

Having a spinal augmentation procedure to treat broken bones in your back

Department of Radiology

Information for Patients

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Introduction

If you are an outpatient please read your appointment letter carefully to check which hospital your appointment is at. This leaflet tells you about your examination and treatment. Please read it carefully as it contains important information and instructions.

What are spinal augmentation procedures?

Spinal augmentation involves injecting a material that hardens like cement, into a broken (fractured) bone in the spine (vertebra) using thin needles. When the cement hardens, the fracture is stable and less likely to cause pain. The procedure is usually done on an outpatient basis. This means that you can usually go home on the same day.

There are 2 types of spinal augmentation. You may have one or both of these procedures:

Vertebroplasty - cement is inserted into the fractured vertebra. A tiny cut is made on your back, through which a small amount of cement is injected through a needle into the affected bone (vertebra). The cement is liquid and sets after a few minutes. This creates a supportive structure that strengthens the bone and helps the pain. More than 1 bone can be injected during the same procedure up to a maximum of 3 bones.

Kyphoplasty - this is like a vertebroplasty but is done on a partially collapsed vertebra. A space is made in a partially collapsed vertebra before the cement is inserted. This procedure is used to both stabilise the (bone) vertebra and add height back into the spine.

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Why do I need a spinal augmentation?

The spine is made up of 33 separate bones, each called a vertebra. They protect your spinal cord and provide support to stand upright. If a fracture occurs in one of the bones it tends to flatten. If a vertebra fractures (sometimes referred to as a 'collapse') it can become very painful and some of the support is lost. It can happen for several different reasons and in more than one bone.

Fractures of the spine are common in patients with osteoporosis and sometimes in patients who have cancer in the spine. Up to 3 in 10 people (30%) with osteoporosis will have at least one fractured vertebra at some point in their life. In 2 out of 3 patients the pain is relatively minor. They may not even know it has happened. In the other 1 out of 3 patients, the collapse of the bone causes a sudden pain in the upper or lower back.

The main treatment is rest and painkillers, which usually helps. For many people, the pain gradually improves and goes away in a few months. The procedure is only useful for some patients in whom the pain persists.

Lots of people cope well with vertebral fractures, needing only pain relief, however for some people the pain is not relieved by medication. Either they cannot take the medication because of side effects or they go on to have severe, lasting (chronic) pain. Spinal augmentation may help relieve the pain for these people.

Spinal augmentation is done for 2 reasons:

- To reduce back pain caused by collapsed / fractured vertebrae
- To prevent vertebral fractures happening (usually in patients who have tumours in their bones).

Asking for your permission (consent)

The doctor who referred you should have talked to you about the reasons for this procedure and any other options.

You have been referred to a hospital doctor who specialises in X-ray treatments, muscles, bones and joints (Musculoskeletal Radiologist) for this procedure. They will confirm that you understand why the procedure is being done, its potential risks and what the chances of success are. You will then be asked to sign a consent form to confirm this. **You should feel that you have had enough explanation before you sign the consent form.**

If after talking to the Radiologist you do not want to have the procedure then you can decide against it at any time. If you decide not to have the procedure before your appointment day please ring the Radiology Department on 0116 258 8765 and cancel the procedure.

If the Radiologist feels that your condition has changed they will talk to you about whether the procedure is still needed. They may then ask you to return to your referring doctor for review.

If you feel during the procedure that you do not want it to continue we will explain the implications of not doing so to help you fully decide.

How do I get ready for the procedure?

Pre-assessment:

If you are an outpatient, you will have a pre-assessment before the procedure. Your pre-assessment may be days or weeks before the procedure. It might be done at the hospital or over the phone.

You will be asked some questions from a checklist about your medications and your health.

Please bring a list of your medications to the pre-assessment. Please tell the staff at the pre-assessment if you use any pain relief patch.

They may also talk to you about 2 other procedures that can be done at the same time as the spinal augmentation procedure.

Radiofrequency ablation. This is a procedure that is sometimes done at the same time as the spinal augmentation. The procedure involves heating a part of a pain-transmitting nerve with a radiofrequency needle. This can prevent the nerve from sending pain signals to the brain.

Bone biopsy. In all spinal augmentation procedures a bone biopsy of the vertebra is also done. This is to help the doctors looking after you find out what the cause of your spine fracture / collapse is. The results of the biopsy will be discussed with you at your follow-up appointment 1 month after the procedure.

Blood test:

Before the day of your procedure you will have a blood test to make sure that you do not have an increased risk of bleeding.

Do I need to stop any of my normal medicines?

Medication that thins the blood:

If you are taking medication that thins the blood (anticoagulants or antiplatelets) it may need to be stopped or replaced with a different one for a few days.

Please tell the staff at the pre-assessment clinic if you take any medication that thins the blood so they can give you advice.

Common examples of these drugs include:

aspirin, warfarin, clopidogrel (Plavix®), apixaban (Eliquis®), betrixaban (BevyxXa®), dabigatran (Pradaxa®), edoxaban (Savaysa®) rivaroxaban (Xarelto®), ticagrelor (Brilinta®), Dalteparin and Heparin.

- For 5 days before and 2 days after the procedure, do not take any **aspirin** products, as it can increase the risk of bleeding.

Non-steroidal anti-inflammatory medicines:

For 5 days before and 2 days after the procedure, you should stop taking **ibuprofen, diclofenac, Voltarol, indomethacin, ketoprofen** and other non-steroidal, anti-inflammatory medications. These pain relievers can also cause bleeding.

Homeopathic supplements:

For 5 days before and 2 days after the procedure, you should stop taking homeopathic supplements that can increase the risk of bleeding. These supplements include **gingko biloba, garlic, ginseng, St. John's wort, ephedra, kava, valerian** and **echinacea**.

Medications that make you more vulnerable to infections (immunosuppressants):

Please bring a list of your medications to the pre-assessment visit. You will be given advice about these medications at your pre-assessment visit. These medications include **prednisolone** and **methotrexate**.

What must I do on the day of the procedure?

- **Eating and drinking:** Do not eat or drink from midnight before the spinal augmentation.
- **Medication:** Please take your normal prescribed medication **before 7am** on the morning of your operation unless you have been told not to at your pre-assessment appointment.
- Please make sure you have a supply of paracetamol and ibuprofen at home unless you are unable to take these for any reason.
- Please arrange for a responsible adult to collect you from the hospital after your procedure and take you home. You must not drive for 3 days after spinal augmentation.
- **You must also arrange to have a responsible adult stay with you for 24 hours after your procedure.**
- **Please bring an overnight bag** with you in case you need to stay in hospital overnight (toiletries, dressing gown, slippers and something to occupy your time). Most patients will have their procedure as a **day case**. This means that you will come in for the day only, provided there are no complications.
- **If you are on blood thinners** you must tell the doctor before starting the procedure.
- **Pain relief** - If you are having pain, normal paracetamol may be taken to relieve pain or discomfort before and after the procedure.

If you are staying in the hospital as an inpatient, the nurses on the ward will help you get ready for the procedure.

What must I not do on the day of the procedure?

- **Do not** smoke or drink alcohol for 24 hours before your operation.
- **Do not** wear contact lenses.
- **Do not** wear jewellery except for a plain wedding band only.
- **Do not** wear makeup on the day of your operation.
- **Do not** wear nail polish or acrylic nails. During your operation, your oxygen levels will be monitored with a probe placed on your finger. Nail polish and acrylic nails can interfere with this.

What happens during the procedure?

- Before the procedure a small plastic tube (cannula) will be put into a vein in your arm. This is so that you may be given medication if necessary.
- You will also be asked to put on a hospital gown.
- The procedure is done under general anaesthetic (GA) so you will be asleep while it is done. There will be an anaesthetic doctor with you throughout to look after you.
- You will be attached to a blood pressure monitoring machine and have a small monitoring device (peg) attached to your finger to check your heart rate (pulse).
- The position of the bones in your spine requiring treatment will be seen using X-rays. If the doctor considers that it is not safe to treat the collapsed vertebra after these pictures then the procedure may not be done.
- Everything will be kept clean (sterile). Your skin will be cleaned with antiseptic and you will have some of your body covered with sterile sheets.
- The radiologist will look at the X-ray images whilst carrying out the procedure to make sure that the needle and cement is placed as accurately as possible.

What happens after the procedure?

- The spinal augmentation will take up to 2 hours.
- At the end of your procedure, you will begin to wake up. You will be given oxygen through a face mask over your nose and mouth for a short while. You may have some common side effects after your anaesthetic such as sickness, feeling cold/shivering or feeling confused. Do not worry, your nurse will recognise these side effects and look after you.
- You will be taken for a CT scan after the procedure to check for any complications and asked to lie flat until the scan is seen by the consultant.
- You will be taken back to your day ward. Nurses will carry out routine observations, such as taking your pulse and blood pressure, to make sure that there are no problems.

- If the consultant is happy with the results of the CT scan then you will be allowed to get out of bed under supervision. You will then be offered food and a drink.
- You will need to stay in hospital until the nurses are satisfied that you have fully recovered after your procedure and general anaesthetic
- After this time, if you are not having any side effects, you can go home. Your dressing will be checked and changed if necessary. A letter, with spare dressings for the district nurse, will be given to you.

Do not drive yourself home after the procedure. Somebody must go home with you and stay with you for the next 24 hours.

Safety advice to follow after a general anaesthetic

General anaesthetics (GA) can affect your memory, concentration and reflexes for 24 to 48 hours. Please rest at home for at least 24 hours after your GA. Do not go to work or school the day after your operation. It is important that you follow these instructions:

- **You must** have a responsible adult to take you home and to stay with you for the first 24 hours.
- **Do not** operate any machinery or appliances that may cause harm or injury.
- **Do not** make important decisions or sign legal documents.
- **Do not** drink alcohol.
- **Do not** smoke.
- **Do not** take sleeping tablets.
- **Do not** drive. After spinal augmentation do not drive a vehicle or bicycle for 3 days.

Important advice to follow when you go home

- **Activity** - You should rest for the remainder of the day and the following day. Do not stay in bed all the time; move between sitting and resting to prevent clots developing in your legs. For the next 48 hours do not lift, stretch or do any strenuous activity such as heavy housework, gardening, sex or walking long distances. After that, activity should be increased gradually, as pain improvement allows. If you suffer from bad osteoporosis you are advised not to lie on your chest in future.
- **Dressing care** - The wound site is very small. When you leave the hospital it will be covered with a small dressing. It is very important to keep the wound site clean and dry. Do not get the wound site wet. A district nurse will be contacted for you to arrange to change your dressing in about 4 days. You may have a shower after 24 hours but keep the wound site and dressings dry.

- **Pain control** - The amount of pain or discomfort you may have in the first few days after the procedure is quite variable. You may have been given a prescription for pain control. This medication is optional. Follow the instructions for use given on the prescription.
- **Work** - Depending on the job you do, it may be necessary for you to take a week off work. Please ask the doctor or one of the nurses if you are not sure.
- **Follow-up appointment** - A follow-up appointment to see the consultant who did the procedure will be made for you by the nurse specialist. This appointment will be made for about 1 month after your procedure. The appointment will be sent to you in the post.
- **Smoking** - If you are a smoker please be aware that smoking can affect the success of the procedure. Patient who continue to smoke have a greater risk of complications. The nurse will be able to give you information on the help that is available to NHS patients to support and encourage them to stop smoking. If you would like help to give up smoking, please telephone the NHS Stop Smoking service on 0300 123 1044.
- **Exercise** - Many patients find that once the bone pain is reduced they get muscular pain. This is because the muscles of the back reduced in size (atrophy) when they are not used. This will need some light exercises, e.g. some physiotherapy, light yoga, swimming or pilates. The muscles can take up to a year to recover their previous strength .

Are there any risks or complications?

As with any procedure or operation, complications are possible. We have included the most common risks and complications in this leaflet, although they are different for each person. Your risks will be discussed with you before you sign the consent form.

In patients with osteoporosis who have a spinal augmentation procedure, minor complications occur in 1 or 2 out of 100 patients (1 to 2%). In patients with cancer in the spine these complications may occur in 3 to 6 out of 100 patients (3 to 6% of cases).

The most common risks are:

- **Swelling** - There will be some swelling at the procedure site for at least 48 hours after the procedure.
- **Pain** - having the procedure can be uncomfortable
- **Bleeding** - a small amount of bleeding is common. A major bleed is rare. it is normal to see a spot of blood on your plaster. If you notice a slight bleed, please press on it firmly for 10 minutes. If the bleeding continues, seek medical advice. If you begin to bleed a lot from your wound site this is an emergency. You need to dial 999 to call an ambulance.

Less common risks are:

- **Infection.** It is possible to introduce infection into the body any time a needle is used.

Everything will be kept sterile to help reduce the chance of infection. . Signs of infection are a high temperature, the injection site being more painful, swollen, hot or red, or a discharge from the injection site. Please seek treatment from your GP, call the NHS helpline on 111 or go to your nearest Emergency Department if you have any of these symptoms. Tell them you had spinal augmentation.

- **Leakage of cement into the spinal canal.** The fractured bone may allow leakage of cement into the spinal canal. If this happens, the cement can interfere with the spinal cord or a nerve. Cement leakage into the spinal cord space can cause complications. In severe cases, it can lead to paralysis of an arm or leg (paraplegia). These patients may need an operation to remove the cement if it is causing severe problems. The reported rate of cement leakage, compression of a nerve (nerve root compression) and paraplegia, according to NICE (National Institute of Clinical Excellence) is 5 out of 100 patients (5%).
- **Leakage of cement into the blood stream.** Cement can leak into the blood stream and travel to the lungs, While this is not common, the consequences can be fatal.
- **Allergic reaction** - It is possible to be allergic to any drug. This is uncommon with the drugs used for spinal augmentation (less than 1 in 100 patients) and the general anaesthetic. The most common allergic symptoms are itching or a mild skin rash. Severe side effects are rare (less than 1 in 10,000), but could include a severe rash, trouble breathing and swelling. Drugs used for spinal augmentation include:

1. General anaesthetic:	Propofol
2. Painkiller:	Fentanyl
3. Skin anaesthetic:	Lidocaine, Marcaine
4. Cement:	Poly Methylmethacrylate
- **Unable to complete the procedure** - Sometimes it is not possible to complete the procedure as the fracture may have got worse since the first assessment and the risks of complications outweigh the benefits on the day of the procedure.

Other side effects that have occurred with spinal augmentation include a fever or a temporary worsening of pain for a few days.

At all times during and after the procedure staff will monitor your responses to minimise the effects of any complications.

Occasionally the procedure might not go ahead because of a technical issue. If this is the case it will be explained to you on the day.

What are the risks from exposure to radiation in this procedure?

The main risk from having X-rays is an increase in the risk of getting a cancer in the future. This risk is thought to be very small. We are all exposed to natural background radiation every day of our lives. This comes from the sun, food we eat, and the ground. Each examination gives a dose on top of this natural background radiation. The risks of radiation are slightly higher for an unborn child so

we must ask some patients aged 10 to 55 years about their periods and possibility of being pregnant.

The benefits of this examination are likely to outweigh any potential risk and the risk from not having the examination could be greater. We will take all safeguards to minimise the amount of X-rays you receive.

Are all procedures successful?

The idea behind spinal augmentation is to stabilise and strengthen the collapsed bone. At least 8 or 9 out of 10 patients (at least 85%) have some pain relief after the procedure. In some patients the pain disappears completely. Doctors believe that the pain from a collapsed bone is due to tiny movements within the fractured bone.

A few patients may not feel any pain relief after this procedure.

Spinal augmentation is NOT a treatment for other causes of back pain, such as disc problems, trapped nerves, arthritis or chronic backache.

Follow-up appointment

You will be given an outpatient clinic appointment for 1 month after the procedure with one of the team who did the procedure. This appointment will be to talk to you about how you are getting on and to discuss the results of the bone biopsy done as part of the spinal augmentation procedure.

What if I need to talk to someone?

If you have any problems relating to your procedure once you have left hospital, please contact your GP for advice.

For further information and advice you can contact the spinal augmentation nurse on 0116 258 5278 or 0116 258 6719, Monday to Friday, 9am to 5pm.



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