Issue date March 2013

Information for the public

National Institute for Health and Clinical Excellence

Reconstruction of the facial bones using customised titanium implants covered over with soft tissue

NICE 'HealthTech 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 covered over with soft tissue can be used in the NHS for reconstruction of the facial bones. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech 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 (primary care trusts and hospital trusts) 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 this. 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?

Customised titanium implants can be used routinely for reconstruction of the facial bones, including reconstruction of the bottom of the eye socket, where the implants will be covered with soft tissue (or soft tissue is expected to grow over them), provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

Reconstruction of the facial bones using customised titanium implants covered over with soft tissue

Reconstruction of the facial bones using customised titanium implants may not be the only method of reconstruction available. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is insertion of customised titanium implants, with 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. The implant is then covered with tissue from around the face or with tissue from a different part of the patient's body. In some places, implants are left partially exposed because it is expected that soft tissue will grow over them in time.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks reconstruction of the facial bones using customised titanium implants is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

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 procedures?
- 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?

Summary of possible benefits and risks

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 10 studies on this procedure.

How well does the procedure work?

Two studies, of 64 and 29 patients, looked at eye position and the shape of the implant in the face. Of the 54 patients in these studies who had customised titanium implants, 20 had their eye position returned to normal 14 months after the procedure, and 28 had improvements to their eye position between 1 and 14 months after the procedure. Of the 39 patients who had standard titanium implants, 23 had improvements to their eye position. The study of 64 patients reported that 23 of the 25 patients who had customised titanium implants had the shape of their face around the eye corrected perfectly, compared with 29 of the 39 patients who had standard titanium implants. Two patients who had customised implants in the study of 64 patients needed an artificial eye, compared with 8 patients who had standard implants. In the study of 29 patients, the customised implants had moved 3 patients' eyes too far, leaving them in a different incorrect position.

A study of 24 patients reported that 12 months after the procedure the 12 patients given customised titanium implants had significantly better vision using both eyes together, better position of their eyes in their face, and improved ability to look up, compared with the 12 patients given standard titanium implants. Fourteen months after the procedure in the study of 29 patients given customised titanium implants, 4 patients had no difficulty moving their eyes, 9 had less difficulty than before the procedure, and 13 had the same amount of difficulty.

The study of 29 patients who had customised titanium implants reported that 14 months after the procedure 5 patients no longer had double

vision, 9 had less severe double vision, and 10 had no change to their double vision.

In a study of 22 patients with abnormalities around their eyes, 1 patient with double vision before the procedure needed surgery to help their eye movement after the implant procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the key aims of the procedure are to fit the implant so that it works well and lasts for a long time, and to allow patients to return to their normal lives.

Risks and possible problems

In a study of 20 patients who had the procedure for defects high in their upper jaw the implant became uncovered in the mouth of 1 patient 36 months after the procedure, and in the eye socket of another patient 4 months after the procedure. Both of these patients had to have more surgery.

The study of 22 patients treated with customised titanium implants reported that 1 patient was able to feel part of the implant and a screw at the edge of her eye, and this caused pain and irritation. The patient had another procedure to trim the implant and remove the screw.

In the case series of 29 patients, 1 patient had an infection of the area near the implant. In the study of 64 patients, 1 patient had an infection of the air-filled cavities in their cheekbone. The patient recovered after the infected tissue was removed.

The study of 20 patients given implants for upper jaw defects reported that 2 patients had oronasal fistulae (abnormal connections between their nose and mouth) 1 year after the procedure. These were sealed with removable partial dentures.

In the study of 22 patients, 1 patient had suddenly worsening vision, and was completely unable to see after 8 hours. These vision problems went away after 1 week once the implant was removed.

A study of 15 patients who had the procedure for eye socket reconstruction reported that 1 patient had scarring within their eye, problems moving their eye and double vision. The double vision improved after a further procedure. The vision of another patient in the same study was affected by the implant pressing on the optic nerve. This was completely corrected by another procedure.

One patient in the study of 64 patients lost the ability to move their eye normally. They had a procedure to correct the squint this caused.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems were bone around the implant being broken down by the body, the implant getting loose, and loss of individual parts of the implant within the body.

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

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The 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. HealthTech 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 titanium implants, with soft tissue cover, for orofacial reconstruction'. This document and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG307

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.

National Institute for Health and Clinical Excellence

Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT; www.nice.org.uk

ISBN 978-1-4731-8819-8

Mar 13