Intramedullary distraction for lower limb lengthening

Interventional procedures guidance
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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. However, 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.

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.

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 Guidance

1.1 Current evidence on the safety and efficacy of intramedullary distraction for
lower limb lengthening does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. Although there is evidence of efficacy in lengthening the femur, evidence on its safety is inadequate. There is inadequate evidence on both efficacy and safety in lengthening the tibia.

1.2 Clinicians wishing to undertake intramedullary distraction for lower limb lengthening should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy in its use for lengthening the tibia and its safety in use for lengthening the femur, and provide them with clear written information. In addition, use of the Institute's information for patients is recommended.
- Audit and review clinical outcomes of all patients having intramedullary distraction techniques for lower limb lengthening (see section 3.1).

1.3 A number of devices are available for the procedure which may have different safety and efficacy profiles. The technology is continuing to evolve and clinicians should consider the choice of device on the basis of the most current available evidence.

1.4 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Length deficiency can occur in one or both legs, and may be acquired (for example, secondary to trauma or infection) or, more rarely, be congenital (for example, due to hypoplasia or dysplasia). The femur, tibia or both can be involved. Deficiency or inequality in leg length can result in a limp and may limit functional ability.

2.1.2 Lengthening of the shorter leg can be attempted using external fixation devices. However, these devices are associated with significant morbidity, including
infection of the pin tracts, pain, hip and knee subluxation or dislocation, and angulation deformity of the bone. External fixation devices may also be impractical or aesthetically unacceptable to some patients.

2.2 Outline of the procedure

2.2.1 Intramedullary distraction devices are similar to the intramedullary nails used in the management of fractures of the femur and tibia. They have two interlocking sections, allowing controlled movement between the two pieces. The device is implanted into the intramedullary space under general anaesthesia. An osteotomy is performed, avoiding damage to the periosteum and blood supply. The proximal and distal sections of the distraction system are then fixed to the relevant sections of the bone with locking screws. The device exerts a force along the long axis of the bone, which stimulates new bone formation and lengthening. This process occurs very slowly. Different devices achieve distraction in different ways.

2.3 Efficacy

2.3.1 The evidence reviewed was based on case series only. The reported mean values for lengthening achieved were 46 mm (n = 48 patients), 50 mm (n = 23) and 63 mm (n = 10) in the femur, and 49 mm (n = 18) in a mixed tibial and femoral case series. The rate of lengthening achieved ranged from 0.82 mm to 1.11 mm per day.

2.3.2 In a case series, the range of knee movement in 21 patients treated with unilateral lengthening was not significantly altered following the procedure. Average knee extension was 2.5 ± 5.9° at baseline and 2.5 ± 6.1° at follow-up. Knee flexion was 155 ± 19.2° at baseline and 145 ± 19° at follow-up.

2.3.3 In one series, results described as 'excellent' (evaluated using a composite outcome that included criteria of joint movement, gait, pain and functional ability) were achieved in 75% (18/24) of patients. Full weight bearing was achieved at a mean of 67 days after the intervention in 48 patients in one case series. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers considered the procedure to be novel and stated that it was still being refined. They also stated that, compared with external fixation
devices, there is a lack of control, which may lead to premature or delayed consolidation.

## 2.4 Safety

### 2.4.1 Few studies reporting safety outcomes were identified. One case series (n = 52) reported femoral fissure and spontaneous bony section (not otherwise defined) during bone reaming in one patient. A second case series reported transient palsy of the peroneal nerve in 9% (2/23) of patients, which resolved within 3 months.

### 2.4.2 The most common postoperative adverse event reported was pain during limb lengthening. In one case series, all 31 patients experienced some degree of pain or discomfort during the lengthening process, and 39% (12/31) required readmission and general anaesthesia to allow ratcheting (the motion that delivers extension of the nail). In two other series, analgesia was required for ratcheting in 4% (2/48) and 9% (2/23) of patients. In a case series that reported pain outcomes quantitatively, pain during ratcheting was rated as between 1.5 and 2.4 on a four-point scale among 48 patients undergoing lengthening of one or both femurs, and 1.5 points during bone-consolidation periods. However, in two case series of 18 and 12 patients, no patient required pain control during lengthening.

### 2.4.3 Bone fractures (either during lengthening or after removal of the nail) were reported in 1 out of 52 (2%) and 2 out of 31 (6%) patients. The reported incidence of mechanical failure of the lengthening nail ranged between 4% (1 out of 24 treated bones) and 16% (4 out of 25 patients). Mechanical failures included nail bending, failure or locking, broken wire, motor failure and ratchet wear. For more details, refer to the ‘Sources of evidence’ section.

### 2.4.4 The Specialist Advisers stated that potential complications include poor bone formation, bone lengthening at an inappropriate rate (resulting in either bone weakness or premature consolidation), fat embolisation, deep vein thrombosis, respiratory distress syndrome and equinus ankle deformity.

## 3 Further information

### 3.1 This guidance requires that clinicians undertaking the procedure make special
arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

Andrew Dillon  
Chief Executive  
December 2006

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of intramedullary distraction for lower limb lengthening', March 2006.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in November 2010 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

19 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.
This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk
nice@nice.org.uk
0845 033 7780

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.