

Intramedullary distraction for upper limb lengthening

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg722

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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 wanting to use intramedullary distraction for upper limb lengthening should:
 - Inform the clinical governance leads in their healthcare organisation.
 - Give people (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 people (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 everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedures 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, which could be registry data, 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). The main potential problems with external fixation include infection of the pin tracts, and external frames that are

impractical and aesthetically unpleasant. In some people with an underlying bone pathology, 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 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 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 of bone.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 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 This is a rare condition and alternative treatment options are limited.
- 3.9 The committee encourages the establishment of a registry for this procedure.

3.10 This procedure should not be used for cosmetic purposes only.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).