NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Intramedullary distraction for lower limb lengthening

People can have different length legs from birth, or because of disease or injury. In this procedure, under general anaesthesia, a bone in the shorter leg is cut surgically and a metal lengthening device (distractor) is put inside the bone (intramedullary) across the cut bone. It may be done to a bone in the upper or lower leg. After the operation, the device is gradually lengthened while new bone forms across the cut, so increasing the length of the bone. There are different techniques used to lengthen the distractor depending on the device used. The process of lengthening and healing takes several months, during which partial weight bearing is possible. The main aim is to lengthen the leg and reduce disability.

NICE is looking at intramedullary distraction for lower limb lengthening. This is a review of NICE's interventional procedures guidance on intramedullary distraction for lower 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 18 November 2021

Target date for publication of guidance: February 2022

1 Draft recommendations

1.1 Evidence on the safety and efficacy of intramedullary distraction for lower limb lengthening is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do intramedullary distraction for lower limb lengthening should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear information to support shared decision making, including NICE's information for the public.
- Ensure 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:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient 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 training and specific experience in limb lengthening techniques.

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, 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 because of trauma or infection (acquired) or, more rarely, because of hypoplasia or dysplasia of the femur or tibial (congenital). Unequal leg length can cause a limp and limit functional ability.

Current treatments

2.2 Lengthening of an abnormally short lower limb can be done using an external fixation device. This exerts force along the long axis of the bone to induce new bone formation (distraction osteogenesis). Problems with external fixation include: infection of the pin tracts, pain, hip and knee subluxation or dislocation, angulation, bone deformity and neighbouring joint stiffness. People may also find that external fixation devices are impractical and aesthetically unacceptable. Often, once the external fixation is removed, the new

bone is augmented by either an internal plate fixation or an intramedullary nail.

The procedure

2.3 Intramedullary distraction systems are used for managing fractures. Once inserted and fixed they can be mechanically lengthened over time using different techniques. The aim is to lengthen the bone in a controlled manner.

2.4 With this procedure, under general anaesthesia, an osteotomy is done while avoiding damage to the periosteum and its blood supply. The adjustable intramedullary nail-like device is then implanted into the intramedullary space. Its proximal and distal sections are fixed to the relevant section of the bone with sterile locking screws. Once implanted and fixed, the device can be adjusted in length to provide an appropriate amount of compression and allow bony alignment at the osteotomy site. It exerts a force along the long axis of the bone, which stimulates new bone formation (distraction osteogenesis) in the gap, causing bone lengthening. Over 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 driven extension. Others are non-invasive and use an external electromagnetic device.

2.6 Soon after the procedure, with help from the physiotherapy team, people are able to partially weight bear. The intramedullary device then remains implanted until bone consolidation is complete. When there is radiological evidence of adequate bone consolidation across the gap, full weight bearing is possible. The device is then usually removed using standard surgical techniques.

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 7 sources, which was discussed by the committee. The evidence included 5 systematic reviews, 1 retrospective cohort study and 1 retrospective matched 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, improved function and improved quality of life.

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

Committee comments

3.4 The committee noted that:

- the technology used for limb lengthening is evolving and external fixator use has become less common
- there are several devices available for use in this procedure, and they may have different efficacy and safety profiles
- this procedure is only for use in people who have limb length discrepancy and not for overall height gain
- assessing and managing the soft tissues is key to successful outcomes.

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Chair, interventional procedures advisory committee

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