NICE National Institute for Health and Care Excellence

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Information for the public

Reconstruction of the facial bones using customised titanium implants (not covered over with soft tissue)

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how customised titanium implants (not covered over with soft tissue) can be used in the NHS for complex reconstruction of the facial bones. It explains guidance (advice) from NICE (the National Institute for Health and Care Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies after considering how well the procedure works and whether it represents value for money for the NHS.

This document is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe reconstruction of the facial bones using titanium implants in detail – a member of your healthcare team should give you full information and advice about these. The document includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 7.

What has NICE said?

There is limited evidence about how well this procedure works and how safe it is. If a doctor wants to use customised titanium implants that are not covered over with soft tissue for reconstruction of the facial bones, they should make sure that extra steps are taken to explain the limited evidence about how well the procedure works, as well as the uncertainty surrounding potential risks, such as infection and other complications that may result from the implant being exposed. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

It is essential that this procedure is only offered to patients for whom it is suitable and for whom there are no other reconstruction treatment options available. These decisions should be made by head and neck surgeons and plastic surgeons.

Reconstruction of the facial bones using customised titanium implants not covered over with soft tissue

The medical name for this procedure is 'insertion of customised titanium implants, without soft tissue cover, for orofacial reconstruction'.

The procedure is not described in detail here – please talk to your surgeon for a full description.

Orofacial reconstruction is a procedure for rebuilding the face where there is severe damage to the bones. This procedure is most commonly

needed after a serious injury. It can also be needed after the removal of facial tumours, and for facial abnormalities present at birth.

Implants for orofacial reconstruction can be made out of parts of the patient's body, silicone, titanium, hydroxyapatite (a mineral similar to human bone), and mixtures of different materials such as titanium set in plastic. Bone or material similar to bone can also be grown in a laboratory to replace the damaged or missing bones of the face.

Using customised titanium implants aims to give a better cosmetic and functional result than traditional implants. An exact model of the patient's skull, or a 3-dimensional computer image of it, is made. The titanium implant is then made using computer-aided design and manufacture methods. The procedure is carried out with the patient under a general anaesthetic. The implant is fixed into the surrounding bone with titanium screws.

Unlike some other reconstruction procedures used, the titanium implant is not covered with soft tissue and soft tissue is not expected to grow over the implant in time.

What does this mean for me?

If your surgeon has offered you reconstruction of the facial bones using customised titanium implants not covered over with soft tissue, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your surgeon should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this document, and have the opportunity to discuss it with your surgeon before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative treatments?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 1 study of 14 patients and reports on 3 other patients who had this procedure.

How well does the procedure work?

A study of 14 patients who had facial bone reconstruction after surgery to remove head and neck tumours reported that reconstructions of the upper jaw, a side of the lower jaw and nose were successful and did not need soft tissue to cover the implants. Partial reconstruction of the lower jaw did not work in 2 patients because surrounding soft tissue did not grow around the implant well. Both patients had the implant removed and they had alternative procedures.

The appearance of 3 patients was described as excellent after the procedure (details for the appearance of the other 11 patients are not known). After 2 years, all 14 patients had an acceptable quality of life and their cancer had not returned.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the main measures of success for the procedure are shorter operating times compared with standard procedures, how long the implants last, how often screws used to attach the implants need to be removed, reduced disease rates, and increased survival rates in patients with cancer.

Risks and possible problems

In the study of 14 patients, a type of implant known as THORP (titanium-coated hollow screw reconstruction plate) ulcerated (broke) through the skin in all patients who had an implant next to their cheek. There were 8 patients who had THORP implants but it was not reported

how many of these had cheek implants. In 1 patient, this was treated by placing an acrylic cover plate over the implant.

One patient in the study had to have the implant taken out because of a methicillin-resistant *Staphylococcus aureus* (MRSA) infection.

Four patients in the study of 14 developed fistulae (abnormal connections between areas usually separated by skin) up to 2 years after the procedure. All 4 were successfully treated, though 1 patient needed several procedures.

In separate reports of 2 patients who had large implants fitted to reconstruct their nose, the implant was exposed unintentionally and both patients needed a number of additional procedures.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems were recurrent infections, bone infection, possible septicaemia (blood poisoning), bone around the implant being broken down by the body, the implant getting loose or being exposed, poor appearance, and the implant not successfully reconstructing the face.

More information about reconstruction of the facial bones

NHS Choices (www.nhs.uk) may be a good place to find out more.

For details of all NICE guidance on reconstruction of the facial bones, visit our website at www.nice.org.uk

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About NICE

NICE provides national guidance and advice to improve health and social care. Interventional procedures guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This document is about 'Insertion of customised exposed titanium implants, without soft tissue cover, for complex orofacial reconstruction'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/IPG457

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this document in their own information about this procedure.

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