Patient information and consent to about otosclerosis and stapedectomy

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Please call the otology and skull base nurse practitioner on 01223 348672 if you have any questions or concerns about this procedure.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.
About otosclerosis and stapedectomy

You have been recommended by your surgeon to have a stapedectomy to try and improve your hearing.

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.

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. A patient with otosclerosis has several options:
- do nothing
- have a hearing aid fitted, or
- have 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 a hearing aid is that it carries no risk to the patient. An audiologist can discuss the various types of hearing aids available and make a recommendation based on your specific needs.

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 a **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 in the day surgery unit. At this clinic, you will be asked for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring any packaging with you.

This procedure involves the use of anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

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.
You will need to stop eating at midnight before the day of surgery. You can drink clear fluids until 06:00 on the day of surgery. After 06:00 on the day of surgery you must be nil by mouth. However, you may have a small amount of water to take any medication.

Please do not bring any valuables into hospital. We will discuss this with you at the pre-admission clinic.

**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 need to see or reach your skin and if this is necessary they will use 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 to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

**During the operation**

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.

**After the operation**

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.

Hearing may not return to normal for up to three months.

**Getting about after the procedure.** We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. If you have any mobility problems, we can arrange nursing or physiotherapy help.
Leaving hospital. You will usually go home the day after the operation after the head bandage is removed, or sometimes the same day. You should consult the surgeon if there is a sudden onset of deafness, dizziness or severe pain after you are discharged from the hospital.

Resuming normal activities including work. You may need to take two or three weeks off work after the operation.

Special measures after the procedure.
- 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.
- You are advised to avoid diving or flying when you have a cold if possible.

Check-ups and results:
- You will receive an appointment to return to the clinic two weeks following surgery to remove the packing and check your ear. The appointment will either be given to you before discharge or posted to you.
- We will see you again at eight weeks following surgery where we will check your ear and perform an audiogram; any further treatments will be discussed then.

Intended benefits
It is intended to help to locate the direction of sound and hear better in a noisy background.

Who will perform my procedure?
This procedure will be performed by an ENT surgeon with appropriate experience.

Alternative procedures that are available
There are currently no alternative procedures. If you have any further questions, please contact the otology nurse practitioner on 01223 348672.
Significant, unavoidable or frequently occurring risks of this procedure

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 occasions, 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.

Anaesthesia
Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness. Sometimes different types of anaesthesia are used together.
Before your operation
Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

Pre-medication
You may be prescribed a ‘premed’ prior to your operation. This a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.

Moving to the operating room or theatre
You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room and before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.

Once that is complete, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.

It is common practice nowadays to allow a parent into the anaesthetic room with children; as the child goes unconscious, the parent will be asked to leave.

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. 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 at the correct level of unconsciousness for the period of the surgery. 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.

Regional anaesthesia

Regional anaesthesia includes epidurals, spinals, caudals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you and, if you are to have a general anaesthetic as well, whether the regional anaesthesia will be performed before you are given the general anaesthetic.

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, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

Sedation

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain, the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties. You may have fewer of these effects after local or regional anaesthesia although when the effects of the anaesthesia wear off you may need pain relieving medicines.

What are the risks of 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 performed in an emergency.

**Very common (1 in 10 people) and common side effects (1 in 100 people)**
- Feeling sick and vomiting after surgery
- Sore throat
- Dizziness, blurred vision
- Headache
- Bladder problems
- Damage to lips or tongue (usually minor)
- 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
- Muscle pains
- Slow breathing (depressed respiration)
- Damage to teeth
- An existing medical condition getting worse
- Awareness (becoming conscious during your operation)

**Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications**
- Damage to the eyes
- Heart attack or stroke
- Serious allergy to drugs
- Nerve damage
- Death
- Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK. For more information about anaesthesia, please visit the Royal College of Anaesthetists’ website: [www.rcoa.ac.uk](http://www.rcoa.ac.uk)
Information about important questions on the consent form

1  Creutzfeldt Jakob Disease (‘CJD’)

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2  Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3  Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4  Use of Tissue

As a leading bio-medical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
Information and support
If you have any further questions, please contact the otology nurse practitioner on 01223 348672.

Privacy & Dignity
Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site.
For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:
If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team:
patient.info@addenbrookes.nhs.uk.
Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history
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Consent Form

Otosclerosis and stapedectomy

A Patient’s side  left / right  or  N/A

Consultant or other responsible health professional

Name and job title: .................................................................

☐ Any special needs of the patient (e.g. help with communication)?

Please use ‘Procedure completed’ stamp here on completion: .................................................................

B Statement of health professional (details of treatment, risks and benefits)

I confirm I am a health professional with an appropriate knowledge of the proposed procedure, as specified in the hospital’s consent policy. I have explained the procedure to the patient. In particular, I have explained:

a) the intended benefits of the procedure (please state)

To help to locate the direction of sound and hear better in a noisy background.

b) the possible risks involved. Addenbrooke’s always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient

Full details are set out in the patient information and include:

- loss of hearing;
- dizziness;
- taste disturbance;
- reaction to ear dressings;
- tinnitus.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
Consent Form

Otosclerosis and stapedectomy

d) any extra procedures that might become necessary during the procedure such as:
☐ Blood transfusion ☐ Other procedure (please state)

The following information leaflet has been provided:

Otosclerosis and stapedectomy

Version, reference and date: Version 4, CF368, November 2017
or ☐ I have offered the patient information about the procedure but this has been declined.

This procedure will involve:
☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation ☐ None

Signed (Health professional): ______________________ Date: D.D./M.M./Y.Y.Y.Y.

Name (PRINT): ______________________ Time (24hr): H.H.: M.M.

Designation: ______________________ Contact/bleep no: ______________________

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.
☐ Yes ☐ No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment.
☐ Yes ☐ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.
☐ Yes ☐ No

3 Students in training
I agree to the involvement of medical and other students as part of their formal training.
☐ Yes ☐ No
Consent Form

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4 Use of Tissue
   a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.
   
      □ Yes  □ No

   b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.
      
      □ Yes  □ No

I have listed below any procedures that I do not wish to be carried out without further discussion.

________________________________________________________________________________________________________

________________________________________________________________________________________________________

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient): ____________________________________________ Date: __________/________/____
Name of patient (PRINT): ______________________________________

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.

Signed: __________________________________________________________ Date: __________/________/____
Relationship to patient: ____________________________

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): ____________________________________________ Date: __________/________/____
Name of witness (PRINT): ______________________________________
Address: __________________________________________________________
Consent Form

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D  Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has
no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): ........................................ Date: ...D.../...M.../...Y...Y...Y...
Name (PRINT): ................................................................. Job title: .................................................................

Please initial to confirm all sections have been completed:

E  Interpreter’s statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient
can understand:

Signed (Interpreter): ........................................ Date: ...D.../...M.../...Y...Y...Y...
Name (PRINT): .................................................................

Or, please note the language line reference ID number:

F  Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): ........................................ Date: ...D.../...M.../...Y...Y...Y...

Signed (Health professional): ........................................ Date: ...D.../...M.../...Y...Y...Y...

Name (PRINT): ................................................................. Job title: .................................................................