

Patient agreement to investigation or treatment

About Otosclerosis and Stapedectomy

Authors: Ear, Nose and Throat (ENT) Department

Brief description:

- You have been recommended by your surgeon to have a stapedectomy to try and improve hearing.
- Here we explain some of the aims, benefits, risks and alternatives and operations (procedure/treatment). We want you to be informed about your choices so that you can be fully involved in making decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website:
<http://www.addenbrookes.org.uk/consent>

Remember, you can change your mind about having the operation at any time.

For staff use:

Does the patient have any special requirements? (For example: requires an interpreter or other additional communication method)

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How do we hear?

The ear consists of the outer, middle and inner ear. Sound travels through the outer ear and reaches the eardrum, causing it to vibrate. The vibration is then transmitted through three tiny bones called the ossicles. The three ossicles are called malleus, incus and stapes, sometimes known as hammer, anvil and stirrup. The vibration then enters the inner ear which is a snail-shaped bony structure filled with fluid. The nerve cells within the inner ear are stimulated to produce nerve signals. These nerve signals are carried to the brain, where they are interpreted as sound.

What is otosclerosis?

Otosclerosis is a disease of the bone surrounding the inner ear. It can cause hearing loss when abnormal bone forms around the stapes and stops it moving, reducing the sound that reaches the inner ear. This is called conductive hearing loss. Less frequently, otosclerosis can interfere with the inner ear nerve cells and affect the production of the nerve signal. This is called sensorineural hearing loss.

What is the cause of otosclerosis?

The cause of otosclerosis is not fully understood, although it tends to run in families and can be hereditary. People who have a family history of otosclerosis are more likely to develop the disorder.

Otosclerosis affects the ears only and not other parts of the body. Both ears can be involved to some extent. However, in most individuals, only one ear is affected. Hearing loss usually begins in the twenties.

What are the symptoms?

The commonest symptom is hearing loss but may take many years before you become aware of it. The degree of hearing loss may range from slight to severe. It can be conductive, sensorineural or both.

In addition to hearing loss, some people with otosclerosis may experience tinnitus or noise in the ear. The intensity of the tinnitus is not necessarily related to the degree or type of hearing loss. Very rarely, otosclerosis may also cause dizziness.

How is otosclerosis diagnosed?

An examination by an otolaryngologist is needed to rule out other disease or health problems that may cause these same symptoms. The amount of hearing loss and whether it is conductive or sensorineural can be determined only by careful hearing tests.

How can otosclerosis be treated?

There is no known cure for otosclerosis. The individual with otosclerosis has several options:

- do nothing
- be fitted with hearing aids, or
- surgery

No treatment is needed if the hearing impairment is mild.

Hearing aids amplify sounds so that the user can hear better. The advantage of hearing aids is that they carry no risk to the patient. An audiologist can discuss the various types of hearing aids available and make a recommendation based on the specific needs of the individual.

The other option is surgery. Details of this are outlined below.

Aims of the operation

If one ear is affected, the operation may help to locate the direction of sound and hear better in noisy background.

The operation is called **stapedectomy**. If both ears are affected, the operation is usually done on the poorer ear. The patient may still need a hearing aid in the opposite ear.

Before your operation

- Most patients attend a pre-admission clinic, when you will meet a nurse practitioner.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring details with you of anything you are taking (for example: bring the packaging with you).
- This procedure involves the use of general or local anaesthesia. See below for further details about the types of anaesthesia/sedation we shall use.
- Most people who have this type of procedure will be discharged on the same day. Sometimes we can predict whether you will need to stay for longer than usual - your doctor will discuss this with you before you decide to have the procedure.

Hair removal before an operation

For most operations, you do not need to have the hair around the site of the operation removed.

However, sometimes the healthcare team may need to remove hair to allow them to see or reach your skin. If the healthcare team consider it is important to remove the hair, they will do this by using an electric hair clipper, with a single-use disposable head, on the day of the surgery.

Please do not shave the hair yourself, or use a razor for hair removal, as this can increase the risk of infection to the site of the operation.

If you have any questions, please ask the healthcare team who will be happy to discuss this with you.

References:

NICE clinical guideline No 74: Surgical site infection (October 2008); Department of Health: High Impact Intervention No 4: Care bundle to preventing surgical site infection (August 2007)

How is the operation done?

The operation usually takes about an hour. You might be put to sleep (general anaesthetic) although it might be performed with only your ear anaesthetised (local anaesthetic). A cut is made inside the ear canal. The top part of the stapes is removed with fine instruments. A small opening is then made at the base, or 'footplate', of the stapes into the inner ear. Some surgeons use laser to perform this procedure. A plastic or metal prosthesis (implant) is then put into the ear to conduct sound from the remaining ossicles into the inner ear. You will have packing (ribbon gauze) placed in the inner ear.

How successful is the operation?

The chance of obtaining a good result from this operation by experienced surgeons is over 90 percent. This means that nine out of ten patients will get an improvement of hearing up to the level at which their inner ear is capable of hearing. You should enquire from your surgeon the general success rate with stapedectomy.

Possible complications

There are some risks that you must consider before giving consent to this treatment. These potential complications are rare. You should consult your surgeon about complication rates.

Loss of hearing

In a small number of patients the hearing may be further impaired due to damage to the inner ear. It can even result in a severe loss of hearing in the operated ear. This may be to the extent that one cannot obtain benefit from a hearing aid in that ear. For experienced surgeons, this complication happens in around one in 100 patients. Therefore the poorer hearing ear is normally selected for surgery first.

Dizziness

Dizziness is common for a few hours following stapedectomy and may result in nausea and vomiting. Some unsteadiness can occur during the first few days following surgery; dizziness on quick head movement may persist for several weeks. On rare occasion, dizziness is prolonged.

Taste disturbance

The taste nerve runs close to the eardrum and may occasionally be damaged. This can cause an abnormal taste on one side of the tongue. This is usually temporary but it can be permanent in one in ten patients.

Reaction to ear dressings

Occasionally the ear may develop an allergic reaction to the dressings in the ear canal. If this happens, the pinna (outer ear) may become swollen and red. You should consult your surgeon so that he can remove the dressing from your ear. The allergic reaction should settle down after a few days.

Tinnitus

Sometimes the patient may notice noise in the ear, in particular if the hearing loss worsens.

Other complications

The uncommon risk of total loss of hearing, disturbance of balance or taste could have a serious implication to certain employments. You should discuss with your specialist about these concerns. Some specialists also advise against scuba diving, sky diving or use of firearm following stapedectomy operation.

What happens after the operation?

You will usually go home the day after the operation after the head bandage is removed, or sometimes the same day. The ear may ache a little but this can be controlled by painkillers provided by the hospital. A slight amount of dizziness is normal after the operation.

There may be a small amount of discharge from the ear canal. This usually comes from the ear dressings. The packing in the ear canal will be removed after two weeks.

You may need to take two or three weeks off work after the operation.

You should keep the ear dry for the first few weeks. Plug the ear with a cotton wool ball coated with Vaseline when you are having a shower or washing your hair. Avoid straining/lifting anything heavy for the first few weeks after surgery. Only blow the nose gently. Avoid air travel for two months. If your ear becomes more painful or swollen then you should consult the Ear, Nose and Throat department on 01223 274283 or your General Practitioner.

Hearing may not return to normal for up to three months. You should consult the surgeon if there is a sudden onset of deafness, dizziness or severe pain after you are discharged from the hospital. You are advised to avoid diving or flying when you have a cold if possible.

Is there any alternative treatment?

There are currently no alternative procedures. If you have any further questions, please contact Melanie Jackson, Otology nurse practitioner on 01223 348672.

General anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

Before your operation

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. If you are a day case patient it may not be until just before your operation. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic.

He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.

Pre-medication is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets, injections or liquids (to children). They relax you and may send you to sleep. They are not always given.

Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may have, so that you can forget your fears and worries.

Before your operation you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe. It is common practice nowadays to allow a parent into the anaesthetic room with children: as the child goes unconscious, the parent will usually be asked to leave.

During your operation

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you.

Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel, and systems, such as Patient Controlled Analgesia (PCA) may be set up to continue pain control on the ward.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel completely normal immediately!

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on; whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.
- Uncommon side effects and complications (1 in 1000 people)
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 your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.

Local anaesthesia

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted and some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut. Usually a local anaesthetic will be given by the doctor doing the operation.

Privacy and dignity

We are committed to treating all patients with privacy and dignity in a safe, clean and comfortable environment. This means, with a few exceptions, we will care for you in same sex bays in wards with separate sanitary facilities for men and women.

In some areas, due to the nature of the equipment or specialist care involved, we may not be able to care for you in same sex bays. In these cases staff will always do their best to respect your privacy and dignity, eg with the use of curtains or, where possible, moving you next to a patient of the same sex. If you have any concerns, please speak to the ward sister or charge nurse.



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact Patient Information: 01223 216032 or

patient.information@addenbrookes.nhs.uk



Document history

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For staff use only:

Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** **If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature Date:

Name (PRINT): Job Title: