NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis

In medial knee osteoarthritis the cartilage in the inner part of the knee joint wears away. The knee tilts and the lower leg bows, causing pain and reduced movement. In this procedure, a cut (osteotomy) is made at the top of 1 of the bones in the lower leg (tibia). An adjustable magnetic nail is inserted into the bone and screwed in place. After the operation the nail can be lengthened or shortened using an external controller, which adjusts the shape of the leg over time. When the bone is fully healed the nail is removed. The aim is to straighten the leg to relieve pain and maintain movement.

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Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2019.

Procedure name

- High tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis

Professional societies

- British Association for Surgery of the Knee
- British Limb reconstruction society
- British Orthopaedic Association

Description of the procedure

Indications and current treatment

Medial knee osteoarthritis is the result of progressive deterioration of the articular cartilage and menisci of the joint. This can cause exposure of the bone surface with chronic and excessive joint loading during movement. Symptoms include joint pain, stiffness, local inflammation, limited movement and loss of knee function. Medial knee osteoarthritis can lead to knee deformity and malalignment, including bowing.

Treatment for knee osteoarthritis depends on the severity of the condition. Current management includes lifestyle changes (such as losing weight and regular exercise), medicines (such as analgesics and corticosteroid injections), physiotherapy and prescribed exercise. When these options do not work or symptoms are severe, surgery may be indicated. Options include high tibial osteotomy, microfracture surgery, and unicompartmental or total knee replacement.

What the procedure involves

The procedure is done using spinal or general anaesthesia. Following a high tibial osteotomy, a magnetic nail is inserted into the medullary canal of the tibia using image intensification and positioned below the tibial plateau. The nail is secured proximally and distally using multiple locking screws. After wound closure the position of the magnet inside the nail is identified and this is marked on the skin. The procedure takes about 2 hours.

During the post-operative phase, the magnetic nail can be gradually lengthened or shortened by placing the external remote controller over the marked skin to control the exact amount of the opening of the osteotomy. New bone forms in the wedge defect that is generated. The nail is removed when the desired alignment has been achieved and bony consolidation is complete, assessed radiologically. The aim is to correct the malalignment of the knee to reduce symptoms.

Outcome measures

The knee injury and osteoarthritis outcome score questionnaire is a self-administered, knee-specific instrument with 42 items in 5 subscales: pain (9 items), other symptoms (7 items), function in daily living (17 items), function in sport and recreation (5 items), and knee-related quality of life (4 items). A 5-point Likert scale is used for each item from 0 (no problems) to 4 (extreme problems).

Efficacy summary

Symptom relief

In a non-randomised comparative study of 11 patients with symptomatic medial compartmental osteoarthritis and no serious (co-morbid) knee pathology, there were improvements in the subscales of the knee injury and osteoarthritis outcome score (KOOS) over 6 months post-surgery. A median improvement of more than 10 points equates to achieving a minimal perceptible clinical improvement[1]. Comparing the nail insertion group with the fixed-plate group, the respective changes were 17 and 8 for pain (p=0.54), 14 and 3 for symptoms

(p=0.54), 18 and 6 for activities of daily living (p=0.082), 38 and 24 for sport and recreation (p=0.18), and 22 and 15 for quality of life (p=0.79).

Patient satisfaction

In the non-randomised comparative study of 11 patients, at 6 months post-surgery, both nail insertion and fixed-plate groups reported a median of 'satisfied' for general and pain-related patient satisfaction, and 'neutral' for activities of daily living, and sport and recreation[1].

Bone healing

In the non-randomised comparative study of 11 patients, at 6 months post-surgery, the median healing impression score was 4 ('union virtually complete', range 3 to 4) for patients who had adjustable magnetic nail insertion compared with 2 ('progressive healing', range 1 to 4) for patients who had fixed-plate (p=0.082)[1]. At the same follow up, bone healing quotient was 1.78 (standard deviation [SD]=1.58) for the nail insertion group compared with 1.30 (SD=1.74) for the fixed-plate group (p=0.18).

Surgical accuracy

In the non-randomised comparative study of 11 patients, at 3 months post-surgery, the mean value of the absolute surgical accuracy was 2.8 (SD=2.3) for patients having adjustable magnetic nail insertion compared with 8.9 (SD=6.0) for patients having fixed-plate (p=0.052)[1]. At 6 months, the mean values were 4.1 (SD=2.3) for the nail insertion group compared with 12 (SD=7.5) for the fixed-plate group (p=0.052).

Safety summary

Safety events

The single study included in the main extraction table (non-randomised comparative study of 11 patients) did not report safety events.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, professional experts listed the following anecdotal adverse event: short-term pain after lengthening.

They considered that the following were theoretical adverse events: delayed bone union, loss of correction and implant failure.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis. The following databases were searched, covering the period from their start to 30 September 2019: 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 the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection 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, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with symptomatic medial knee osteoarthritis.
Intervention/test	High tibial osteotomy with magnetic nail insertion.
Outcome	Articles were retrieved if the abstract contained information relevant to the 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 IP overview

This IP overview is based on 11 patients from 1 non-randomised comparative study.

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

Table 2 Summary of key efficacy and safety findings on high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis

Study 1 Jonker L (2019)

Details

Study type	Non-randomised comparative study
Country	UK (single centre)
Recruitment period	Not reported
Study population and number	n=**11 (adjustable magnetic nail n=6 compared with fixed-plate n=5)** Patients with symptomatic medial compartmental osteoarthritis and no serious (co-morbid) knee pathology
Age and sex	Adjustable magnetic nail group: mean 51 years; 100% (6/6) male Fixed-plate group: mean 49 years; 100% (5/5) male
Patient selection criteria	Inclusion criteria: treatment with medial open-wedge proximal tibial osteotomy, either with Tomofix fixed-plate or with OPTY-LINE nail for symptomatic medial compartmental osteoarthritis, provision of written informed consent, males, and mental capacity. Exclusion criteria: under the age of 18, lacking mental capacity, females, current use of nicotine products (including smoking), and cannot understand English. The following pre-existing clinical exclusion criteria were applied: varus deformity greater than 10°, flexion contracture greater than 15°, knee flexion under 90°, medial/lateral tibial subluxation over 1 cm, medial bone loss of over 3 mm if demonstrated on radiographs, inflammatory arthritis (including use of methotrexate), arthritis in the lateral compartment, patella baja, weight over 115 kg, severe patella femoral symptoms, unaddressed ligamentous instability, fixed flexion contracture, known or suspected osteoporosis or osteopenia based on medical history and radiographic image, and requirement for other major surgical procedures at the time of the high tibial osteotomy surgery.
Technique	Adjustable magnetic nail group: The OPTY-LINE system (NuVasive Specialised Orthopaedics, San Diego, California, USA) was used and the OPTY-LINE nail surgical procedure was performed. After the operation, daily correction for each patient was typically 0.5 mm, divided into 2 sessions, starting 5 to 7 days. Weekly follow up for up to 6 weeks with long leg alignment radiography to optimise the corrections. Fixed-plate group: The Tomofix plate (Depuy Systhes, West Chester, Pennsylvania, USA) was used. To minimise the risk of deep vein thrombosis all patients had a calf pump and clexane while in hospital and, prescribed rivaroxaban for 2 weeks after discharge home.
Follow-up	**6 months**
Conflict of interest/source of funding	One author received honoraria from NuVasive for conference presentations. The other authors had no conflict of interest to declare.

Analysis

Follow-up issues: After the operation, patients were followed up weekly for 6 weeks and then at 3 and 6 months. One of the patients who had adjustable magnetic nail insertion died during follow up, probably caused by non-surgery or medical device-related reasons. Therefore, 6 patients with nail insertion were included in the analysis.

Study design issues: This prospective, open label, two-armed study evaluated the clinical and patient-related short- to medium-term performance of the adjustable magnetic nail for high tibial osteotomy, comparing a case series of this device to the established fixed-plate. The primary outcome was the radiologist's assessment of healing, as determined from computed tomography (CT) imaging according to a 5-point Likert-type scale. Patients had computed tomography

assessment and they completed the Knee Injury and Osteoarthritis Outcome score (KOOS) and osteotomy surgery patient satisfaction questionnaires. A radiologist impression score and a quantitative digital bone density analysis were done by 2 independent radiologists, each of whom has over 10 years experience as a consultant radiologist. Because this study was considered as a first pilot study on the application of the adjustable magnetic nail, no formal power calculation was performed to determine a required sample size a priori.

Study population issues: There was no statistically significant difference between the 2 treatment groups in terms of age, weight, height, BMI, leg affected and length of stay in hospital. For KOOS at baseline, comparing the adjustable magnetic nail group with the fixed-plate group, there were differences in pain (68 compared with 44, p=0.052), symptoms (58 compared with 41, p=0.009), activities of daily living (71 compared with 47, p=0.052), and sport and reaction (22 compared with 6, p=0.13; and 32 compared with 20, p=0.33).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **11 (adjustable magnetic nail n=6 compared with fixed-plate n=5)**

Radiologists' impression scores and quantitative assessment of bone healing

Time point	Type of rating	Adjustable magnetic nail (median; range)	Fixed-plate (median; range)	p Value
3 months post-operatively	Radiologist's impression score[a]			
	Average of 2 raters	1.75 (1 to 2)	0.5 (0 to 2)	0.082
	Inter-rater concordance	0.83	0.80	
	Digital quantification of bone healing[b]			
	Average of 2 raters	0.40 (0.19)	0.32 (0.077)	0.54
	Inter-rater concordance	0.89	1	
6 months post-operatively	Radiologist's impression score[a]			
	Average of 2 raters	4 (3 to 4)	2 (1 to 4)	0.082
	Inter-rater concordance	1	1	
	Digital quantification of bone healing[b]			
	Average of 2 raters	1.78 (1.58)	1.30 (1.74)	0.18
	Inter-rater concordance	0.89	0.64	

[a]Radiologist's impression score: 0= no healing (0 to 20%); 1= some healing (21% to 40%); 2= progressive healing (41% to 60%); 3= advanced healing (61% to 80%); 4= union virtually complete (81% to 100%)
[b]Digital quantification of bone healing: bone density quotient = ROI defect area/ ([ROI superior area + ROI inferior area]/2)

Callus appearance at 6 months:
- Adjustable magnetic nail: fixation callus n=4 and irritation callus n=2
- Fixed-plate: fixation callus n=1 and irritation callus n=4

Hinge fracture at 6 months:
- Adjustable magnetic nail: type I n=4 and type II n=1
- Fixed-plate: type I n=3 and type II n=2

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Achieved versus intended Mikulicz at 3 and 6 months follow up

Device	Patient no.	Planned Mikulicz value	Achieved Mikulicz value, 3 months (SD)	Surgical accuracy targeting error[c]	Surgical accuracy (absolute value (SD))	Achieved Mikulicz value, 6 months (SD)	Surgical accuracy targeting error[c]	Surgical accuracy (absolute value (SD))
Adjustable magnetic nail	1	55	50	-5	5	48	-7	7
	2	55	58.9	3.9	3.9	53	-2	2
	3	55	53.4	-1.6	1.6	51	-4	4
	4	55	54.9	-0.1	0.1	51.8	-3.2	3.2
	5	55	55.6	0.6	0.6	53.3	-1.7	1.7
	6	55	60.3	5.3	5.3	61.6	6.6	6.6
	Mean				2.8 (2.3)			4.1 (2.3)
Fixed-plate	7	50	67.4	17.4	17.4	73	23	23
	8	55	66	11	11	71.2	16.2	16.2
	9	55	64	9	9	63.8	8.8	8.8
	10	55	49.2	-5.8	5.8	48.8	-6.2	6.2
	11	55	53.7	-1.3	1.3	49.4	-5.6	5.6
	Mean				8.9 (6.0)			12 (7.5)
p Value[d]					0.052			0.052

[c]A value of 0 equates to accuracy of 100%

[d]Adjustable magnetic nail compared with fixed-plate

The changes in KOOS sub-scale scores over 6 months – improving more than 10 points equates to achieving a MPCI

KOOS sub-scale	Adjustable magnetic nail	Fixed-plate	p Value
Pain	17	8	0.54
Symptoms	14	3	0.54
Activities of daily living	18	6	0.082
Sport and recreation	38	24	0.18
Quality of life	22	15	0.79

Osteotomy surgery patient satisfaction questionnaires:

- Initial appraisal: little or no difference in how patient perceived the outcome of each surgery.
- 6 months: a median of 'satisfied' for general and pain-related patient satisfaction, and 'neutral' for activities of daily living, and sport and recreation for both groups.

Abbreviations used: KOOS, knee injury and osteoarthritis outcome score; MPCI, minimal perceptible clinical improvement; ROI, region of interest; SD, standard deviation.

Validity and generalisability of the studies

- Only 1 non-randomised comparative study with 11 patients, who had been followed up for 6 months, was included in table 2.
- This procedure has been used to correct the malalignment of the knee caused by conditions such as Blount's disease, Ollier's disease, rickets and pseudoachondroplasia. These conditions might be associated with or lead to knee osteoarthritis. Therefore, 7 case series of patients who had any of these conditions but without a clear description of knee osteoarthritis were included in the appendix.
- In the 7 case series the identified complications (such as irritation infection, pain, delayed bone healing or bone non-union, and implant failure) may also occur during and after high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Joint distraction for knee osteoarthritis without alignment correction. NICE interventional procedures guidance 529 (2015). Available from https://www.nice.org.uk/guidance/ipg529
- Implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis. NICE interventional procedures guidance 512 (2015). Available from https://www.nice.org.uk/guidance/ipg512

- Partial replacement of the meniscus of the knee using a biodegradable scaffold. NICE interventional procedures guidance 430 (2012). Available from https://www.nice.org.uk/guidance/ipg430

- Mini-incision surgery for total knee replacement. NICE interventional procedures guidance 345 (2010). Available from https://www.nice.org.uk/guidance/ipg345

- Individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee. NICE interventional procedures guidance 317 (2009). Available from https://www.nice.org.uk/guidance/ipg317

- Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. NICE interventional procedure guidance IPG230 (2007). Available from https://www.nice.org.uk/guidance/IPG230

NICE guidelines

- Osteoarthritis: care and management. NICE clinical guideline 177 (2014). Available from https://www.nice.org.uk/guidance/cg177

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two professional expert questionnaires for high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has

received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 1 company who manufactures a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

References

1. Jonker L, Fallahi F, Saraswathy JJ et al. (2019) OPTY-LINE remote-controlled adjustable intramedullary device implantation in open-wedge high tibial osteotomy: a prospective proof-of-concept pilot and comparison with Tomfix fixed-plate device method. Journal of Orthopaedic Surgery 27(3): 1-9

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/09/2019	Issue 9 of 12, September 2019
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/09/2019	Issue 9 of 12, September 2019
HTA database (CRD website)	30/09/2019	n/a
MEDLINE (Ovid) & MEDLINE In-Process (Ovid)	30/09/2019	1946 to September 27, 2019
MEDLINE ePubs ahead of print (Ovid)	30/09/2019	September 27, 2019
EMBASE (Ovid)	30/09/2019	1974 to 2019 September 27
BLIC	30/09/2019	n/a

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

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

1 Osteoarthritis, Knee/ (18328)
2 exp Knee Joint/ (57798)
3 Bone Malalignment/ (1632)
4 OA.tw. (27155)
5 ((tibia* or tibiae* or knee* or patella* or meniscal* or articular* or patellofem* or unicompartment* or (medial* adj4 compartment*)) adj4 (OA or osteoarthrit* or osteo-arthrit* or osteoarthros* or cartilag* or degenerat* or diseas* or deteriorat* or deform* or injur* or defect* or malalign* or malform* or damag*)).tw. (51622)
6 ((cartilage* or joint* or cap* or varus* or bone*) adj4 (degenerat* or diseas* or deteriorat* or deform* or injur* or defect* or malalign* or malform* or pain*)).tw. (114970)
7 Gonarthrosis*.tw. (947)
8 (degenerativ* adj4 arthriti*).tw. (1483)
9 or/1-8 (214165)
10 Osteotomy/ (29170)
11 (osteotom* or osteoplast* or osteogen*).tw. (63381)
12 ((knee* or tibia*) adj4 (surger* or resect* or incis* or cut*)).tw. (8177)
13 or/10-12 (81384)
14 Fracture Fixation, Intramedullary/ (9641)

15 ((intramedull* or intra-medull*) adj4 (nail* or osteosynth* or device* or (fractur* adj4 fixat*))).tw. (6784)
16 Bone Nails/ (10802)
17 ((bone* or magnet* or lengthen* or lock* or precis*) adj4 (nail* or rod* or pin* or screw*)).tw. (8754)
18 ((limb* or leg*) adj4 lengthen*).tw. (1407)
19 or/14-18 (25122)
20 9 and 13 and 19 (524)
21 Nuvasive.tw. (18)
22 (opty-line or optyline).tw. (0)
23 or/20-22 (542)
24 animals/ not humans/ (4586713)
25 23 not 24 (471)
26 limit 25 to english language (359)

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but 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	Direction of conclusions	Reasons for non-inclusion in table 2
Fragomen AT and Rozbruch R (2017) Lengthening and deformity correction about the knee using a magnetic internal lengthening nail. SICOT J 3, 25	Review	The internal lengthening nail is a great advancement in the area of limb deformity and lengthening, particularly in the femur.	Review article
Green SA, Fragomen AT, Herzenberg JE et al. (2018) A magnetically controlled lengthening nail: A prospective study of 31 individuals (The PRECICE intramedullary nail study). J Limb Lengthen Reconstr 4: 67-75	Case series n=31 (mean 24 years; 65% [20/31] male)	On an average, 30 patients achieved 96.3% ± 23.2% of the preoperative target lengthening (3.5 cm; range 1.8 cm to 6.0 cm) over an average of 48.5±15.6 days. The average time to full weightbearing (permitted when the regenerate was consolidated on 3 sides) was 141.1±80.7 days. The knee joint, at consolidation, lost an average of 6.5° of flexion and 0.3° of extension. The ankle lost an average of 1.4° of dorsiflexion and 5.4° of plantar flexion. The hip joint lost, on average, 2° of flexion, and gained 1.6° of extension. There was 1 deep infection involving the implant, successfully treated with intravenous antibiotics and superficial debridement. Nearly 25.8% of patients had pain issues during lengthening, often over prominent hardware. In 1 patient, the nail failed to elongate during lengthening at home and had to be exchanged. One interlock screw broke. The internal components separated during implant extraction in the 1 patient had his nail exchanged by a trauma nail. Only 17 patients exited the protocol by	Aetiology included traumatic injury (n=12), congenital discrepancy (n=10), development cause (n=6), Ollier's disease (n=1), unknown (n=1) and not recorded (n=1).

		presenting to clinic for evaluation 2 years after consolidation. None experienced significant deterioration of outcome.	
Karakoyun O, Sokucu S, Erol MF et al. (2016) Use of a magnetic bone nail for lengthening of the femur and tibia. Journal of Orthopaedic Surgery 24(3): 374-378	Case series n=23 (mean 24 years; 35% [8/23] male)	At a mean follow up of 21 months, the mean lengthening was 48.2 mm, and the mean acute angular correction was 15.5 ^{0}. The mean time to full weight-bearing was 5.15 months, and the mean consolidation index was 1.12 months per cm. The mean maturation index was 0.78 months per cm. One patient had nail breakage during the consolidation phase. The nail was replaced by an intramedullary nail until consolidation, after which another PRECICE nail was used to treat the residual shortening. Eight patients had over-lengthening and the nails were driven back to the desired length. No patient had infection.	The reasons for lengthening included trauma (n=7), hemihypertrophy (n=2), focal femoral deficiency (n=2), Ellis-van Creveld syndrome (n=1), hip septic arthritis sequelae (n=1), hereditary multiple exostosis (n=1), club foot sequela (n=1), congenital tibial pseudoarthrosis (n=1), fibrous dysplasia (n=1), idiopathic limb length discrepancy (n=7), and cosmetic (n=1).
Kirane YM, Fragomen AT and Robert Rozbruch S (2014) Precision of the PRECICE internal bone lengthening nail. Clin Orthop Relat Res 472, 4	Case series n=24 (mean 31 years; 79% [19/24] male)	The magnet operated PRECICE nail is a valid option to achieve accurate and precise limb lengthening to treat a variety of conditions with limb shortening or length discrepancy.	Aetiology of bone deficiency included congenital/developmental (n=11), posttraumatic growth arrest (n=5), fracture malunion (n=4), short stature (n=2), post-arthrodesis (n=1) and post-tumour resection (n=1)
Panagiotopoulou VC, Davda K, Hothi HS et al. (2018) A retrieval analysis of the PRECICE intramedullary limb lengthening system. Bone Joint Res 7: 476-484	Case series n=13 (54% [7/13] male)	All patients obtained the desired length with no implant failure. Surface degradation was noted on the telescopic part of every nail design, less on the latest implants. Microscopical analysis confirmed fretting and pitting corrosion. Following sectioning, black debris was noted in all implants. The early designs were found to have fractured actuator pins and the pin and bearings showed evidence of corrosive debris. The latest designs showed evidence of biological deposits suggestive of fluid ingress	This was a retrieval analysis and examination of device degradation.

		within the nail but no corrosion.	
Rozbruch SR (2017) Adult posttraumatic reconstruction using a magnetic internal lengthening nail. J Orthop Trauma 31: S14-S19	Case series n=2 (mean 23.5 years; 100% male)	Distraction was completed on POD 39 for 1 patient and on POD 25 for another patient. Consolidation progressed and full weight bearing was allowed at 3 to 4 months. The tibial nail was removed 12 months after the initial surgery. The patient is fully functional and has normal ROM of the knee and the ankle or the hip.	There were 2 posttraumatic cases.
Tiefenboeck TM, Zak L, Bukaty A and Wozasek GE (2016) Pitfalls in automatic limb lengthening – First results with an intramedullary lengthening device. Orthopaedics & Traumatology: Surgery & Research 102: 851-855	Case series n=10 (mean 43 years; 50% [5/10] male)	In all patients, limb lengthening goals were reached within a range of ± 0.5 cm after a mean time of 53 days. However, in 2 patients, mechanical failures with unintended shortening were observed. In a further patient nail breakage occurred. Overall, 7 patients presented with complications during the follow-up period.	Aetiology included posttraumatic (n=7) and congenital deformity (n=3).
Wiebking U, Liodakis E, Kenawey M et al. (2016) Limb lengthening using the PRECICE nail system: complications and results. Arch Trauma Res 5(4): e36273	Case series n=9 (mean 32 years; 56% [5/9] male)	The mean distraction rate was 0.5±0.1 mm per day, and 7 patients did not achieve the lengthening goals (average, 1.6 mm; range, -20.0 mm to 5.0 mm). Average lengthening was 34.7±10.7 mm. All patients reached normal alignment and normal joint orientation. An unintentional loss of the achieved length during the consolidation phase was noticed in patients with delayed bone healing in 2 cases. In the first case (loss of 20 mm distraction) the nail could be redistracted and the goal length was achieved. In the second case (loss of 10 mm distraction) the nail broke shortly after the diagnosis and the nail was exchanged.	Aetiology included posttraumatic (n=5) and congenital deformity (n=4).