

Patient agreement to investigation or treatment

Ossiculoplasty

Authors: Ear, Nose and Throat (ENT) Department

Brief description:

- You have been recommended by your surgeon to have an ossiculoplasty to try and improve your hearing.
- Here we, explain some of the aims, benefits, risks and alternatives to this operation (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 an ossiculoplasty?

An ossiculoplasty is a surgical procedure designed to repair damaged bones of hearing (the ossicles) with carefully designed artificial bones.

Why have an ossiculoplasty?

- The middle ear bones are often damaged by infection or chronic retraction of the tympanic membrane.
- Usually, the ear drum is repaired at the same time.
- Trauma may dislocate the ear bones without creating a hole in the ear drum. In this case only the bones are repaired.

Aims of the operation?

The aim of the surgery is to improve the hearing. How much the hearing will improve is dependent on how severe the damage to the ear bones and middle ear has been, and what type of artificial bone of hearing we must use to repair the damage.

Before the operation

- Most patients attend a pre-admission clinic, when you will meet consultant and nurse practitioner.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations, for example audiogram. 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 anaesthesia. See below for further details about the types of anaesthesia we shall use.
- Most people are discharged on the day of the procedure.
- You will need to stop eating and drinking the day before surgery. You may have a small amount of water to take any medication. Please do not bring any valuables into hospital. This will have been discussed 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 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?

- This procedure is carried out under general anaesthesia.
- The operation usually takes about an hour to perform.
- The procedure is usually performed down the ear canal. However, occasionally an incision is made behind the ear.
- The damaged bones of the ear are removed and replaced with artificial bones that are usually made out of titanium.
- Once the bones are replaced it might be necessary to take cartilage from just inside the ear to support the eardrum.
- You will have packing coated with antiseptic paste placed in the ear.
- It is usual for you to be discharged later on the same day but occasionally you might have to stay in overnight.

How successful is the operation?

The likelihood of obtaining a good result from this operation is in the region of 85%. This means that the operation will give you good, useful hearing in the operated ear. This does depend on inner ear function. If inner ear hearing is down, then potential benefits are limited.

What happens after the operation?

- You will usually go home on the same day as the operation, but you may need to stay overnight.
- 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 a week or two 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 and heavy lifting for the first few weeks after surgery.
- Only blow the nose gently.
- Avoid air travel for two months.
- If the ear becomes more painful or swollen then you should consult the Ear, Nose and Throat department 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.

Benefits

The benefit of having this procedure is to potentially improve your hearing.

What are the risks of the operation?

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. This complication happens in less than one in 100 patients. Therefore the poorer hearing ear is normally selected for surgery first.

Dizziness:

Dizziness can occasionally occur for a few hours following ossiculoplasty 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 and sky diving following ossiculoplasty operation.

Is there any alternative treatment?

There is no alternative surgical treatment but a hearing aid can boost hearing in your non operated ear.

Contact

If you have any questions please contact Melanie Jackson, Otology and Skull base 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.

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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Patient agreement to investigation or treatment

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

Responsible health professional/job title

Special requirements
 (For example, other language/other communication method)

Name of proposed procedure or course of treatment

Ossiculoplasty **Side (left/right)**

Statement of health professional

(To be filled in by 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:

- The intended benefits of the procedure: Potentially improve hearing
- Any serious or frequently occurring risks from the procedures including those specific to the patient: 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. This complication happens in less than one in 100 patients. Therefore the poorer hearing ear is normally selected for surgery first; **Dizziness:**

Dizziness can occasionally occur for a few hours following ossiculoplasty 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 and sky diving following ossiculoplasty operation. Other (please specify):

• Any extra procedures that might become necessary during the procedure

Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

• The following information leaflet has been provided: Ossiculoplasty. Version/Date/Ref: 2/December 2011/CF112

This procedure will involve:

General and/or regional anaesthesia Local anaesthesia

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand: Interpreter's signature Date:

Name (PRINT):

Important notes: (tick if applicable)

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

See also advance directive/living will

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:

Copy accepted by patient: yes / no (please circle)