly if you have a major disability prior to your operation and/or any other medical problems; or if there have been any post-operative complications. You must be medically fit to go home.

Sometimes the achieved reconstructive stability is less than optimal due to disease or osteoporosis or multi-factorial. This makes mobilisation least or non-mobilisation time (in bed time) increased to variable weeks to months.

Recovery process length?

To accurately tell the degree of pain relief and when that occurs after surgery is impossible. But its severity reduces. After surgery relief from pain can occur in days to months. It depends on surgery and condition of patients before surgery. In some cases, residual numbness, weakness, and/or pain remain but most of the times they are tolerable.

People without hard laborious job can return to work six to eight weeks after surgery wherever it is possible and advised (decided solely by your surgeon's discretion because he knows what are your favourable and non-favourable aspects of your spine) at 3 months in case of jobs with heavy labour. You may wish to consider the possibility of a change in career if needed to avoid long term damage to other structures of spine, prevent recurrence and to achieve the maximum benefit from your operation.

Changes in procedure during surgery?

Doctors can evaluate spinal problems with more accuracy during surgery. If unknown conditions before surgery, arise at the time of surgery doctors must perform additional procedure or change the procedure to preserve and restore optimal health or in rare cases save the life of the patient.

Operating Doctors qualification?

This procedure will be performed by a consultant orthopaedic spine surgeon or consultant neurosurgeon or or neuro-ortho surgical specialist registrar/residents/fellows supervised by a consultant. SAG associated doctors have completed postgraduate training in orthopaedics / neurosurgery which qualifies by Medical Council of India (MCI) guidelines to operate spine surgery. His elected practice is primarily the evaluation and treatment of spinal disorders. By the virtue of his special training (or fellowship/s in spinal surgery) over his postgraduate and /or extensive practice experience, spine doctor has developed the knowledge and ability to practice spine surgery safely and use many different internal fixation devices and biological substances. Newer technologies and principles as updated have been incorporated into his/her practice for betterment of patient in all possible ways.

Surgery Pictures/videos and surgery observation/ assistance?

I understand that medical or non-medical personnel may be present to observe and assist with surgery. I also understand that pictures or videotapes of my surgery or x-rays may be used for educational purposes. I give my consent to these educational efforts and realize that this in no way affects my care. My identity will not be disclosed, if my x-rays, pictures or videotapes are used at any time.

Cancellation of surgery

Patient may also contact doctor or the spine team for further consultation in case of any confusion. At any time, patient has freedom to seek second opinion from another doctor or cancel the surgery before starting the surgery.

Necessity of surgery

Doctors always try to treat spinal problems with conservative treatment without surgery if possible. It includes medications, physical therapy and exercise, injections, nerve blocks. Spine surgery is usually prescribed when there is no possible alternative option which can treat patient and if the patient is not ready for other modalities of treatment after weighing its benefits against surgery.

Neuromonitoring

Neuromonitoring may be necessary to protect spinal cord or nerves from injury by providing useful and real time information on the status of spinal cord or nerves during surgery. Risks are infection, tongue or oral laceration, seizures or failure of the effective monitoring due to technical or other medical reason. In this event, surgeon would be blinded to the real time status of spinal cord or nerves in during surgery which increases chances of permanent neurological deficit from surgery. In such cases doctors take the opportunity to discuss with patients' attenders to stop surgery or continuing with the planned procedure. The method of neuromonitoring may not be FDA: Food & Drug Association USA or DCGI: Drug control General of India approved and may require specific anaesthetic protocols necessary for optimal neurologic assessment.

Use of new techniques and tools

The FDA (Food and drug administration) of USA has mentioned use of certain implant, devices and substances as investigational and not properly approved them to use in certain spine conditions. It is quite common, and legally and medically appropriate, to use FDA approved devices, substances or mediations for uses other than those for which they are specifically approved. In some cases, doctor believe that use of a fixation device or substances within spine will significantly improve the chances that fusion will heal, or patient's condition will improve. Surgeon, due to his/her experience and expertise in spinal research, may have designed many spinal implants and procedures that may or may not be approved by the FDA/DCGI which may be utilized in spinal procedure. If research product or unapproved product is used, the patient should be informed. FDC of India licensed implant be used.

Investigations: Many investigations are needed to arrive at diagnosis. These all have different sensitivities and specificities. That means they may be specifically identifying one disease or

many diseases. They may be identifying mildest grade or only severe grade of disease. All investigations have false positive and false negative results and have a range of true positivity.

O-ARM: it's a mobile CT scan machine that guides surgeon in the operation theatre. It increases the preciseness but has cost implication and increase time duration of surgery.

Navigation system: It helps in navigating the screws during surgery .

Microscope: magnification and illumination aids the surgeon to do more precise surgery when needed, camera and light source fall from outside the body.

Endoscope: camera and light source are incorporated with the stick of the endoscope, so possible to work within the body through the stick.

Burr: rotating cutting instrument for bone to do precise and faster surgery rotating cutting instrument for bone to do precise and faster surgery

Bone scalpel: oscillating cutting instrument for bone to do precise and faster surgery

3D Printing: A technology in which materials are joined to obtain 3 dimensional models under computer control. This is used to make specifically crafted implant or for putting screws in complex deranged deformity of spine.

Biologicals: Products usually medicines or bone graft substitutes which are produced by genetic engineering

Absorbable Implants: Implants which may get absorbed

X Ray: Usually identifies Bone and joint status. Its strength alignment and movement and stability including position of implants.

MRI and its varying sequences: Identify all structures and its pathological affections. Its more for disc, joints, muscle and nerves. Contrast is a medicine which when injected gets localised in some type of tissue more, thus helping in identifying the diseases specifically.

EMG NCV: Its nerve test and uses needles pricked on body and low grade current passed to identify its functioning.

CT SCAN: It give precision findings of bones and joints and implants.

Dexa scan: Test to quantify and grade osteoporosis (Weak bones).

PET scan: It is a CT scan but detects hot spots of diseased parts in body especially for detecting Cancers and its spread.

Diagnostic Blocks: Injections given with anaesthetic agents or saline in operation theatre which helps to pin point source of pain generators in spine when some confusions exist about the exact source of pain. Many a times added steroids are also given with the injections. These

injection doses of steroid is very low and its action is very localised. It does not cause major spread in the body or side effects which occurs with usual daily injections or tablets of steroid.

Research participation

Surgeon, due to his interest in spinal research, may ask patient to participate in research protocols sponsored by various spinal research societies, industry or of doctor's own design.

Conflict of interest

Surgeon at times maybe participating as a paid consultant or have a financial interest in the development of products that may be used in planned spinal procedure. This is informed to the patient if any.

Smoking/Drugs/Alcohol risks

Smoke and nicotine exposure from cigarette, cigars, nicotine patches, chewing tobacco, and other forms of smoke/nicotine may significantly worsen the outcome of surgery. It is patient's responsibility to avoid these all to achieve best possible recovery after discharge from the hospital.

Disposal of Tissue - Tissue removed from the body may be used to confirm or to make a medical diagnosis and can be sent to the pathologist and/or laboratory for diagnosis.

Insurance

Usually all surgeons have a standard insurance policy to cover legal and financial liabilities against malpractice/indemnity (20 lac). If patient requires a higher rate of cover due to the nature of his/her profession (or any other reason) i.e. professional sportsman, celebrity or businessman, high net worth, more dependents on you, then it is your responsibility to ensure that extra cover for you from insurance agency prior to surgery. You must let us know before proceeding to surgery rather disclosing it in the event of any mishap or litigation later.

Hippocratic Oath

When a medical student starts his journey of being a professional practitioner, he takes an oath named Hippocratic Oath is the oldest and widely followed in medicine since more than 2500 years. In Hippocratic oath the doctor swears to treat the ill to the best of one's ability.

Traditional oath was about a best ethical practice and focusing on humanity. Whereas revised oath includes ethics about research recent advances and teaching also. This has created scope for more advanced and evidences based practice. The Indian Medical students take an oath about and against pharma-physician nexus, cross-practice and cut practice. Additionally, Indian Medical students also take pledge that they will always respect their teachers, colleges and patients. So, when you take treatment from the doctor you can have complete faith in your doctor.

Attack on doctor

When a doctor treats a patient, he gives best possible treatment to the patient. Then also sometimes unfortunately he fails to provide a treatment as per the patient's expectations. Occasionally, such patients/relatives of patient get uncontrollably angry. In anger patients/relatives takes inappropriate steps and become violent. They attack doctor or their staff or try to damage hospital property. In extreme cases they have attempted to kill the doctor also. Previously such incidences are reported in Gujarat and India elsewhere. After that the Government and Medical Council of India have formulated some rules and regulation. This includes how doctor can defend himself in such cases legally. It also includes imprisonment punishment and/or heavy fines. Due to current environment of hostility towards doctors these rules are also becoming strict. Also, In the event of rage, in violation of rule of land if patients or relative attack surgeon, the doctor being human to save his life can also retaliate and behave in unpredictable ways including reverse attack. This is normal reaction for any human or animal.

Difference in opinion

In today's time there are many practitioners available for same medical conditions around us. When patient visits more than one doctor, sometimes there is a conflict in diagnosis or management of two doctors for the same patient's complaint. Patients take it very unusually, but this should be accepted wisely by the patients. When you visit the doctor, the way you are approaching a doctor makes a very big difference in doctor's decision about your diagnosis and management. A doctor method of working, experience, and area of expertise also influence their decisions. Additionally, different mind works in different ways according to their abilities and understanding. In such conditions you should take decision accordingly your priorities and preferences.

Support group

There are many supporting group for people affected with spinal diseases. Below are listed some groups who can help you to communicate directly with patients similar to you. With this you can have supporting community who can understand your condition and challenges which you face. You may find some support and additional helpful information regarding your condition. Please contact your spine surgeon before changing any medication or going for any additional surgery or physiotherapy or drastic life style change.

<https://www.facebook.com/groups/degenspine.backpain/>

<https://www.spine-health.com/forums/>

References: Below are some references which can be further read in detail by the patient or concerned to understand about consent/patient rights and the disease/treatment options.

1. <https://mayfieldclinic.com/pe-anat spine.htm>

2. <https://spinesurgeryofidaho.com>
3. <http://www.spinesurgeons.ac.uk/patients-area/consent/>
4. <https://www.londonspine.com>
5. <http://www.theindianlawyer.in/blog/2018/03/10/supreme-court-informed-consent-india/>
6. <https://www.spineuniverse.com>
7. <https://www.mayoclinic.org/tests-procedures/spinal-fusion/about/pac-20384523>
8. <https://www.umms.org/ummc/health-services/orthopedics/services/spine/patient-guides/complications-spine-surgery>
9. Bohl DD, Webb ML, Lukasiewicz AM, Samuel AM, Basques BA, Ahn J, Singh K, Vaccaro AR, Grauer JN. Timing of complications after spinal fusion surgery. Spine. 2015 Oct 1;40(19):1527-35.
10. Smith JS, Klineberg E, Lafage V, Shaffrey CI, Schwab F, Lafage R, Hostin R, Mundis GM, Errico TJ, Kim HJ, Protosaltis TS. Prospective multicenter assessment of perioperative and minimum 2-year postoperative complication rates associated with adult spinal deformity surgery. Journal of Neurosurgery: Spine. 2016 Jul 1;25(1):1-4.
11. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. Jama. 2010 Apr 7;303(13):1259-65.

IMPORTANT:

Please do not hesitate to speak to your family doctor or any of the spinal team doctors or nurses if you are unsure about any aspects of your treatment or wish to discuss other treatment options. Only you can decide whether your symptoms are severe enough to go ahead and have an operation done with the potential associated risks. The main problem with back surgery is that the result is not always predictably excellent or gratifying and can, on occasions though rarely, even make your symptoms worse.

FOR SUGGESTIONS:

Patient or surgeon can suggest more information needed to be added. This may be considered and incorporated if appropriate. The consent committee will decide the merits of suggestion and new version of the Information document will be uploaded. Please mail to spineassociationofgujarat@gmail.com