NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of intramedullary distraction for lower limb lengthening

Some people have an abnormally short leg or legs because of disease or injury. Intramedullary distraction involves the surgical insertion of a special metal rod (distractor) inside either the shin (tibia) or the thigh bone (femur), which gradually forces the bone to lengthen.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in March 2006.

Procedure name

- Intramedullary distraction for femoral and tibial lengthening
- Internal distraction osteogenesis
- Internal lengthening nail

Specialty societies

- British Orthopaedic Association (British Limb Reconstruction Society)

Description

Indications

Limb length deficiency could be acquired (e.g. secondary to trauma or infection) or, more rarely, congenital (e.g. due to hypoplasia or dysplasia for the femur and/or the tibial bone. The condition could be unilateral or bilateral. Limb length deficiency is usually associated with leg length inequality (or discrepancy) which can lead to limp and limit functional ability.

Current treatment and alternatives

Lengthening of the abnormally short lower limb can be attempted using external fixation devices, which exercise force along the long axis of bone to induce new bone formation (so called distraction osteogenesis). Significant potential problems with external fixation include: infection of the pin tracts, pain, hip and knee sublaxation or dislocation and angulation deformity of the bone. External fixation devices may also be less practically and aesthetically acceptable to the patient than a fully internal system.

What the procedure involves

Intramedullary distraction systems are intramedullary devices which are similar to intramedullary nails used for the management of fractures of the femur and tibia. They are designed in two sections so that controlled movement between the two pieces can be achieved. Under general anaesthesia the device is implanted into the intramedullary space and an osteotomy is performed without damage to the periosteum and blood supply. The proximal and distal section of the distraction system are then fixed to the relevant section of the bone with locking screws. Once implanted and fixed the device can exert 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. For example mechanically by releasing a pre-loaded spring or by using a motor drive.

Where correction of abnormal angulation of the bone is also required, an osteotomy can be performed across the apex of the angulation using an intramedullary saw, which in turn acts as the point of distraction.

Patients are mobilised rapidly with limited weight bearing. When radiological evidence of bone consolidation across the gap is evident full weight bearing is permitted and the nail may be removed after complete consolidation. (which requires another operation), or the nail may be left in place depending on clinical considerations.

Efficacy

No randomised or non-randomised controlled studies that compared the efficacy of the intramedullary distraction with external fixation distraction were found. This overview is therefore based on case series.

Lengthening (and rate of lengthening)

A number of case series reported the mean lengthening achieved: 46 mm[1], 50 mm[2] and 63 mm[3] in femoral case series, and 49 mm in a mixed tibial and femoral case series.[4]

The rate of lengthening achieved ranged from 0.82 mm[4] to 1.11 mm[1] per day.

Range of movement of the knee joint

During femoral lengthening, knee flexion was found to be reduced to a mean of 65° in one case series of 12 patients, although by 2 years this had improved to 115°.[6] In another case series in which either unilateral or bilateral lengthening was attempted, knee range of movement in 21 patients treated for unilateral lengthening was not significantly altered following lengthening: knee extension changed from a mean of 2.5° (± 5.9°) at baseline to 2.5° (± 6.1)° at follow-up; knee flexion changed from 155° (± 19.2°) to 145° (± 19)°, respectively.[3]

Ability to work

One case series of 18 patients found that 89% were able to work after lengthening, compared with 39% at baseline.[4]

Other outcomes

In a case series of 91 patients progression of lengthening as planned was reported in 71% (29/41) of patients who were included in the initial analysis; in 10% (4/41), however, distraction progressed too rapidly for adequate osteogenesis.[5]

In another series, excellent results (evaluated by a composite outcome of incorporating criteria on joint movement, gait, pain and functional ability) were reportedly achieved in 75% (18/24) of patients.[2] Full weight bearing was reportedly possible at a mean of 67 days after the intervention among 48 patients with an intramedullary distraction device,[1] and in another series of 12 patients full weight bearing was reportedly achieved at between 3.2 and 8.8 months.[6]

Safety

There were no controlled trials available to determine safety.

Intra-operative complications

Few studies reported intraoperative safety outcomes. One case series reported femoral fissure and spontaneous bony section (not otherwise defined) during bone reaming in one of 52 patients.[1] A second case series reported transient palsy of the peroneal nerve in 9% (2/23) of patients, which resolved within 3 months.[2] A third case series noted that mean operative blood loss was 574 ml per limb treated.[3]

Post-operative complications

Pain during distraction

The most common postoperative complication reported was pain during distraction. In one case series, all 31 patients experienced some degree of pain or discomfort during the lengthening process, and 39% (12/31) required re-admission and general anaesthesia to allow ratcheting.[3] In two other series, analgesia was required for ratcheting in 4% (2/48)[1] and 9% (2/23)[2] of patients, although the type and dose of analgesia required was not stated.

In a case series that reported pain outcomes in a quantitative fashion, 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 at 1.5 points during bone consolidation periods.[1] However, in another case series of 18 patients, no patient required continuous treatment to facilitate lengthening.[4] Distraction also proceeded painlessly in another case series study of 12 patients.[6]

Fracture

Bone fracture (either during lengthening or after removal of the nail) was reported in only 3 patients altogether: 1/52 (2%)[1] and 2/31 (6%)[3] of patients. Bone fracture did not occur in the other studies.[2,4–6]

Device-related complications

Mechanical failure of the lengthening nail was reported as follows (denominators are number of bones, unless stated otherwise):

- nail bending – 4% (1/24)[2]
- nail failure – 10% (2/20 patients)[4]
- mechanical failure (not otherwise defined) – 10% (3/31 patients)[3]
- nail locking – 16% (4/25)[1]
- broken wire / motor failure – 16% (2/12)[6]
- ratchet wear – 10% (5/52).[1]

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to intramedullary skeletal kinetic distraction. Searches were conducted via the following databases, covering the period from their commencement to 01/03/2006: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good-quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with limb length deficiency of any aetiology
Intervention/test	Intramedullary skeletal kinetic distractor
Outcome	Articles were retrieved if the abstract contained information relevant to safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on six case series described in detail in Table 2. An additional five studies are listed in appendix A, from a total of 217 items found from electronic searches.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) have been listed in appendix A.

Existing reviews on this procedure

There were no published reviews identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures

None applicable

Technology appraisals

None applicable

Clinical guidelines

None applicable

Public health

None applicable

Table 2 Summary of key efficacy and safety findings on intramedullary skeletal kinetic distraction for femoral and tibial lengthening

Abbreviations used: ISKD – intermedullary skeletal kinetic distractor, (SOFCOT) French Society of Orthopaedic & Trauma Surgery

Study details	Key efficacy findings	Key safety findings	Comments
Cole JD et al. (2001)[4] **Case series** USA **n = 18 (20 bones)** Study period: April 1995 to June 1998 Population: Mean age = 40 years (range 18–67), male = 78%; femur n = 6, tibia n = 14 Indications: patients with shortened limbs resulting from trauma, infection, polio or childhood burn contracture. Technique: Lengthening with the ISKD device (largest diameter tolerated) by linear distraction through rotational oscillations as occur when walking; patients avoided weight bearing in first postoperative week, then proceeded to walk on crutches. The device was replaced with a standard intramedullary nail after lengthening and bone consolidation. **Mean follow-up = 28 months** Disclosure of interest: Not stated.	**Lengthening** The mean lengthening achieved was 49 mm, achieved at a rate of 0.82 mm per day. The maximum length of distraction was 327 days in a patient who underwent two consecutive procedures. **Functional ability** Able to work / Able to walk / Able to drive Baseline: 39% / 94% / 94% During lengthening: 34% / 100% / 100% After lengthening: 89% / 100% / 100% **Quality of life** 15 of the 18 patients had previously been treated with external fixation distraction devices. All these patients reported that quality of life was substantially higher when being treated with the ISKD (method of evaluation was not described).	**Post-operative complications** No instances of infection, non-union or mal-union or joint contractures were reported. All patients showed excellent new bone formation during and after lengthening. There were no fractures. No patient complained of or required continuous treatment for severe pain during the lengthening period. **Device-related complications** The extending nail failed in 10% (2/20) of bones after lengthening was completed. In both these cases the device was replaced with a standard intramedullary nail and the bone continued to heal without loss of length.	Not stated whether this was a consecutive series of cases; method of case accrual was not defined. One patient died from congestive heart failure but had been followed up to 29 months. The design of the device was changed during the study to increase strength. In discussion section, functional outcomes were compared with outcomes observed in patients undergoing lengthening by external fixation, but no details were provided of clinical or demographic similarity of this cohort. Method of assessing quality of life outcomes was not defined. Potential for lengthening too quickly with excessive motion identified. Authors stated that exchange for a standard intramedullary nail after lengthening may be unnecessary. Not stated whether these were the first cases treated at the centre, or after a learning period.

Abbreviations used: ISKD – intermedullary skeletal kinetic distractor, (SOFCOT) French Society of Orthopaedic & Trauma Surgery			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Thonse R et al. (2005)[5] **Case series** USA **n = 91 (both tibial and femoral bones were treated)** Study period: 2001 to 2004 Population: Clinical and demographic characteristics of patients not reported. Indications: . Inclusion criteria included: mature skeleton, length discrepancy of 20–80 mm, adequate bone length to accommodate the nail, non diseased bone. Technique: lengthening with the ISKD device. Patients were mobilised one day after surgery, with limited weight bearing. Isometric muscle exercise and gentle joint mobilisation were encouraged. Physical therapy for 5 days a week during lengthening and 2 or 3 days a week during consolidation period. The ISKD was removed 12 months after initial surgery if radiological evidence of complete consolidation was found. **Mean follow-up:** not stated Disclosure of interest: Not stated.	Only one efficacy outcome was reported. In the initial review of follow-up, distraction progressed normally in 71% (29/41) of patients; there was difficulty inducing traction in 20% (8/41) of patients; distraction was too rapid in 10% (4/41).	No operative complications were reported. Patients who experienced slow distraction required manipulation exercises, which sometimes required analgesia, sedation or anaesthesia (epidural or general).	Mainly a technical paper reporting technique; only minimal description of clinical outcomes in discussion section Methods of outcome assessment and follow-up are not described. No details of patient selection or case accrual method were provided. Authors stated that the ISKD cannot be shortened or adjusted once inserted; precise preoperative planning is therefore required. Authors stated that published data and their experience suggest that ISKD is capable of lengthening tibial and femoral bones in a diverse group of patients who have experienced trauma, infection, congenital deficits, or other causes of limb length discrepancy.

Abbreviations used: ISKD – intermedullary skeletal kinetic distractor, (SOFCOT) French Society of Orthopaedic & Trauma Surgery

Study details	Key efficacy findings	Key safety findings	Comments
Guichet JM et al. (1995)[1] **Case series** France **n = 48 (52 femoral bones)** Study period: not stated Population: Mean age = 21 years, male = 50% Indications: injury = 48%, congenital = 21%, infection = 8%, short stature = 8%, neurological = 4%, other = 11%. Technique: lengthening using the Albizzia nail, produced by alternative inward and outward movement of the distal part of the lower limb. Lengthening began on the fifth day after surgery; full weight was bearing allowed at the end of lengthening. **Mean follow-up = 8.9 months** Disclosure of interest: Not stated.	**Lengthening** Mean length gain was 45.6 mm, at a rate of 1.11 mm per day. **Range of movement of the knee joint** Knee flexion was maintained from a mean 125° at baseline to 122° after lengthening. **Other outcomes** Full weight bearing was achieved at a mean of 67 days after surgery. Of cases followed up to 1 year, removal of the nail was possible in 56% (15/27) of patients. Mean patient satisfaction with the procedure was 8.8 on a 10-point scale.	**Operative complications** Rate (n = 52 bones) Femoral fissure during reaming 2% (1/52) Spontaneous bony section at reaming 2% (1/52) **Postoperative complications** 31% of patients had complications that required cessation of lengthening, 25% required additional surgery; lengthening was not completed in 8% of patients using SOFCOT classification. Two patients required analgesia for ratcheting. Rate (n = 52 bones) Nail rupture 2% (1/52) Ratchet wear 10% (5/52) For both of the above complications patients were able to bear weight fully Rupture of the proximal screw 2% (1/52) Rupture of the distal screw 2% (1/52) Locking of the lengthening nail 16% (4/25) Fracture after removal of nail 2% (1/52) Transitory paresis of the peroneal nerve 2% (1/52) Dislocation of the knee 2% (1/52) Dislocation of the hip 2% (1/52) Reactivation of osteitis 4% (2/52) Superficial infection 4% (2/52) Delayed bone healing requiring grafting 10% (5/52) **Pain** Pain (on a four-point scale) was 1.5–2.4 during ratcheting and 1.5 outside of the ratcheting period.	A short report Not stated whether this was a consecutive series. This series represents the initial experience at one centre; complications may therefore relate in part to learning curve. Concomitant surgery (axial correction) was undertaken in 10% of patients. No details were provided of the scale used for pain assessment or whether this was validated.

Abbreviations used: ISKD – intermedullary skeletal kinetic distractor, (SOFCOT) French Society of Orthopaedic & Trauma Surgery

Study details	Key efficacy findings	Key safety findings	Comments
Garcia-Cimbrelo E et al. (2002)[2] **Case series** Spain **n = 23 (24 femoral bones)** Study period: 1993 to 2000 Population: Mean age = 16.8 years, male = 52% Indications: Congenital shortening n = 9, injury n = 2, developmental (poliomyelitis, Ollier's disease, fracture, infection, avascular necrosis, growth hormone deficiency) n = 13 Technique: Computed tomography scanning used to determine leg length in difficult cases. Lengthening using the Albizzia nail. Began on fifth day after surgery; full weight bearing allowed when newly formed bone had bridged two cortices on radiograph. **Mean follow-up = 44.7 months** Disclosure of interest: No commercial benefits received directly or indirectly by the authors.	**Lengthening** The mean lengthening achieved was 5.0 cm, with a mean distraction period of 57 days. The mean time to consolidation was 164 days (from index procedure) in the 22 femoral bones in which full bone healing was achieved. **Composite clinical outcomes** Scores were rated as excellent, good, fair or poor based on evaluation of six criteria: • range of knee movement • lengthening obtained • gait • lateral distal angle • pain • ability to perform daily activities. Results were excellent in 75% (18/24) of patients (although two required further surgery), good in 17% (4/24) and fair in 8% (2/24) (in whom the intended lengthening did not occur by at least 3 cm). Pre-operative knee function was preserved in all patients. The gait of patients was considered normal at 1-year follow-up.	**Operative complications** Transient palsy of the peroneal nerve (resolving within 3 months) occurred in 9% (2/23) patients. No failure of lengthening nerves was reported nor was there any soft tissue infection or delayed wound healing. In one case, open osteotomy was required because of a breakage of the intramedullary saw. **Postoperative complications** Late infection around a distal fixing screw (resolved with removal of the implant following bone consolidation) — Rate (n = 23 patients): 4% (1/23) Pain during first few postoperative days making ratcheting difficult — 22% (5/23) Analgesia required for ratcheting — 9% (2/23) Valgus tibial deformity requiring posterior tibial osteotomy — 4% (1/23) Delayed bone healing — 9% (2/23) Pseudoarthritis with nail fracture — 4% (1/23) No axial femoral deformities were reported. **Device-related complications** Nail bending occurred in 4% (1/24 bones).	Disparity noticed between the number of cases described in text and those presented in tables (one case). Many patients underwent concomitant surgical procedures. Not clear whether this report describes the initial cases treated, or whether the surgeon was experienced. Patients were classified at baseline as to whether the complexity of the procedure was expected to be mild, moderate or severe; however, this grouping was not used in the analysis.

Abbreviations used: ISKD – intermedullary skeletal kinetic distractor, (SOFCOT) French Society of Orthopaedic & Trauma Surgery

Study details	Key efficacy findings	Key safety findings	Comments
Guichet JM et al. (2003)[3] **Case series** France and Italy **n = 31 (41 femoral bones)** Study period: not stated Population: Mean age = 20 years, male = 45%. Previous related surgery = 48%. Bilateral lengthening n = 10, unilateral n = 21 Indications: Patients with short stature or limb length discrepancy Technique: Albizzia nail, modified with an outer tubing to increase the distal diameter designed for multiaxial correction. Enoxaparin, 20 mg/day, administered subcutaneously until distraction complete; ketoprofen, 100 mg twice daily, in the immediate postoperative period. Postoperative pain controlled by continuous epidural infusion or patient-controlled analgesia. Lengthening began un the fifth day after surgery. Full weight bearing allowed at the end of lengthening. All patients who had unilateral therapy were allowed to bear weight on crutches on the third day after surgery and received outpatient physical therapy. **Mean follow-up = 50 months** Disclosure of interest: Authors received benefits from a commercial party related to the study.	**Lengthening** Average length gain was 3.4 cm for unilateral procedures and 6.3 cm for bilateral procedures (more cases with short stature). All patients eventually obtained desired bone lengthening, and had bone healing. Three patients (10%) required re-operation because of device failure (all were treated with exchange nailing, which allowed lengthening) **Knee range of movement** Data for unilateral lengthening (n = 21 patients) Knee extension: Baseline 2.5 ± 5.9°; Final follow-up 2.5 ± 6.1°; P value NS Knee flexion: Baseline 155.0 ± 19.2°; Final follow-up 145 ± 19 °; P value NS At final follow-up, 74% (23/31) of patients walked without a limp. **Other outcomes** The nail was removed in all patients who requested it (one refused) (30/30) at a mean period of 14 months after insertion.	**Operative outcomes** Mean blood loss was 574 ml per limb treated. **Post-operative complications** All patients experienced some degree of discomfort or pain during the lengthening process; 39% (12/31) o required re-admission and a general anaesthetic for ratcheting. Sporadic ratcheting could be felt for up to 10 days after desired lengthening was achieved. Hypaesthesia on the dorsal aspect of the ankle: Rate (n = 31 patients) 3% (1/31) Superficial wound infection: 6% (2/31) No pain at final follow-up: 90% (28/31) Slight pain at final follow-up: 10% (3/31) Fracture of femur after nail removal: 6% (2/31) Abscess requiring drainage: 6% (2/31) Six major complications occurred in 3 patients who had undergone previous lengthening. There were no long-term sequelae and patients were satisfied with the functional outcome **Device-related complications** 10% (3/31) of patients required re-operation because of device failure.	Duration of ratcheting each day to produce lengthening varied between patients. Some patients included in this study may also be included in Guichet et al (1995), although the case accrual period postdates that study and 20 cases came from the Italian centre, which will not have been reported in the aforementioned report. Two patients underwent simultaneous correction of alignment during insertion of the lengthening nail. No details of method for assessing pain outcome were provided. Patients who underwent additional lengthening surgery because of mechanical failure were included in the outcomes analysis.

Abbreviations used: ISKD – intermedullary skeletal kinetic distractor, (SOFCOT) French Society of Orthopaedic & Trauma Surgery

Study details	Key efficacy findings	Key safety findings	Comments
Baumgart R (1997)[6] Case series Germany **n = 12 (femoral bones)** Study period: 1990 to 1994 Population: Mean age = 25.5 years, male = 42% Indications: trauma or osteomyelitis n = 6, congenital n = 5, Ewing's sarcoma resection n = 1 Technique: Lengthening with an implantable motorised intramedullary nail at a rate of 0.5–2 mm per day. After surgery weight bearing to 20 kg was allowed and physiotherapy could proceed. **Mean follow-up = minimum 2 years** Disclosure of interest: Not stated.	**Lengthening success** Desired lengthening was achieved in all patients (12/12). All bones had healed at 2-year follow-up. The mean duration of lengthening was 47.8 days, with a distraction index of 1 cm every 12.4 days. **Range of movement of the knee joint** During lengthening, knee flexion was reduced to a mean of 65°, but at 2-year follow-up this had recovered to 115°. **Gait** At 2 years gait was normal in all patients (6/6) treated for shortness resulting from trauma or pervious operations, but only 20% (1/5) of patients with congenital shortening had normal gait. **Other outcomes** Full weight bearing was resumed at 3.2–8.8 months. The nail had been removed at 2-year follow-up in 42% (5/12) of patients.	**Post operative complications** Rate (n = 12 patients) Bone or soft tissue infection: 0% (0/12) Delayed wound healing: 0% (0/12) Re-operation: 25% (3/12) Broken wire: 8% (1/12) Motor failure: 8% (1/12) Bone graft at docking site for Ewing's sarcoma: 8% (1/12) Fracture: 0% (0/12) Soft tissue irritation at site of nail-locking screw: 8% (1/12) Temporary hyperthesia on anterior proximal tibia: 8% (1/12) Corrosion or permeability of nails removed after lengthening: 0% (0/12) The patients could not feel the motor moving, and distraction proceeded painlessly. **Device-related complications** Rate (n = 12 patients) Broken wire: 8% (1/12) Motor failure: 8% (1/12) Corrosion or permeability of nails removed after lengthening: 0% (0/12)	Consecutive cohort of patients Some patients had undergone previous surgery after acute shortening, but these were not analysed separately. This report documents the first 12 cases treated at the site; outcomes may therefore be partially related to learning curve. The motor used in the lengthening nail was updated during the series. The authors stated that this procedure is limited to patients where the medullary cavity is large enough for the nail to be inserted.

Validity and generalisability of the studies

- Some studies include cases treated for either tibial or femoral lengthening, but results were not analysed separately.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr C Bradish, Mr M Laverick, Prof. H Simpson.

- Two of the advisors considered the procedure to be novel and of uncertain safety and efficacy, and one considered it to be a minor variation on existing techniques
- The aim of the procedure is to provide successful lengthening, without the need for an external fixator or additional procedures.
- Reported complications include intramedullary nail breakage, and delayed bone healing.
- Additional theoretical complications that may arise are poor bone formation, and lengthening at an inappropriate rate, either too quickly with the potential for bone weakness, or too slowly causing premature consolidation, fat embolisation, deep vein thrombosis, pain, respiratory distress syndrome, and equinous ankle complications
- Training is required to undertake the procedure or a visit to a surgeon who practices this technique
- A number of different lengthening devices are available.
- The technique is still being refined.
- The is a lack of control of lengthening once the device is inserted.
- Treatment by a multidisciplinary team is advisable offering the full range of lengthening options.
- One advisors commented that there is more concern about complication rates during lengthening of the tibia.
- Useful audit criteria may include lengthening achieved, time taken for lengthening, range of movement in joints, SF-36 or other quality of life score, infection and reoperations rates, inappropriate lengthening, and joint stiffness.

Issues for consideration by IPAC

- Lengthening of bones other than the tibia and femur is not considered in the overview, as only these two bones were notified and thus included in the search.
- Foreign language reports were not considered for inclusion, as sufficient studies in the English language were available.
- There was some variation in devices and techniques used to stimulate lengthening, with either motor driven extension or kinetic based principles.

- It is unclear whether (and when) removal of device after lengthening and consolidation is recommended. Removal would require another operation.
- All studies included in table 2 come from the USA or the continent, the procedure is less popular in the UK.

References

1. Guichet JM, Lascombes P, Grammont PM et al. (1995) Gradual elongation intramedullary nail for femur (Albizzia(TM)). Results of the 52 first cases in 48 patients. *Journal of the Japanese Orthopaedic Association* 69 (2)(3): S310

2. Garcia-Cimbrelo E, Curto dlM, Garcia-Rey E et al. (2002) The intramedullary elongation nail for femoral lengthening. *Journal of Bone & Joint Surgery – British Volume* 84:971–7.

3. Guichet JM, Deromedis B, Donnan LT et al. (2003) Gradual femoral lengthening with the Albizzia intramedullary nail. *Journal of Bone & Joint Surgery – American Volume* 85-A:838–48.

4. Cole JD, Justin D, Kasparis T et al. (2001) The intramedullary skeletal kinetic distractor (ISKD): first clinical results of a new intramedullary nail for lengthening of the femur and tibia. *Injury* 32(Suppl 4):SD129–39.

5. Thonse R, Herzenberg JE, Standard SC et al. (2005) Limb lengthening with a fully implantable, telescopic, intramedullary nail. *Operative Techniques in Orthopaedics* 15: 355-362.

6. Baumgart R, Betz A, Schweiberer L. (1997) A fully implantable motorized intramedullary nail for limb lengthening and bone transport. *Clinical Orthopaedics & Related Research* 343: 135–43.

Appendix A: Additional papers on intramedullary skeletal kinetic distraction for femoral and tibial lengthening not included in summary table 2

The table below outlines studies that are considered potentially relevant to the overview but which were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up (FU)	Direction of conclusions	Reasons for non-inclusion in Table 2
Baumgart R, Burklein D, Hinterwimmer S et al. (2005) The management of leg-length discrepancy in Ollier's disease with a fully implantable lengthening nail. *Journal of Bone & Joint Surgery – British Volume* 87(7):1000–4.	Case report n = 1 FU = ?	Both femur and tibia treated; lengthened by 10.6 and 4 cm, respectively	Larger case series included in Table 2.
Hankemeier S, Pape HC, Gosling T et al. (2004) Improved comfort in lower limb lengthening with the intramedullary skeletal kinetic distractor. Principles and preliminary clinical experiences. *Archives of Orthopaedic & Trauma Surgery* 124(2):129–33.	Case series n = 4 FU = ?	Average lengthening of 3 femoral bones and 1 tibia was 31 mm Return to work in 11 weeks No complications observed	Larger case series included in Table 2.
Hankemeier S, Gosling T, Pape HC et al. (2005) Limb lengthening with the Intramedullary Skeletal Kinetic Distractor (ISKD). *Operative Orthopadie und Traumatologie* 17(1):79–101.	Case series n = 4 FU = 14.2 months	Planned distraction achieved in all patients One required analgesic during distraction Weight bearing in 10 weeks	Larger case series included in Table 2.
Perttunen JR, Anttila E, Sodergard J et al. (2003) Effect of intramedullary gradual elongation of the shorter limb on gait patterns. *Pediatrics International* 45(3):324–32.	Case series n = 7 FU = ?	Clear improvement in gait at 1-year follow-up	Larger case series included in Table 2.
Vitale K, Miller T, Jimenez AC. (2006) Rehabilitation after intramedullary skeletal kinetic distractor implantation: a report of two cases and a suggested therapy program. *American Journal of Physical Medicine & Rehabilitation* 85(2):176–80.	Case series n = 2 FU =	Study report not available as being catalogued at British Library.	

Appendix B: Related published NICE guidance for intramedullary skeletal kinetic distraction for femoral and tibial lengthening

Guidance programme	Recommendation
Interventional procedures	None applicable
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for intramedullary skeletal kinetic distraction for femoral and tibial lengthening

Procedure number: 358	Procedure name: Intramedullary kinetic distraction for tibial and femoral lengthening	
Databases	**Version searched (if applicable)**	**Date searched**
The Cochrane Library	2006 Issue 1	8/3/2006
CRD	February 2006	8/3/2006
Embase	1980 to 2006 Week 08	2/3/2006
Medline	1966 to February Week 3 2006	1/3/2006
Premedline	February 28, 2006	1/3/2006
CINAHL	1982 to February Week 4 2006	2/3/2006
British Library Inside Conferences (limited to current year only)	1993 to date	8/3/2006
National Research Register	2006 Issue 1	8/3/2006
Controlled Trials Registry		8/3/2006

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1	intramedullary skeletal kinetic distract$.tw.
2	ISKD.tw.
3	(intramedullary adj5 (lengthen$ or distract$)).tw.
4	(internal adj5 (lengthen$ or distract$)).tw.
5	(implant$ adj5 (lengthen$ or distract$)).tw.
6	(two rod adj3 distract$).tw.
7	(double rod adj3 distract$).tw.
8	Osteogenesis, Distraction/
9	fitbone.tw.
10	albizzia$.tw.
11	or/1-10
12	Bone Malalignment/
13	Bone Lengthening/
14	12 or 13
15	Femur/
16	Tibia/
17	femora$.tw.
18	tibia$.tw.
19	or/15-18
20	14 and 19
21	Leg Length Inequality/
22	(leg adj3 (lengthen$ or shorten$ or elongat$)).tw.
23	(lower limb adj3 (lengthen$ or shorten$ or elongat$)).tw.
24	(femora$ adj3 (lengthen$ or shorten$ or elongat$)).tw.
25	(femur adj3 (lengthen$ or shorten$ or elongat$)).tw.
26	(tibia$ adj3 (lengthen$ or shorten$ or elongat$)).tw.
27	or/21-26
28	20 or 27
29	11 and 28
30	Animals/
31	Humans/
32	30 not (30 and 31)
33	29 not 32