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Prosthetic intervertebral disc replacement in the cervical spine

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/IPG143

- 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:

- N0933 (full guidance)
- N0934 (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 prosthetic intervertebral disc replacement in the cervical spine. 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 prosthetic intervertebral disc replacement is safe enough and works well enough for it to be used routinely for the treatment of for acute disc herniation (a 'slipped disc') and cervical spondylosis (see below) affecting the neck.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of prosthetic intervertebral disc replacement 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

In the backbone, spongy pads of tissue called discs lie between the small bones (called vertebrae). They act like cushions, and have a tough outer ring and a soft jelly-like inside. Acute disc herniation, which is more commonly called a slipped disc, happens when the tough outer ring of a disc tears. The jelly-like middle bulges out through the tear and this may press on nearby nerves, causing pain and weakness in the muscles. The procedure NICE has looked at specifically covers slipped discs in the neck (the bones here are called the cervical vertebrae).

In cervical spondylosis or cervical osteoarthritis, the cartilage and bones in the neck become abnormally worn, and the discs between the small bones start to disintegrate. Bony growths may develop on the bones. These changes can cause pressure on nearby nerves and this can cause pain in the neck and arm, weakness, and changes in sensation.

Surgery is an option for slipped discs and cervical spondylosis if painkillers, rest, exercises and injections don't help, or if there's a likelihood of serious problems involving the nerves. The standard operation involves removing the part of the disc or discs that is bulging out or pressing on the nerves. Sometimes the bones in the area are then joined ('welded' or fused) together with the aim of making the area more stable. This is done using a bone graft or artificial rods or cages and is known as fusion surgery.

The new procedure NICE has looked at involves replacing damaged discs in the neck with artificial ones. The patient has a general anaesthetic for the procedure.

How well the procedure works

What the studies said

Two studies compared patients who were given artificial discs with patients who had standard fusion surgery. One study checked on 13 patients after 6 months, and the other checked on 9 patients after 24 months. There were no real differences between the groups that had artificial discs and those that had fusion surgery. All the patients in these studies had better quality of life, with improvements in neck and arm pain.

Another study followed what happened in 7 patients after they'd had the new procedure. Six months after the procedure, there were good improvements in arm and neck symptoms and in the disability affecting the neck.

In another study, 65% (32 out of 49 patients) who had one disc replaced, and 77% (20 out of 26 patients) who had surgery at two sites, rated the improvement in their symptoms as 'excellent'. Tests showed that the muscle strength and sensations in the neck and arm had improved in these patients.

Some studies also included details of how well the person could move in the area that had the artificial discs. Most patients had well-preserved mobility when it was measured up to 12 months after they'd had the procedure.

What the experts said

The experts said that more information was needed about what happened in the long term to patients with artificial discs so that a comparison could be made with fusion surgery.

Risks and possible problems with the procedure

What the studies said

There were no problems with the artificial discs themselves in the studies that reported on this (which involved a total of 40 patients). In another study, the discs moved slightly in 2 out of 103 patients (2%). The discs weren't touching nerves in either of these cases so they didn't cause symptoms. Three out of 103 patients (3%) needed to have another procedure following the disc replacement. Two patients still had symptoms and so needed further work done on the area. One patient had a haematoma, which is a blood-filled swelling, and needed another procedure to remove it.

Other problems that affected small numbers of people in the studies were:

- hoarse voice, which lasted a short time – this affected 2 out of 15 people (13%) in one study
- moderate problems with swallowing – this affected 1 person out of 27 (4%) in one study
- periods when the nerve supplying the voicebox became paralysed – this also affected 1 person out of 27 (4%) in one study.

What the experts said

The experts said that in theory, an artificial disc could move and start to press on nerves, causing the symptoms to come back. There is also a risk it could block an airway if it moved forward in the neck. The experts also said that if the artificial disc doesn't work properly, the spinal cord, which contains important nerves, could become damaged.

What has NICE decided?

NICE has considered the evidence on the safety of prosthetic cervical disc replacement and how well the discs work in the short term. It has recommended that when doctors use this procedure for people with a slipped disc in the neck or cervical spondylosis, they should be sure that:

- the patient understands what is involved in the procedure and what alternative treatments are available
- the patient agrees (consents) to the treatment, and
- the results of the procedure are monitored.

Cervical disc replacement should only be carried out in specialist units where surgery on the bones in the neck is regularly performed.

What the decision means for you

Your doctor may have offered you prosthetic cervical disc replacement. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough in the short term for use in the NHS, providing it is carried out in a specialist unit where surgery on the neck is regularly performed. Nonetheless, you should understand the benefits and risks of the procedure before you agree to it. You should also be told about the other treatment options that are available. Your doctor should discuss these with you.

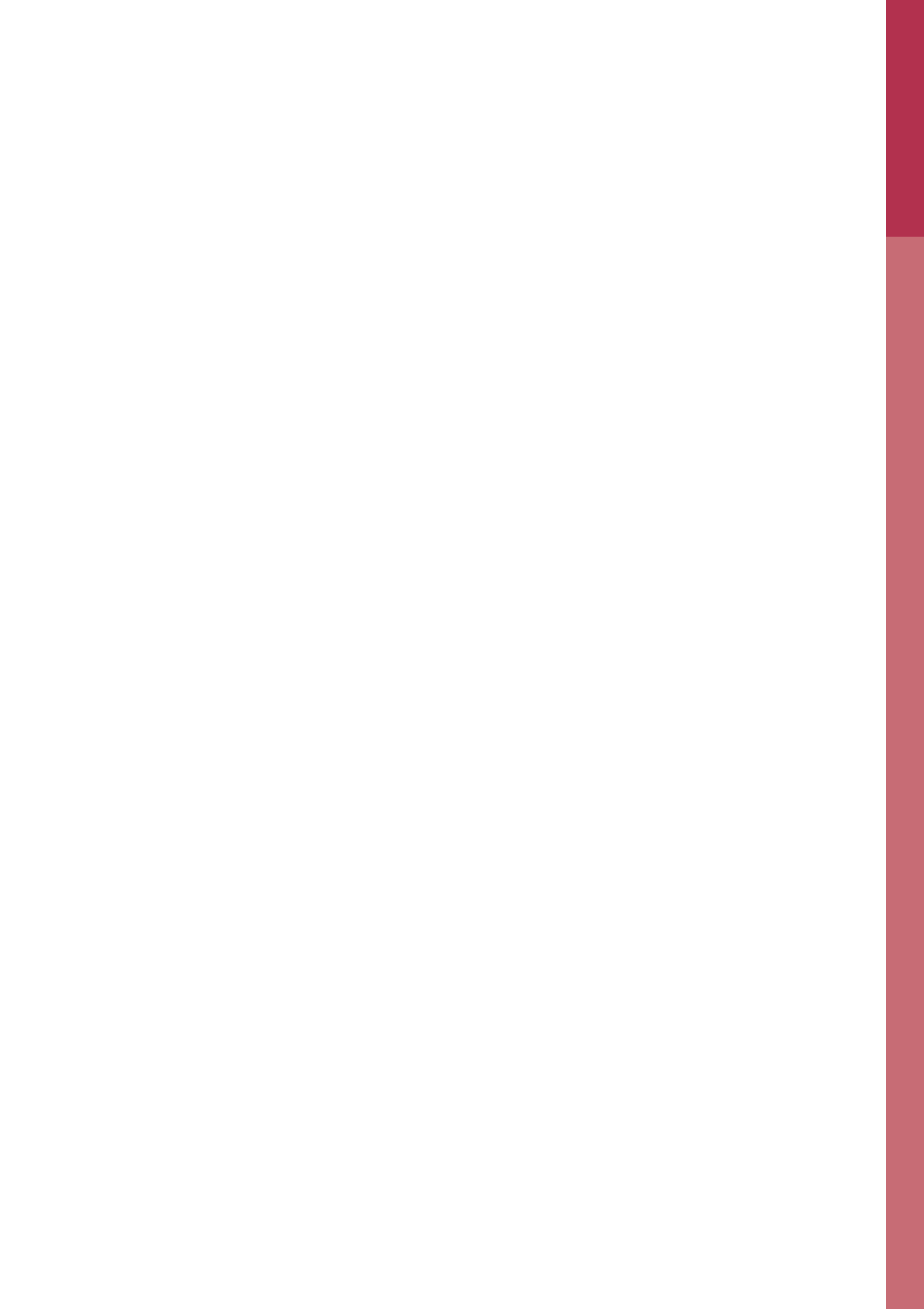
Further information

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 prosthetic intervertebral disc replacement in the cervical spine 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 slipped discs and cervical spondylosis on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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