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Original article

Pitfalls in automatic limb lengthening – First results with an intramedullary lengthening device

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Abstract

Background

The treatment of leg length discrepancy and deformities has become more common over the last few decades due to newly developed implants. Lengthening using fully implantable intramedullary nails provides many advantages; however, only little data is available. Therefore, we aimed to determine: (1) safety of the implant, (2) the complication rate and (3) functional outcome after magnetic driven intramedullary bone lengthening with a telescopic implant.

Hypotheses

Automatic bone lengthening with intramedullary nails provide good short-term outcome.

Patients and methods

Ten patients with limb length discrepancy of lower extremity, treated with an Ellipse PRECICE® nail, were included in this retrospective follow-up study. The mean limb length discrepancy was 4.7 cm (range: 2.5–7.0 cm).

Results

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.

Discussion

The PRECICE® nail represents a new, fully implantable, magnetically driven device for limb lengthening. However, due to a high rate of complications, a

close follow-up is necessary to identify early implant failures and to avoid severe adverse outcomes.

Level of evidence

Retrospective follow-up study, case series, level IV.

- **Previous** article in issue
- **Next** article in issue

Keywords

Leg length discrepancy

Intramedullary lengthening

Magnetically actuated

Complications

Preliminary results

1. Introduction

Limb length discrepancy is caused by either congenital or acquired conditions, growth arrest, osteomyelitis, trauma or tumor. The treatment of length discrepancy and deformities has become more common over the last few decades due to newly developed implants. Since the days of Ilizarov [1], osteogenesis has become far better understood, and has subsequently been brought into clinical use. Although external systems (e.g., ring fixation, monolateral and hybrid fixations) have been constantly improved over the years [2], problems concerning soft-tissue transfixation, pin track infections, joint stiffness, pain, poor cosmetic results, patient's frame fatigue e.g. are still frequently seen [3].

Lengthening with fully implantable intramedullary nails provides many advantages, compared to lengthening with external devices [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12]. However, it still remains an infrequent procedure [8].

In contrast to modern external fixation systems, intramedullary lengthening devices allow no postoperative axis correction. Distraction control and implant stability in general remain problematic and have to be solved once such a device has been implanted.

Over the last few years, several different fully implantable devices have been presented [6], [9], [10], [13], [14], [15], [16], [17], [18], [19]. Earlier designs of internal lengthening devices, however, lacked a reliable mechanism for distraction monitoring and control [10], [11], [20], [21]. Several authors reported inconsistent distraction, leading to nonunions, nerve injuries, nail fractures, joint contractures and other serious complications [4], [5], [6], [10], [13], [22], [23], [24], [25], [26].

Therefore, the aim of our study was to evaluate outcome after magnetic driven intramedullary bone lengthening with regard to:

- safety;
- complication rate;
- postoperative function.

2. Material and methods

2.1. Patients

Since 2013, 10 magnetically actuated nails (PRECICE®) have been implanted at our Department because of leg length discrepancy.

All patient information, including disease and treatment-related data, was collected by a retrospective review of patients' charts. Prior to this investigation, the study was approved by the corresponding institutional Review Board (EK No.: 1997/2014) and all patients gave written, informed consent.

The patient group consisted of 5 male and 5 female patients, with a mean age of 42 years (range: 12.3–74.1 years) suffering from a mean limb length discrepancy of 4.7 cm (range: 2.5–7.0 cm) (Table 1). All but 3 patients had undergone several previous surgical procedures (range: 2–8) at other hospitals. One patient had been treated conservatively for a tibial fracture. PRECICE® nails were used in 5 patients for tibial, and in 5 patients for femoral lengthening. The mean follow-up time was 18 months (range: 12–23 months; median: 19 months).

Table 1. Patient characteristics.

Case	Sex	Age in years	Cause of LLD	LLD in cm	Location	Angular deformity	Rotational deformity	Previous surgery	Complications	Healed
1	Male	35	Posttraumatic	3	Tibia	Valgus 15°	No	Yes	Yes	No
2	Male	60	Posttraumatic	3.5	Tibia	No	10° malrotation	No/conservative	Yes	1.3
3	Male	25	Posttraumatic	4	Femur	Varus 10°	26° malrotation	Yes	Yes/multiple	No
4	Female	49	Posttraumatic	2.5	Femur	Valgus 8°	16° internal rotation malalignment	Yes	Yes/multiple	No
5	Female	12	Congenital deformity	7	Tibia	Valgus 16°	Rotational malalignment	No	Yes/multiple	0.8
6	Female	49	Posttraumatic	3.5	Tibia	No	No	Yes	No	1.3
7	Male	74	Congenital deformity	6	Tibia	Valgus 10°	No	No	Yes/multiple	1.4
8	Female	28	Congenital deformity	5	Femur	Varus 7°	No	No	Yes	No
9	Male	47	Posttraumatic	6.5	Tibia	No	Rotational malalignment	Yes	No	1.7
10	Female	53	Posttraumatic	5.5	FEMUR	Varus 5°	No	Yes	No	1.5

LLD: leg length discrepancy.

The initial assessment was comprised of a clinical examination, X-rays depicting the involved long bone in 2 planes, a long standing view of both legs for preoperative planning and, when necessary, a computed tomography (CT) scan to evaluate the deformity and axis deviation.

Preoperative planning as well as the surgical procedure was carried out in all patients by the senior author.

2.2. Surgical method

In all patients, a single-level osteotomy was preoperatively planned at the centre of rotation and angulation (CORA) of any associated deformity, to permit acute correction during surgery.

The selected nail size depended upon planned lengthening and osteotomy height. Hereby, the thinner nail segment should be at least 4 cm within the distracting bone segment to maintain stability.

The nail entry point was located either at:

- the greater trochanter for an antegrade femoral nail;
- the intercondylar notch for a retrograde femoral nail;
- at the anterior edge of the tibial plateau for a tibial nail.

Additionally, in three patients, the reamer–irrigator–aspirator (RIA) system (DePuy Synthes) was used to retrieve bone graft. Routinely bone graft was collected and placed at the osteotomy side in all of our cases (either from the iliac crest or during reaming) to improve callus maturation. Reaming was performed 2 mm greater than the selected nail diameter to enable nail insertion without greater forces. The nail was implanted and the tip was placed near the planned osteotomy level. Then, the bone was cut either with a Gigli saw or a drill. Rotation, angulation and deformity were acutely corrected under fluoroscopic control. After implanting and interlocking, the magnet was pinpointed under fluoroscopy and its position marked on the skin to facilitate intraoperative testing (distance 1 mm) of the lengthening mechanism of the nail. Blocking screws were used in special cases but not routinely.

2.3. Postoperative procedure

Lengthening started at day 5–0.5 mm in the morning, and 0.5 mm in the afternoon and was controlled by X-ray. Patients were instructed to an initial postoperative period of non-weight bearing, and then to partial weight bearing (15–20 kg) at the end of the lengthening procedure. As soon as callus formation was seen radiologically (i.e., three cortices had healed), full weight bearing was allowed. Implant removal is not routinely required; however earliest performed after complete bony healing, which is usually seen after 1 to 2 years.

2.4. Methods of assessment

The outpatient care follow-up protocol included clinical examination and radiological follow-up imaging on a weekly basis during lengthening. Once the patient achieved limb equality, subsequent follow-up visits were scheduled at 2–3 week intervals according to the new callus formation.

Additionally, quality of life was assessed at final follow-up with the Short-Form 36 (SF36), which consists of 8 subgroups; each subgroup is scored on a points scale ranging from 0 (worst outcome) to 100 (best outcome) [27].

2.5. Statistical analysis

Descriptive data (mean, median, range, \pm SD) were reported for the entire patient cohort. Statistical analysis focused on surgical, radiological and functional outcomes. Therapeutic variables (surgery and function), pathological variables (complications) and demographic variables (sex, age and follow-up) were examined. All calculations were made using Microsoft Excel®, SPSS® software (Version 22.0, SPSS Inc., Chicago, IL, USA) and GraphPad Prism® software (Version 4.00, 2003, GraphPad Software Inc., La Jolla, CA, USA).

3. Results

We achieved limb lengthening goals in all patients within SD of \pm 0.37 cm of the preoperatively calculated length inequality, as evaluated by long leg X-

rays. The average lengthening was 42 mm (47 mm \pm 15 mm in femoral lengthening and 42 mm \pm 13 mm in tibial lengthening). The average duration of distraction was 53 days (range: 40–75 days) (57 days \pm 13 days in femoral lengthening and 50 days \pm 13 days in tibial lengthening). The average healing index was 1.4 \pm 0.75.

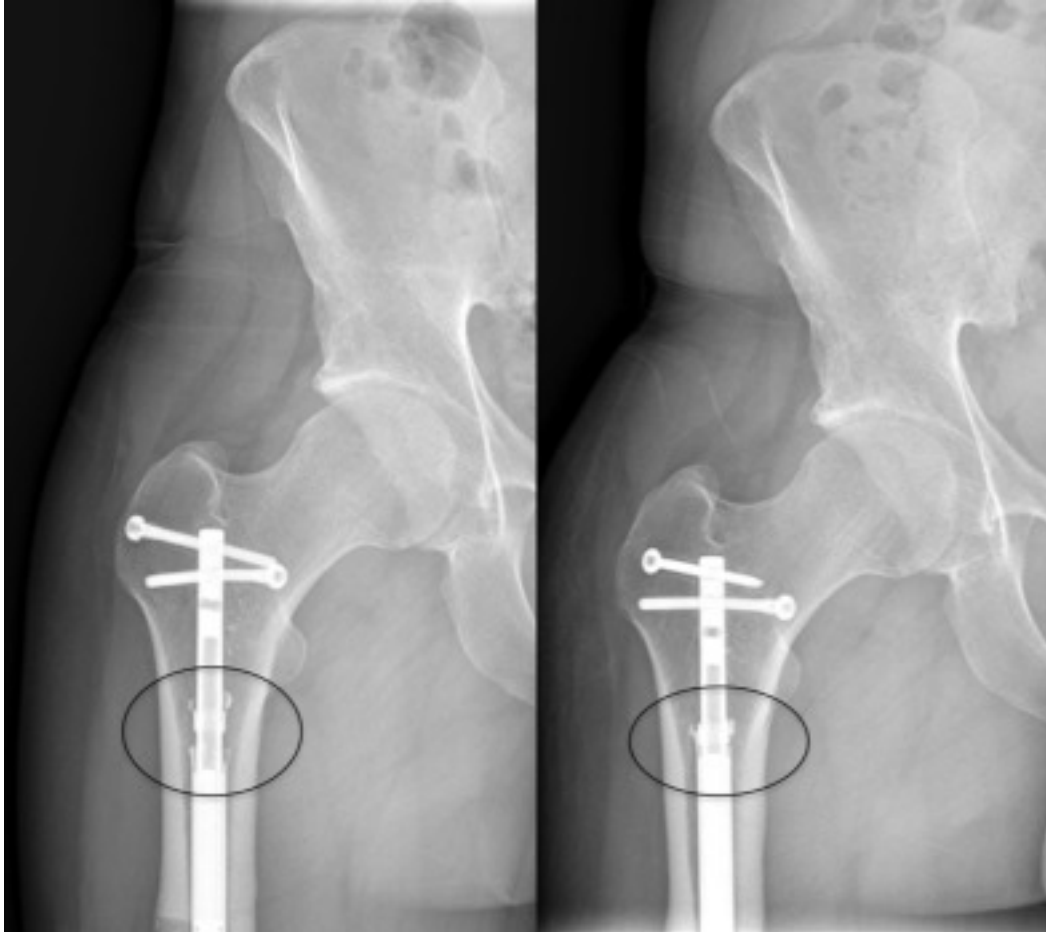
In one patient, the distraction had to be stopped for 1 week due to persisting pain in the ankle joint, however, lengthening was continued without any further complications.

In one patient worse outcome in SF36 subscales was seen ([Table 2](#)). This patient suffered from a car accident with severe concomitant injuries and complained about persisting pain after backwinding and bolt loosening ([Fig. 1](#), [Fig. 2](#)), finally resulting in a nonunion. He was then successfully treated with an exchange interlocking nail.

Table 2. SF36 scoring at latest follow-up.

Case	pfi	rolph	rolem	Social	mhi	Pain	Vital	ghp
1	90	100	100	100	96	72	85	100
2	100	100	100	100	100	72	90	95
3	80	75	25	50	60	41	45	52
4	85	80	100	100	96	72	90	95
5	75	100	100	100	96	72	95	87
6	85	100	100	100	100	100	100	100
7	75	100	100	100	100	61	100	100
8	85	100	100	100	100	100	100	100
9	75	100	100	100	100	61	100	100
10	80	100	100	100	96	100	90	100

ghp: general health perceptions index; mhi: mental health index; pain: bodily pain index; pfi: physical function index; rolem: role-emotional index; rolph: role physical index; social: social functioning index; vital: vitality index.



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Fig. 1. A/P radiograph (5 months postoperatively) of the area of interest marked with a circle showing breakage of the lengthening mechanism. A/P radiograph (8 months postoperatively) of the area of interest marked with a circle after breakage and shortening of 1 cm.



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Fig. 2. X-ray showing loosening of the distal interlocking bolts and nonunion one year after PRECICE® implantation in the same patient.

In 7 patients, complications occurred during the follow-up period, 3 in patients with femoral lengthening and in 4 patients with tibial lengthening. In 4 of them, various non-implant-related complications were seen, whereas in 3 cases nail-related ones appeared, however, only in femoral nails. Two were due to mechanical failure of the telescopic nail resulting in unintended shortening of the lengthened bone, and in one case a late nail breakage occurred. Details of complications regarding the classification by Paley [28] are listed in [Table 3](#). Overall, 4 nonunions occurred during the follow-up period, 3 after femoral lengthening and 1 after tibial lengthening, which were all treated by nail exchange and local bone grafting (in two patients bone biologics were used additionally). All patients were subjectively satisfied at their last follow-up. The postoperative range of motion (ROM) of

the knee joint was comparable to preoperative ROM and did not change significantly. In one patient, ROM even improved due to deformity correction and arthrolysis of the knee joint. No cases of superficial or deep infection – were seen.

Table 3. Overview of complications.

Type	Complications	Number	Details
1	Local	2	Soft-tissue irritation (bolt)
			Soft-tissue irritation (bolt)
	Systemic	–	
2	Intraoperative		
	Early	1	Compartment syndrome
	Late	–	
3	During distraction	3	Backwinding
			Claw toe
			Temporary impairment of preexisting pes equinus
4	During fixation	6	Nonunion
			Nonunion
			Nonunion
			Nonunion
			Backwinding
			Nail breakage

4. Discussion

Our results show that the PRECICE® nail, to correct limb length discrepancy and deformity, is accurate and effective. However, high rates of postoperative complications were seen in seven out of 10 of our patients ([Table 3](#)).

Nevertheless, limb lengthening goals and satisfaction were achieved in all patients. Our high rate of complications might be caused by the fact that in seven out of 10 patients multiple surgeries had been performed prior to telescopic nail implantation. Additionally there was dispersion in age of our patients, different aetiology and multiple angular deformity corrections, which might also influence the results.

We acknowledge several limitations to our study. It is a small case series and therefore only limited conclusion can be drawn. However, this case series presents potential pit falls in automatic limb lengthening. It covers the most important features of fully implantable lengthening devices as described by Thaller et al. [15]. Moreover, further prospective studies with larger patient numbers will be necessary to generate more conclusive data.

Overall, in literature, the PRECICE® nail for intramedullary limb lengthening presents a safe procedure [29], [30], [31], however, implant-related complications have to be considered. Due to developments regarding the implant, weak points like the welding seam had changed in the second generation of nails and improved the stability and safety of the implant. Surgery itself, is a standard nailing procedure. However, during the postoperative period a number of complications appeared. These have been described previously in the literature, like insufficient bone regeneration, nonunions and even nail breakage, leading to a postoperative complication rate of 4 to 50% [4], [13], [15], [29], [31], [32], [33]. Accadbled et al. for example presented in a recent series of 2016 a rate of 15.3% of postoperative complications after bone lengthening with the ISKD, leading to the assumption that also the newest implants present with a considerable rate of complications [33]. However, in our study 70% of the patients presented with complications, which is clearly in contrast to literature (Table 4).

Table 4. Literature review of complications related to telescopic nails.

Used device	Author	Number of patients	Implant-related complications
ISKD	Cole et al. (2001) [11]	18	11%
	Simpson and Kenwright (2009) [25]	33	30%
	Schiedel et al. (2011) [24]	69	47%
	Kenawey et al. (2011) [13]	53	33%
	Mahoubian et al. (2012) [22]	11	50%
	Accadbled et al. (2016) [33]	23	15.4%
Albizzia/Guichet	Garcia-Cimbrelo et al. (2002) [18]	23	20.8%
	Guichet et al. (2003) [10]	31	29%
Fitbone	Krieg et al. (2008) [16]	32	12.5%
	Dincyurek et al. (2011) [17]	14	13.3%

Used device	Author	Number of patients	Implant-related complications
Phenix	Thaller et al. (2013) [15]	10	–
	Konofaos et al. (2012) [19]	5	n.a.
PRECICE®	Kriane et al. (2014) [29]	24	4%
	Schiedel et al. (2014) [31]	24	17%

ISKD: intramedullary skeletal kinetic distractor; n.a.: not available.

In two of our cases the lengthening mechanism failed, one in an obese patient performing extensive physiotherapy and one for unknown reasons. Nail breakage has been reported infrequently in literature [\[15\]](#) and mostly after adequate trauma [\[31\]](#). One late fatigue tibial nail breakage (15 months after nailing), was seen at the welding seam in our series [\[32\]](#). The broken implant was removed, lengthening was regained, bone grafted and stabilized with an interlocking nail.

Summarizing, limb lengthening was achieved within a SD of ± 0.37 cm in all of our patients with finally good functional outcome. These results are well in line with previous reported series in literature [\[29\]](#), [\[30\]](#), [\[31\]](#). In one patient, a worse outcome in the SF 36 score was reported, however, not influencing final functional outcome.

5. Conclusion

We found a higher complication rate compared to other studies, which might be explained by previous surgeries in our posttraumatic cases, the age dispersion, or even the different aetiology in our cases. However, further developments (such as revision of the interlocking bolts, end caps in various lengths and improvements in the lengthening mechanism) will be necessary to improve the implant.

Author contribution

According to the definition given by the International Committee of Medical Journal Editors (ICMJE), the authors listed above qualify for authorship

based on making one or more of the substantial contributions to the intellectual content of:

- conception and design [TT, GW]; and/or;
- analysis and interpretation of data [TT, LZ, AB, GW]; and/or;
- participated in drafting of the manuscript [TT, LZ, AB, GW]; and/or;
- critical revision of the manuscript for important intellectual content [TT, LZ, AB, GW].

Disclosure of interest

The authors declare that they have no competing interest.

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