NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Intramedullary distraction for upper limb lengthening

People can be born with different length arms, or this can be caused by disease, injury, nerve damage at birth, or surgery to remove bone tumours. In this procedure, through an incision, the upper arm bone is cut and a metal lengthening device (distractor) is put inside the bone (intramedullary) across the cut. After the operation, the device is gradually lengthened while new bone forms across the cut, increasing the length of the bone. The device is lengthened using an electric or magnetic internal motor, operated through a connecting cable or remotely. This process of lengthening and healing takes several months. The device may be removed through surgery or left in place.

NICE is looking at intramedullary distraction for upper limb lengthening.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 2 November 2021

Target date for publication of guidance: March 2022

1 Draft recommendations

1.1 Evidence on the safety and efficacy of intramedullary distraction for upper limb lengthening is inadequate in quantity and quality. But because this is a rare condition with limited alternative treatments, the procedure can be considered as long as special arrangements for clinical governance, consent, and audit or research are in place. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians who want to use intramedullary distraction for upper limb lengthening should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Make sure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Make sure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 This technically challenging procedure should only be done in specialist centres by surgeons with specific training and experience in upper limb lengthening techniques, using a multidisciplinary approach.

1.5 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

1.6 Further research should report details of patient selection, device selection, technique used, procedural outcomes, long-term outcomes including quality of life, the need for repeat interventions or surgery, and complication rates.

2 The condition, current treatments and procedure

The condition

2.1 People may have different limb lengths caused by trauma or infection or, more rarely, hypoplasia or dysplasia (congenital conditions such as achondroplasia, Ollier's disease, and brachial plexus palsy). The condition can be unilateral or bilateral. Unequal limb lengths can lead to disability and limit functional ability.

Current treatments

2.2 Lengthening of a short upper limb can be attempted using external fixation devices, which exert force along the long axis of bone to induce new bone formation (called distraction osteogenesis). Often, the external fixation is removed and the new bone is augmented either by internal plate fixation or a nail inside the bone. Potential problems with external fixation include infection of the pin tracts, pain, angulation deformity of the bone, and neighbouring joint stiffness. External fixation devices may also present some practical and aesthetic challenges compared with a fully internal system.

The procedure

2.3 Intramedullary distraction systems are intramedullary devices that are similar to intramedullary nails used for managing fractures. Once inserted and fixed, they can be mechanically lengthened over time using different techniques, resulting in a controlled lengthening of the bone. The device can be inserted into the humerus from the top (antegrade), though this may cause damage to the shoulder muscles, or the lower end (retrograde).

2.4 Under general anaesthesia, a humeral osteotomy is done avoiding damage to the periosteum and its blood supply. The adjustable nail-like intramedullary device is then implanted into the intramedullary canal, and the proximal and distal sections of the device are fixed to the appropriate section of the humerus with sterile locking screws. Once implanted and fixed, the length of the device can be adjusted to provide an appropriate amount of compression and allow bony alignment at the osteotomy site. The device exerts a force along the long axis of the bone, which stimulates new bone formation (distraction osteogenesis) in the gap, causing bone lengthening. Over a period of days, weeks or months, sequential distractions are used to produce the target limb length.

2.5 Different devices achieve distraction in different ways. For example, some work mechanically by releasing a preloaded spring or using a motor. Others are non-invasive and use an external electromagnetic device.

2.6 The intramedullary device remains implanted until bone consolidation is completed. When there is radiological evidence of adequate bone consolidation across the gap, full function and limb use (weight bearing) is permitted. The device can usually be removed using standard surgical techniques or may be left in place indefinitely.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 2 sources, which was discussed by the committee. The evidence included 2 retrospective case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: achievement of target limb length, patient-reported outcomes, improved function and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: infection, pain, joint stiffness, device-related complications, and delayed or non-union.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that there is more than 1 device available for this procedure.

3.6 The committee was informed that postoperative physiotherapy is essential for muscle strengthening and functional recovery.

3.7 The committee was informed that it is important to carefully control the rate of limb lengthening to reduce the risk of damage to muscles, joints and nerves.

3.8 The committee noted that this is a rare condition and that alternative treatment options are limited.

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Chair, interventional procedures advisory committee

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