

Intramedullary distraction for lower limb lengthening

Interventional procedures guidance

Published: 2 March 2022

www.nice.org.uk/guidance/ipg718

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.

This guidance replaces IPG197.

1 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. This guidance is not intended to cover this procedure for bilateral lower limb lengthening for people with short stature.
- 1.2 Clinicians wanting 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 Patient selection should be done by a multidisciplinary team that ideally includes physiotherapy and psychological support.
- 1.5 This technically challenging procedure should only be done in specialist centres by surgeons with training and specific experience in limb lengthening techniques.
- 1.6 Report any problems with a medical device using the [Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme](#).
- 1.7 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. This research could be registry data.

2 The condition, current treatments and procedure

The condition

- 2.1 People may have different limb lengths because of trauma or infection (acquired) or, because of hypoplasia or dysplasia of the femur or tibial (congenital). Unequal leg length can cause a limp, limit functional ability and have effect on other joints.

Current treatments

- 2.2 Lengthening of an abnormally short lower limb can be done after an osteotomy using an external fixation device. This exerts force along the

long axis of the bone to induce new bone formation (distraction osteogenesis). The main problems with external fixation include infection of the pin tracts, and external frames that are impractical and aesthetically unacceptable. Once the external fixation is removed, in some people with underlying bone pathology, new bone is augmented by either an internal plate fixation or an intramedullary nail.

The procedure

- 2.3 Once inserted and fixed, intramedullary distraction systems can be 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. It then 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.
- 2.6 Soon after the procedure, with help from the physiotherapy team, people are able to partially weight bear. After clinical assessment, and when there is radiological evidence of adequate bone consolidation across the gap, full weight bearing is possible. The intramedullary device is usually removed after about 2 years 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 12 sources, which was discussed by the committee. The evidence included 5 systematic reviews, 2 retrospective cohort studies, 2 case series, 1 retrospective matched case series, 1 cross-sectional study and 1 case report. 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.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 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
 - assessing and managing the soft tissues is key to successful outcomes.
- 3.6 The committee was informed that some people with short stature have had bilateral limb lengthening using this technique. However, no evidence of benefit for this indication was reviewed by the committee, so this guidance is not intended to cover it.
- 3.7 The committee encourages the establishment of a registry for this procedure.

ISBN: 978-1-4731-4456-9

Endorsing organisation

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

Accreditation

