ORIGINAL ARTICLE

Complications in Elective Removal of 271 Bone Lengthening Nails (FITBONE, PRECICE and STRYDE)

Markus W Frost[1], Søren Kold[2], Ole Rahbek[3], Anirejuoritse Bafor[4], Molly Duncan[5], Christopher A Iobst[6]

Abstract

Background: Intramedullary lengthening nails have shown excellent short-term results. The FITBONE and the PRECICE nail are the two most commonly used intramedullary lengthening nails. The manufacturer of each nail recommends the removal of the implant after the completion of the treatment. Despite the need for removal of each nail, the authors are not aware of any prior publications documenting the results of standard intramedullary lengthening nail removal. Therefore, the aim of this study was to examine the intraoperative and postoperative complications of elective intramedullary lengthening nail removals.

Materials and methods: We performed a retrospective chart review of patients operated with intramedullary lengthening nails at two limb reconstruction centres (one in the United States, and the second in Denmark). Data retrieved from the patient charts included patient demographics, nail information and any complications occurring at or after nail removal. Only lower limb lengthening with FITBONE and PRECICE or STRYDE nails that had an elective nail removal was included.

Result: A total of 271 elective nail removals were included in the study. Complications occurred during 3% of the nail removals and in 13% after nail removal. There were 18 reported cases with postoperative knee pain. All these patients had nail removal through the knee joint, representing 8% of the retrograde femur nail removals and 7% of the tibia nail removals. Four postoperative fractures occurred, of which two needed surgery. Eleven percent of femur removals and 26% of tibial removals sustained a complication.

Conclusion and clinical significance: This study emphasises the importance of adequate follow-up of the bone lengthening patient even after the nail has been removed. It also shows that the recommended removal of the intramedullary nail (IMN) lengthening nails must be included in studies reporting on the overall risks of complications using bone lengthening nails.

Keywords: Bone lengthening, Bone lengthening nails, Bone nails, FITBONE, Intraoperative complications, Postoperative complications, PRECICE, STRYDE.

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Introduction

An external fixator is a well-established treatment for lower limb lengthening by distraction osteogenesis.[1–3] Due to high complication rates and patient discomfort with external fixators, externally controlled motorised (FITBONE) or magnetically driven (PRECICE or STRYDE) intramedullary lengthening nails have been introduced.[4–7] Previously published large case series on intramedullary bone lengthening have shown excellent short-term results for both the FITBONE.[8] and the PRECICE nails.[9] However, a recent systematic review demonstrated that complication rates are still high in limb lengthening even with externally controlled lengthening nails.[10] Furthermore, it is recommended to remove both the FITBONE[11] and the PRECICE or STRYDE[12–14] nails after treatment. It is known that complications, such as fracture or malalignment, can occur after the removal of an external fixator,[15,16] but so far no studies have examined the risk of complications after removal of externally controlled intramedullary lengthening nails. Therefore, the purpose of this study is to examine the intraoperative and postoperative complications of elective removals of the FITBONE and the PRECICE or STRYDE lengthening nails from two different centres.

Materials and Methods

This study was performed as retrospective case series from two centres, one in the Midwestern United States and the other in Denmark. Institutional approval was obtained at each institution. Patients were included if they had a PRECICE®, PRECICE STRYDE® (Nuvasive, San Diego, California, United States) or FITBONE® (Wittenstein Intens, Igersheim, Germany) bone lengthening nail removed from the lower limb as elective surgery. Patients were excluded if the bone lengthening nail was removed acutely or subacutely due to unexpected incidents (e.g. infection, peri-implant bone fracture, malfunction of the nail) leading to an urgent need

[1–3]Department of Orthopedic Surgery, Aalborg University Hospital, Aalborg, Denmark; Department of Clinical Medicine, Faculty of Medicine, Aalborg University, Aalborg, Denmark

[4–6]Department of Orthopedic Surgery, Center for Limb Lengthening and Reconstruction, Nationwide Children's Hospital, Columbus, Ohio, United States of America

Corresponding Author: Christopher A Iobst, Department of Orthopedic Surgery, Center for Limb Lengthening and Reconstruction, Nationwide Children's Hospital, Columbus, Ohio, United States of America, Phone: +(614) 722-5175, e-mail: Christopher.Iobst@nationwidechildrens.org

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for nail removal. Bone transport nails, stump lengthening nails and nail removals after humeral lengthening were excluded. Nail removals were performed between 2017 and 2020 at the U.S. institution, and between 2006 and 2020 in Denmark. Patient charts were reviewed to identify patient demographics (Table 1). Aetiology was classified as congenital, developmental, posttraumatic or short stature. Short stature represented cases where the indication for bone lengthening was to increase the height. Since short-stature leg length discrepancy (LLD) was zero, it was not included in the LLD mean calculation. Patients with multiple nail removals represented patients with either sequential bone lengthening of the same segment or bone lengthening of multiple segments. Nail removals were categorised as shown in Table 2 regarding: (a) site (femur/tibia), (b) nail approach (antegrade/retrograde), (c) nail type (FITBONE, PRECICE and STRYDE) and (d) other interventions at nail removal. Follow-up time was defined at the time from nail removal to last follow-up in the patient chart. Complications were defined as an unexpected deviation from the treatment plan and were categorised either to occur intraoperatively during the nail removal procedure or to occur postoperatively after nail removal. Postoperative knee pain was reported as a binary and subjective event if the journal chart reported patient complaints of anterior knee pain such as anterior knee pain when laying on the knee, anterior knee pain when stair climbing or any other anterior knee pain.

Statistics and Data Management

Study data were collected and managed using two separate, but identical REDCap electronic data capture tools hosted at both sites. Microsoft Excel 2019 version 16.45 (Microsoft Corp, Redmond, Washington, United States) was used for anonymised data fusion and descriptive analysis. Demographic data were described with the absolute number, percentage or means with minimum to maximum range.

Results

Forty-two elective nail removals were performed at the U.S. site, and 229 elective nail removals were performed at the Denmark

Table 1: Demographics

Site		*Total*		*Denmark site*		*U.S. site*	
Number of patients		225		184		41	
Number of patients with multiple nail removals		30	13%	29	13%	1	2%
Sex	Female	100	44%	78	42%	22	54%
	Male	125	56%	106	58%	19	46%
Age (years), mean (min–max)		26	(10–79)	28	(14–79)	17	(10–34)
Limb length discrepancy (cm), mean (min–max)		3.6	(1–14)	3.4	(1–14)	4.4	(2–13)
LLD aetiology	Congenital	101	45%	81	44%	20	49%
	Posttraumatic	75	33%	67	36%	8	20%
	Developmental	28	12%	16	9%	12	29%
	Short stature	21	9%	20	11%	1	2%
Time from nail insertion to nail removal: Mean (min–max) days		536	(121–2,372)	570	(133–2,372)	348	(121–553)
Length of follow-up, mean (min–max) days		282	(0–2,882)	314	(0–2,882)	107	(0–831)

Table 2: Combined data and data split up on the two participating centres

Removal classifications		*Total*		*Denmark site*		*U.S. site*	
Nail removals performed		271		229		42	
Nail removal site	Femur	225	83%	183	80%	42	100%
	Tibia	46	17%	46	20%	0	0%
Nail type	FITBONE	194	72%	194	85%	0	0%
	PRECICE	70	26%	35	15%	35	83%
	STRYDE	7	3%	0	0%	7	17%
Nail approach	Antegrade femur	42	15%	16	7%	26	62%
	Retrograde femur	183	68%	167	73%	16	38%
	Antegrade tibia	42	15%	42	18%	0	0%
	Suprapatellar. tibia	4	1%	4	2%	0	0%
Nail removal without or with other surgery	Only nail removal	250	92%	213	93%	37	88%
	Exchange to lengthening nail	6	2%	6	3%	0	0%
	Exchange to trauma nail	8	3%	3	1%	5	12%
	Deformity correction	3	1%	3	1%	0	0%
	Soft tissue correction	4	1%	4	2%	0	0%
Length of stay (days), mean (min–max)		1	(0–7)	1	(0–7)	0	(0–0)
Length of stay if other surgery was performed, mean (min–max)		46	(0–25)	4	(0–25)	0	(0–0)

Percentage is calculated in relation to the number of nail removals

site. Thus, a total of 271 elective nail removals were included in the study. At the U.S. site, no subacute or acute nail removals were performed, and thus, the 42 nail removal represent all lower limb nail removals at the U.S. site in the study period. In Denmark, a total of 267 lower limb nail removals were performed with 38 of the nail removals being subacute or acute, and thus, the 229 nail elective removals represent 86% of lower limb nail removals in Denmark in the study period. Indications for the 38 subacute and acute nail removals were: (a) failure of distraction in 2 cases; (b) stability-related problems in 14 cases; (c) infection in 4 cases; (d) broken FITBONE chord in knee joint in 2 cases; (e) delayed/nonunion of regenerate in 11 cases; and (f) peri-implant bone fracture in 5 cases. The 271 elective nail removals included in the study were performed in 225 patients. Seventy-six nail removals were performed in 30 patients who had more than one nail removal (2–5 removals). The mean (min–max range) follow-up time after nail removal was 282 days (0–2882 days). Demographics data from our chart review are summarised in Table 1. The lower bound of LLD for inserting a lengthening nail was 1 cm. In this case, the patient had premature growth arrest of the distal femur after physeal fracture leading to shortening and deformity of the distal femur. Deformity correction and lengthening were performed at the same time through the same distal osteotomy, and as the patient was still growing, the limb was lengthened more than 1cm to allow for equal limb lengths at bone maturity.

The majority of the nails (72%) were FITBONE nails with femur as the predominant removal site in 83% of the cases. All FITBONE and tibial nails were removed at the Denmark site. The seven included STRYDE nails were removed at the U.S. site and had no complications. PRECICE removals represented 28% of removals and were performed at both sites. Table 2 presents both combined data and data for each centre. For the combined data, removal of a retrograde femur nail was the most frequent (68%) followed by the antegrade femur and antegrade tibia with a proportion of 15% each. In 7% of the nail removals, additional surgery was performed (exchange to lengthening nail, exchange to trauma nail, deformity correction, soft tissue correction), meaning that 93% had isolated elective lengthening nail removal. At Nationwide Children's Hospital (NCH), 12% of the nails were replaced by a trauma nail to protect the bone regenerate after nail removal in a total of five patients. Preoperative assessments leading to replacement with trauma nail were: Fibrous dysplasia in one patient, previous sarcoma in one patient, previous radiation due to lymphoma in one patient and previous infection in one patient (changed to antibiotic-coated trauma nail). In one patient, it was judged intraoperatively that the regenerate needed to be secured by a trauma nail.

All complications are listed in Table 3. Intraoperative complications at nail removal were found in 3% of cases. In three cases, problems with hardware removal were identified, and in five cases, the hardware could not be removed. The two FITBONE cord removal problems were assessed to be the only nail type-specific complications. Two intra-articular complications occurred during the removal of retrograde femoral nails through the knee joint. In one case, an intra-articular lesion occurred as the nail was extracted without prior preparation of an extraction canal (Fig. 1). In the other case, the cord from the FITBONE broke during the removal, and a small part of the cord was left *in situ* in the knee joint (Fig. 2). Both patients were asymptomatic at the latest follow-up (106 and 421 days, respectively).

The mean (range) follow-up after nail removal was 282 (0–2882) days. Thirteen percent had complications after nail removal with a wide span in complication types (Table 3). Knee joint problems were the most common patient-reported complaint with 20 cases. There were 18 reported cases with postoperative knee pain. All these patients had nail removal through the knee joint, representing 8% of the retrograde femur nail removals and 7% of the tibia nail removals. Four postoperative fractures occurred, of which two needed surgery (Fig. 3). Two of the four cases with hematoma/wound leaking were associated with the receiver removal specific for the FITBONE nail.

Table 4 presents the number of complications for specific factors that might influence the risk of complications. It shows that 11% of femur removals and 26% of tibial removals sustained a complication.

Discussion

We found that in elective removal of bone lengthening nails, complications occurred intraoperatively during 3% of the nail removals and in 13% after nail removal. This finding suggests

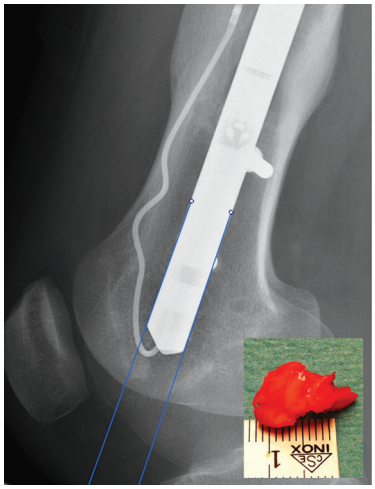

Fig. 1: Sagittal radiograph of the distal femur with marked (blue lines) nail extraction canal. Since the nail extraction canal had not been correctly enlarged with a reamer prior to extraction, an intra-articular lesion (picture lower right corner) occurred during nail extraction

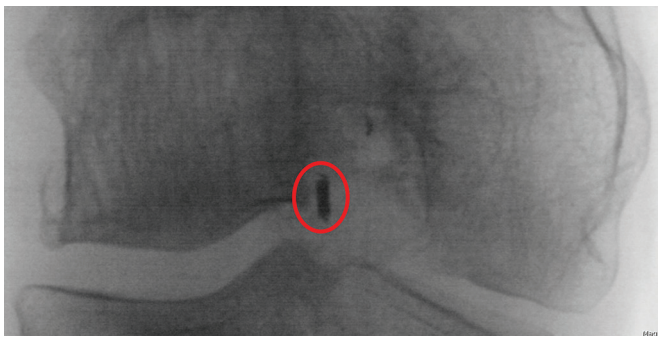

Fig. 2: Radiograph of the distal femur. A small part of the FITBONE chord (red circle) broke off during nail removal and was left *in situ* in the knee joint

Table 3: Description and distribution of complications

Complications during nail removal	*8 (3%)*		
Types of complications: Hardware left behind	5	1	A small intraosseous metal part was seen on X-ray in trochanter major. Could not be palpated and was left *in situ*.
		1	Intra-articular broken FITBONE chord at nail removal; small chord left in recess
		1	It was not possible to grab the nail with the removal guide. The nail was removed at a later operation.
		1	Part of the FITBONE chord was left behind.
		1	Broken screw in proximal tibia and the fibula was left in the patient who had no symptoms.
Types of complications: Hardware removal problem	3	1	Intra-articular lesion of femoral notch at nail removal. Asymptomatic at follow up.
		1	A broken screw was removed with core drill.
		1	The tip of the nail was fractured (about 15 mm long). Over reaming was needed to remove the tip.
Complication after nail removal	36 (13%)		
Complication type: Bone	5	2	Fracture of the bone. Conservatively treated.
		2	Fracture of the bone. Treated with trauma nail
		1	Tibia pain with periosteal reaction after removal of a PRECICE nail. MR-scanning was without malignant suspicion.
Complication type: Joint problem	20	18	Knee pain
		1	Pain and sensation of knee instability. Missing cruciate ligament. Was resolved with physiotherapy
		1	Retro-patellar rubbing in the knee. No pain. Full range of knee movement
Complication type: Hematoma/ wound leaking	4	1	Seroma proximal medial thigh which needed interventional radiology drainage
		2	Hematoma after receiver was removed
		1	Bleeding and leaking from the incision were reported and assessed to be from antibiotic injected into the bone
Complication type: Neurological problem	1	1	Chronic neurogenic pain. Buzzing sensation laterally on crus going laterally on foot.
Complication type: Infection	3	2	Delayed skin healing over screw hole. Assessed to be superficial infection: 1 nonsurgically and 1 surgically treated
		1	Osteomyelitis after trauma nail inserted.
Complication type: Soft tissue	2	1	Muscle hernia at the site of removed FITBONE receiver
		1	Pain at running at the previous location of the FITBONE receiver
Complication type: Device related	1	1	Soft tissue irritation after removal of trauma nail screws

Table 4: Complications distributed on possible specific risk factors

Classification of removal		*Removals (N)*	*Complications (n)*	*Complications (n/N × 100)*
Overall complications related to nail type	FITBONE	194	30	15%
	PRECICE	70	6	9%
	STRYDE	7	0	0%
Overall complications related to segment	Tibia	46	12	26%
	Femur	225	24	11%
Overall complications related to approach	Antegrade femur	42	3	7%
	Retrograde femur	183	21	11%
Overall complications related to aetiology (per nail removals)	Congenital	105	13	13%
	Posttraumatic	78	12	15%
	Developmental	31	1	3%
	Short stature	56	10	18%
Complications occurring during nail removal	FITBONE	194	8	4%
	PRECICE	70	0	0%
	STRYDE	7	0	0%

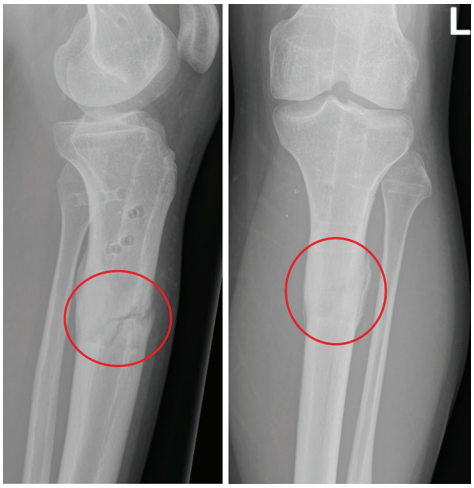

Fig. 3: Tibial fracture through the regenerate after nail removal

that the recommended removal of the intramedullary nail (IMN) lengthening nails[11–13] must be included in studies reporting on the overall risks of complications using bone lengthening nails. Our results highlight the fact that as more information becomes available on new techniques, more knowledge is also gained about the true risk profile.[17] So far, no studies have reported on the complications of removals of bone lengthening nails. In a recent systematic review of studies reporting on complications with the FITBONE and PRECICE nails, a total of 332 complications could be identified from 983 lengthened segments.[10] In only half of the complications, it was possible to establish the timing of the complication, and no complications were reported to occur during nail removal.[10] In contrast, it is known that removal of trauma nails might result in complications.[18,19] In 5% of tibial trauma nail removals, a complication occurred with the majority of complications (4%) being iatrogenic fractures leading to the development of a checklist for removal of IMNs.[18] We found no iatrogenic fractures during the removal of 271 bone lengthening nails. However, we had two postoperative fractures needing additional surgery and two postoperative fractures that were treated conservatively. Other complications were an iatrogenic intra-articular lesion during nail removal and the failure to remove part of a broken intra-articular cord from the knee joint. Postoperative knee pain was found in 8% of the retrograde femur nail removals and 7% of the tibia nail removals. Whether the knee pain arises from nail insertion or nail removal or other reasons, such as a previous knee trauma, cannot be established. However, the occurrence of postoperative knee pain is likely to be underreported considering the methodical limitation of this retrospective review of journal charts, where only reported events can be assessed. In comparison, Zhang et al. showed that knee pain after removal of tibial trauma nails occurred in 15% of preoperative asymptomatic patients[19] indicating that pain could be under-reported in our study. In the removal of tibial trauma nails, higher operation time and higher blood loss have been found with titanium nails as compared with stainless steel nails, but no differences were found regarding postoperative complications or postoperative functional outcome.[20] In our study, the FITBONE nail is made of stainless steel[11,21] sustained an intraoperative complication in 4% of removals compared with no intraoperative complications during removal of the PRECICE nail made of titanium alloy.[21] This difference might be due to both a learning curve for the removal of nails and the FITBONE design. The FITBONE nails were predominantly used at the beginning of the study period when the learning curve was steepest. In addition, the FITBONE nail has a cord and receiver that also must be removed, which adds extra opportunities for potential complications compared to the PRECICE nail. Four postoperative complications were specific for the soft-tissue pouch made for the FITBONE receiver with two cases of hematoma/wound leakage, one case of muscle hernia at the site of removed FITBONE receiver, and one patient with pain at the previous location of the FITBONE receiver. For the seven included STRYDE nails made of stainless steel, no complications were seen related to the removal or after removal.

At both centres, it is routine to remove the nails as recommended by the manufacturer. However, the timing of the elective removal is to a large extent up to the patient wishes. This is reflected in the large variation in time (121–2372 days) from nail insertion to nail removal. In Denmark, the treatment is fully covered, including nail removal, and all patients at both centres have consented for nail removal. Thus, no patients have finished treatment at either NCH or Aalborg University Hospital (AAUH) without having the lengthening nail removed.

We chose to focus on elective nail removals in order to investigate the complications arising from the nail removal procedure and the postoperative risk after nail removal. By excluding the subacute and acute nail removals, we avoided mixing of our results with complications occurring immediately prior to nail removals, such as infection, peri-implant fracture or joint subluxation. An interesting finding is that one of the centres (the U.S. site) could manage to remove all the nails as elective cases, whereas the other centre (in Demark) had to remove 15% of the nails acutely or subacutely. Another difference between the two centres was that at the U.S. site all nail removals were performed as outpatient surgery, whereas at the Denmark site, the majority (80%) of patients were staying one or more nights in the hospital after nail removal. At the U.S. site, the same surgeon removed all the nails, and 12% of the nails were replaced by a trauma nail. At the Denmark site, multiple surgeons removed the nails with 1% of the nails being replaced by a trauma nail. Only at the Denmark site, FITBONE nails and tibial nails were removed. Thus, the comparison between the different groups should be made with caution; however, it is of interest that the complication rate was higher for tibial nail removals compared with femoral removals. The postoperative length of our study was a mean of 282 days, but patients with no follow-up after discharge were included. This might lead to underreporting of complications after nail removal. Furthermore, the retrospective design might lead to underreporting or the lack of accurate reporting of complications in elective surgery.[22]

Conclusion and Clinical Significance

In elective removal of bone lengthening nails, complications occurred during 3% of the nail removals and in 13% after nail removal. This study emphasises the importance of adequate follow-up of the bone lengthening patient even after the nail has been removed. The findings also suggest that future studies documenting the overall risks of complications using bone lengthening nails should incorporate the nail removal procedure as part of the analysis.

Acknowledgements

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Manufacturer Name: Nail name: PRECICE®, Nuvasive, 7475 Lusk Blvd, San Diego, California, United States. Nail name: PRECICE STRYDE®, Nuvasive, 7475 Lusk Blvd., San Diego, California 92121, United States. Nail name: FITBONE®, WITTENSTEIN intens GmbH, Walter-Wittenstein-Strasse 1, 97999 Igersheim, Germany.

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