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Metatarsophalangeal joint replacement of the hallux

Understanding NICE guidance –
information for people considering
the procedure, and for the public



Ordering information

You can download the following documents from www.nice.org.uk/IPG140

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0927 (full guidance)
- N0928 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called metatarsophalangeal joint replacement of the hallux (which is artificial joint replacement in the joint at the base of the big toe). It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether metatarsophalangeal joint replacement is safe enough and works well enough for it to be used routinely for the treatment of osteoarthritis or rheumatoid arthritis that affects the joint at the base of the big toe.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of metatarsophalangeal joint replacement of the hallux and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Osteoarthritis and rheumatoid arthritis affect the joints, making them painful and stiff. If the joint at the base of the big toe is affected, the joint can become very stiff (called hallux rigidus) or deformed (called hallux valgus). The joint is called the metatarsophalangeal joint and the medical name for the big toe is the hallux.

The first types of treatments that are usually offered to patients are exercises, painkillers, anti-inflammatory medicines, and steroid injections into the joint. Surgery may be an option if these don't work and the person has severe symptoms. The main operations are:

- arthrodesis, in which the bone is 'welded' or fused to the one below using pins
- Keller's procedure, which involves trimming some of the bone in the joint
- replacing the joint with an artificial one.

The new procedure NICE has looked at, which is called metatarsophalangeal joint replacement, involves removing the problem joint and replacing it with an artificial one. The patient has a general or local anaesthetic. An opening is made at the base of the toe and the surfaces of the two bones in the joint are removed. Space is made in the joint for the artificial joint, and this is tested using a trial implant. If everything is all right, the parts of the artificial joint are put in place and the joint is closed up. A splint is placed on the toe after the operation to keep it in the right position.

How well the procedure works

What the studies said

In the studies that looked at how well this operation worked, the main results that were reported were patients' pain levels and how satisfied patients were with the results. Three studies had the following results:

- 8 out of 11 patients (73%) had no pain 17 months after having the operation (73% means 73 out of 100)
- 46 out of 58 patients (79%) had no pain 12 years after having the operation
- 7 out of 7 patients (100%) had no pain nearly 3 years after the operation.

Another study found that patients had an improvement in pain after the operation. And another study said that the pain improved after 59 out of 90 operations (66%) when patients were checked on 3 years later. Nearly all the patients in another study had less pain when they were checked 8 years later (the numbers for this were 30 out of 32 patients or 94%).

The studies that asked patients how satisfied they were with the results of the operation found that from 29 out of 39 patients (74%) to 7 out of 8 patients (88%) were completely satisfied with the results when they were asked 12 to 17 months afterwards.

What the experts said

The experts said that this procedure was already being used with good results. But they pointed out that there is not much information about how long these artificial joints last.

Risks and possible problems with the procedure

What the studies said

The main problem that affected people in the studies was that bony growths formed around the artificial joint. In one study this happened in 2 out of 49 joints (4%), but in another study it affected 41 out of 58 joints (71%).

X-rays were used to check for fractures in the artificial joint. Fractures were found in 0 out of 106 joints in one study and 21 out of 73 joints (29%) in another. Older joints that had been in place for longer were more likely to have fractures.

When patients in one study were checked on 17 months after the operation, none of the 11 artificial joints put in place had been removed. But in another study that checked on patients nearly 6 years later, 3 out of 37 joints had been removed.

Other problems that affected people in the studies were that the artificial joint was put in the wrong position, infection, inflammation, dislocation of the joint (when the two bones become unhinged), and lasting pain.

What the experts said

The experts said that the possible problems were lasting pain, infection, the joint becoming loose, fracture in the artificial joint, the bone starting to disintegrate, bony growths, the formation of cysts (sacs filled with fluid), silicone from the artificial joint leaking causing inflammation, and pain in the other joints in the foot. Some of these problems may mean that the joint has to be removed.

What has NICE decided?

NICE has considered the evidence on metatarsophalangeal joint replacement of the hallux. It has recommended that when doctors use this procedure for people with osteoarthritis or rheumatoid arthritis in the joint at the base of the big toe, they should be sure that:

- the patient understands what is involved
- they explain that it's not clear how the results from the procedure compare with the results from the other operations for the same complaint
- the patient agrees (consents) to the treatment, and
- the results of the procedure are monitored.

The procedure isn't suitable for everyone, and the effect of the operation on the person's ability to use their foot fully should be considered.

More studies are needed that look at how long the different types of artificial joint last, and what happens in people who've had them in place for a long time.

Other comments from NICE

Although X-rays can show that the artificial joint has become fractured, it's not clear whether such fractures are painful or affect the way the artificial joint works.

What the decision means for you

Your doctor may have offered you artificial joint replacement for your big toe. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of metatarsophalangeal joint replacement before you agree to it. Your doctor should discuss the benefits and risks with you. He or she should also explain that it's not clear how well the results from this procedure compare with the results from the other operations that are options for your condition.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on metatarsophalangeal joint replacement of the hallux that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on osteoarthritis and rheumatoid arthritis on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

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