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Complications and risk factors of intramedullary bone lengthening nails: a retrospective multicenter cohort study of 314 FITBONE and PRECICE nails

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Background and purpose — Intramedullary bone-lengthening nails have become increasingly popular. The 2 most used and successful nails are the FITBONE and the PRECICE nails. Uniform reporting is lacking on complications of intramedullary bone-lengthening nails. The purpose was therefore to assess and categorize the complications of lower limb bone-lengthening nails and investigate risk factors.

Patients and methods — We performed a retrospective review of patients operated on with intramedullary lengthening nails at 2 hospitals. We included only lower limb lengthening with FITBONE and PRECICE nails. Recorded patient data was patient demographics, nail information, and any complication. Complications were graded according to severity and origin classification. Complication risk factors were assessed with modified Poisson regression.

Results — 314 segments in 257 patients were included. The FITBONE nail was predominantly used (75%), and most of the lengthenings were performed in the femur (80%). 53% of the patients had complications. 269 complications were identified in 175 segments (144 patients). Device-related complications were most frequent (0.3 complications/segment), followed by joint complications (0.2 complications/segment). An increased relative risk was found for complications in the tibia compared with the femur and for age groups above 30 years compared with the 10–19 years group.

Conclusion — Complications with intramedullary bone-lengthening nails were more frequent than has previously been reported, with 53% of patients sustaining a complication. Future studies need to document the complications meticulously so that the true risk can be established.

Intramedullary bone-lengthening nails were introduced in an attempt to reduce complications with external fixation and improve patient comfort (1,2). The initial mechanically driven intramedullary bone-lengthening nails had challenges controlling the lengthening rate, which was resolved by the introduction of electrical (FITBONE) or magnetically (PRECICE) driven motorized intramedullary bone-lengthening nails (2-7). So far, comparative studies comparing external fixation with FITBONE or PRECICE lengthening nails are few and with small patient samples (8,9). A systematic review on FITBONE and PRECICE nail complications found that the literature is mostly composed of small studies and with inconsistent complication reporting (10). Analysis of the complications, including risk factors, may improve the treatment and shared decision-making with patients. The aim of the study was to review a consecutive treatment series with the FITBONE and the PRECICE lengthening nails from 2 centers to assess the proportion, severity, and origin of complications. The secondary aim was to investigate potential risk factors of sustaining a complication with these lengthening nails.

Patients and methods

Study design and participants

We performed a retrospective cohort series review, according to STROBE guidelines, of intramedullary bone-lengthening nail patients from 2 hospitals: the Nationwide Children's Hospital (NCH), Ohio, USA and Aalborg University Hospital (AAUH), Denmark. Patients were included if they had a PRECICE (Nuvasive, San Diego, CA, USA) or FITBONE (Ortho-

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Table 1. Complication severity grade (9)

Complication severity grade	Examples of complications
I	**Minimal intervention required; treatment goal still achieved** Temporary joint contracture resolved by physiotherapy. Device stop lengthening due to suboptimal placement of the external transmitter, resolved by repositioning of the external transmitter
II	**Substantial change in treatment plan; treatment goal still achieved** Unplanned return to surgery, such as delayed consolidation requiring additional intervention, or device problem needing revision
IIIA	**Failure to achieve treatment goal, no new pathology or permanent sequelae** Premature consolidation with aborted lengthening, inability to tolerate lengthening, and fracture at fixation site or regenerate bone with shortening
IIIB	**Failure to achieve treatment goal and/or new pathology or permanent sequelae** Joint subluxation, joint dislocation, regenerate fracture with deformity, and deep infection. Thromboembolic complication such as deep vein thrombosis

fix, Lewisville, TX, USA/Wittenstein Intens, Ingersheim, Germany) bone-lengthening nail and if the bone-lengthening nail had been removed after the end of treatment. Exclusion criteria were bone-transport nails, stump-lengthening nails, compression nails, PRECICE STRYDE, nail insertion or removal at a hospital other than NCH or AAUH, lengthening nails in upper extremities, and extramedullary lengthening. The treatment period was 2017–2020 at NCH and 2005–2021 at AAUH. Some patients had multiple segments lengthened. To avoid correlation bias for patients with multiple segments, a random segment was included in the regression analysis. Thus, in the sub-cohort used for regression analysis, only 1 segment of lengthening per person was included.

Over the years, we have adjusted our clinical practice to the importance of blocking screws to ensure deformity correction or to increase the bone-to-nail stability, especially in the tibia (11–13). Rigid reamers are used with the straight nail designs (14,15). To reduce the surgical impact on the soft tissues and especially the knee joint during retrograde femoral nailing, tube systems are used for both inserting and removing nails (16,17).

Measures of demographic characteristics

Patient charts were reviewed to identify age, sex, clinical preoperative limb length discrepancy (short stature patients were reported as zero), and other surgical procedures at nail insertion. Etiology was classified using the Stricker and Hunt classification with an added category: unknown (10,18) (see Supplementary material). Duration of implantation was defined as days between nail insertion and nail removal. Length of follow-up was defined as days from nail insertion to the last follow-up. Deformity was defined as a lack of cortical alignment on the postoperative radiograph. Nail information was bone (femur/tibia), nail approach, nail type (FITBONE/PRECICE), nail length (mm). End length of bone regenerate (total bone length gained) on radiograph was defined as end minus start length of the telescopic male part (mm).

Outcome measures of complication

The primary outcome of complication severity and origin was identified through a review of patient charts. The severity was classified according to Black et al. (Table 1) (9). By definition, deep vein thrombosis, osteomyelitis, and joint subluxation/luxation were graded as type IIIB complications. The manufacturers state that nail removal is mandatory for both FITBONE and PRECICE nails, and therefore we did not classify scheduled and uneventful nail removal as a complication (19,20).

The type of complication was categorized into origin, representing 8 main groups and 33 subgroups according to Frost et al. and by applying a predefined set of interpretations (10) (see Supplementary material).

Complications were assessed in the period from nail insertion to the last follow-up according to the timing of occurrence in the treatment period, which was divided into 6 time slots (intraoperative, postoperative before distraction, distraction, consolidation, intraoperative nail removal, and after nail removal). A subset of the complications after nail removal has previously been reported but is included to provide the complete complication pattern throughout treatment (21).

Outcome measures of risk factors

Clinical and literature subject-matter knowledge was used to pinpoint measurable variables of interest. As multiple variables were of interest, model construction and variables selection were guided by directed acyclic graphs (DAG) (22). DAGs for each outcome variable were created to ensure the appropriateness of regression analysis (Figure 1, see Appendix). Our DAG models led us to investigate the following possible risk factors for complications: age, bone, increasing bone lengthening, femur approach, deformity correction, etiology, previous bone lengthening, and nail type.

Statistics

Continuous variables were described as median, range, and interquartile range (IQR), or mean and standard deviation (SD) as appropriate according to sample distribution. Categorical variables were described with count and proportions with the Wilson confidence interval (CI). In the full cohort complications were reported as complications per segment (Table 5). In the sub-cohort, complications were dichotomized as complications (yes/no) for regression analysis. The overall proportions of complication were reported according to the sub-cohort (Table 4). As regression analysis, a modified Poisson regression with robust CI was used to calculate the relative risk (RR) of a complication (Table 6) for relevant risk factors (23). Both crude and adjusted regression models were chosen based on DAGs (Figure 1, see Appendix). Miss-

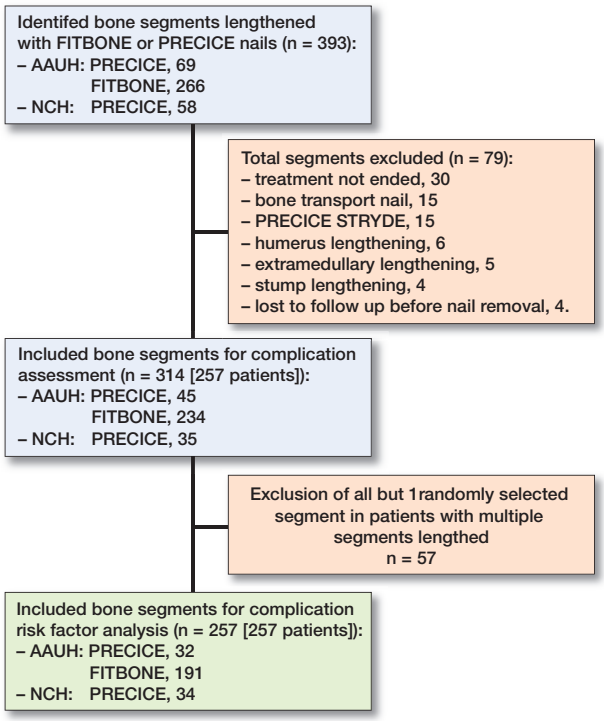

Figure 2. Segment selection flow chart. NCH: Nationwide Children's Hospital. AAUH: Aalborg University Hospital

ing values were observed only in the variables "Time point at which complication first recognized" and "Length of inserted nail." Both variables were not included in the risk analysis, and therefore sensitivity analyses were not performed. Covariate estimates of regression analysis can be found in Table 2 (see Appendix). Data analysis was performed with Stata/MP 17.0 (StataCorp, College Station, TX, USA). The significance levels were set to 5%, and estimates were given with 95% CI.

Ethics, registration, funding, and disclosures

Institutional ethics approval was granted at Nationwide Children's Hospital (STUDY00000908) and Aalborg University Hospital [project ID. no. 2020-157]). No external funding was received. CI is a consultant for Orthofix, which distributes the FITBONE nail, Wishbone Medical, Inc., Smith & Nephew, and NuVasive, which manufactures the PRECICE nail. AB is a consultant for Wishbone Medical, Inc. SK is a consultant for Wishbone Medical, Inc. The other authors have no conflicts of interest to declare. Completed disclosure forms for this article following the ICMJE template are available on the article page, doi: 10.2340/17453674.2023.8479

Results

Demographic characteristics

We identified 393 consecutive segments lengthened with FITBONE or PRECICE nails, of which 79 segments were excluded (4 segments were lost to follow-up and 75 segments discounted due to the exclusion criteria) (Figure 2). The remaining 314 included segments belonged to 257 patients with a median age of 19.5 years. Demographic data is summarized in Table 3. Most lengthenings were performed in the femur (80% of 314 segments), and the FITBONE nail was used predominantly (75% of 314 segments). Nail demography is presented in Table 4.

Table 3. Segment demographic characteristics. Data is presented as numbers (%) and median, interquartile range (IQR), and (minimum–maximum)

Factor	All segments	Sub-cohort of segments [a]
Lengthened segments	314	257
AAUH, Denmark [b]	279 (87)	223 (87)
NCH, USA [c]	35 (13)	34 (13)
Patients	257	257
Patients with multiple segments	35 (14)	0
2 lengthened segments	24	
3 lengthened segments	3	
4 lengthened segments	7	
7 lengthened segments	1	
Male sex	165 (53)	143 (56)
Female sex	149 (47)	114 (44)
Age at nail insertion		
median (IQR)	19.5 (16.4–29.9)	19.5 (16.4–33.6)
(min–max)	(9.5–76.9)	(9.5–76.9)
LLD [d] etiology		
Congenital	64 (20)	61 (24)
Acquired/developmental	143 (46)	133 (52)
Short stature	69 (22)	25 (10)
Unknown	38 (12)	38 (15)
Median (IQR) preoperative LLD [e]	3.1 (2.5–4)	3.0 (2.5–4)
(min–max)	(1–14)	(1–13)
Other procedure at primary surgery	153 (49)	127 (49)
Duration of implantation, days		
median (IQR)	410 (336–632)	393 (329–569)
(min–max)	(45–2,372)	(45–2,166)
Length of follow-up, days)		
median (IQR)	646 (478–1,073)	583 (478–1,073)
(min–max)	(176–3,718)	(176–3,718)
Previous lengthening [f]		
None	248 (79)	214 (83)
Segment	32 (10)	24 (9)
Limb	34 (11)	19 (7)
Angle correction in frontal or sagittal plane	80 (25)	64 (25)

[a] Sub-cohort of segments used for regression analysis of risk is the unique group that by random selection ensures that every patient was represented by only 1 segment.
[b] AAUH: Aalborg University Hospital.
[c] NCH: Nationwide Children's Hospital.
[d] LLD: Limb length discrepancy
[e] Short stature is not included.
f in the same patient

Complications

269 complications were identified consisting of 314 (56%) segments (257 patients) and occurred in 175 segments (144 [56%] patients). The proportion of complications per patient

Table 4. Nail demography. Data is presented as numbers (%) unless otherwise specified

Factor	All segments (n = 314)	Sub-cohort of segments [a] (n = 257)
Bone		
Femur	251 (80)	208 (81)
Tibia	63 (20)	49 (19)
Right side	157 (50)	130 (51)
Nail type		
FITBONE	234 (75)	191 (74)
PRECICE	80 (26)	66 (26)
Nail approach		
Antegrade femur	41 (13)	37 (14)
Retrograde femur	210 (67)	171 (67)
Antegrade tibia	56 (18)	44 (17)
Suprapatellar tibia	7 (2)	5 (2)
Length of inserted nail, mm (n = 303)		
median (IQR)	245 (225–245)	245 (225–245)
(min–max)	(115–365)	(115–365)

[a] See footnote Table 3.

was 0.53 (CI 0.47–0.59) in the sub-cohort. The complication distribution on severity grading in the full cohort is presented in Table 5. The median number of complications per segment in the full cohort was 1, with a maximum of 5 complications per segment. Type II complication was the most common complication seen in the proportion 0.35 (CI 0.30–0.41) of patients followed by type I complication seen in 0.25 (CI 0.21–0.31) of patients. Failure to achieve the lengthening goal (type IIIA complication) represented the proportion of 0.03 (CI 0.01–0.05) of patients. A permanent sequela or a new pathology (type IIIB complication) was observed in the proportion of 0.09 (CI 0.06–0.12) of patients.

Device-related complication (Table 6) was the most frequent origin of complications, occurring in 32% of the lengthened segments, but did not result in any type IIIA or IIIB complications. Contracture was the leading cause of joint complications, and the joint was the 2nd most frequent origin of complications as it occurred in 23% of the segments. Bone was the 3rd most frequent origin of complications with complications occurring in 10% of segments.

Of the 268 complications (1 missing data), most occurred during the distraction phase (46% [n = 123]), followed by the consolidation phase (31% [n = 83]), after implant removal (15% [n = 40]), during intraoperative nail removal (3.7% [n = 10]), postoperatively before distraction (2.6% [n = 7]), and intraoperatively (1.9% [n = 5]).

Risk factor analysis (Table 7)

All age groups showed a clinically relevant increased risk of complication in comparison with the reference age group of 10–19 years (both adjusted and crude); however, the age group 20–29 years showed no clinically significantly increased risk compared with the reference. After the age of 30 years the adjusted analysis showed a significant increase in risk of complications with approximately a doubled risk (RR ranged from 1.9 to 2.6) of complication compared with the baseline group. For the age group 20–29 years compared with the older age groups, the largest reduction (40%) was seen when compared with age groups above 50 years. Overall, most age groups showed a statistically significant and a clinically relevant increased risk of complications with increasing age. The etiology short stature as a risk factor showed an 80% complication increase (RR 1.8 [CI 1.2–2.8]) relative to unknown etiology. The estimate of congenital and acquired/developmental etiology showed RR 1.1 (0.7–1.7) and 1.3 (0.90–2.0) complication risk, respectively. The crude model of nail type effect on complication showed a significant 30% risk reduction of the PRECICE nail compared with the FITBONE nail, which was not present in the adjusted model (RR 0.9 [CI 0.7–1.3]). The tibia showed a 70% increased risk of complication (RR 1.7 [CI 1.4–2.0]) compared with the femur, with an estimated effect

Table 5. Complications and their severity. The proportion of the dichotomized complication outcome (complication [yes/no]) for both the full cohort and the sub-cohort used for the regression analysis. The proportion confidence interval (CI) was calculated using Wilson's CI for independent and identically distributed (IID) variables. The assumption of IID was only approximately true in the full cohort for overall complications per patient proportion as each patient could have multiple segments

Factor	Complications severity grade I	II	IIIA	IIIB	Overall [a]
Full cohort (257 patients with 314 segments)					
Absolute number of complications	86	144	9	30	269
Complication (yes/no) per segment (CI)	0.25 (0.21–0.30)	0.35 (0.30–0.41)	0.03 (0.01–0.05)	0.09 (0.06–0.12)	0.55 (0.50–0.61)
Complication (yes/no) per patient (CI)	0.26 (0.21–0.32)	0.35 (0.29–0.41)	0.04 (0.02–0.07)	0.11 (0.07–0.15)	0.56 (0.50–0.62)
Sub-cohort (257 patients with 257 segments)					
Absolute number of complications (CI)	63	113	7	26	209
Complication (yes/no) per patient [b]	0.23 (0.18–0.28)	0.33 (0.28–0.40)	0.03 (0.01–0.06)	0.09 (0.06–0.14)	0.53 (0.47–0.59)

[a] The overall proportion is not necessarily equal to the summation of the complication grading when looking at the dichotomized complication outcome. This is obvious as each person or segment may experience multiple complications, which are graded differently.
[b] For the sub-cohort only 1 segment is included for each patient (for the sub-cohort, the complications per patient are equal to the complications per segment). Thus the complication (yes/no) per patient and segment is exactly the same.

Table 6. Complications categorized into 8 main groups (soft tissue, joint, vascular, bone, neurological, infection, device-related, others) and 33 subgroups after Frost et al. (10). Severity grading by Black et al. (9). Values are count and complications per segment (fraction = n/314)

Factor	Severity grade and origin of complications I	II	IIIA	IIIB	Sum
Soft tissue					
Skin	2				2
Muscles	1	2			3
Tendons					0
Pain	5				5
Others				1	1
Sum (fraction)	8	2		1	11 (0.04)
Joint					
Pain	12		2	1	15
Contracture	19	19	3	10	51
Subluxation				2	2
Dislocation					0
Others	2	1		1	4
Sum (fraction)	33	20	5	14	72 (0.23)
Vascular					
Vascular damage				2	2
Deep vein thrombosis				1	1
Hemorrhage/hematoma					0
Others					0
Sum (fraction)				3	3 (0.01)
Bone					
Premature consolidation	1	2			3
Delayed healing	2	14			16
Secondary malalignment		1	1	1	3
Fracture	4	10			14
Others				1	1
Sum (fraction)	7	27	1	2	37 (0.12)
Neurology					
Paresthesia	1				1
Paralysis				2	2
Others	2			2	4
Sum (fraction)	3			4	7 (0.02)
Infection					
Superficial soft tissue	2	4			6
Deep soft tissue		3		1	4
Osteomyelitis				3	3
Others	3	1			4
Sum (fraction)	5	8		4	17 (0.05)
Device-related					
Distraction mechanism	17	5			22
Mechanical strength	2	4	1		7
Attachment failure	1	27	1		29
Others	7	35			42
Sum (fraction)	27	71	2		100 (0.32)
Others					
Patient		1	1		2
Surgical	2	14		1	17
Others	1	1		1	3
Sum (fraction)	3	16	1	2	22 (0.07)

Table 7. Relative risk (RR) of a complication developing during bone lengthening using modified Poisson regression model with robust confidence intervals (CI) (23)

Factor	Crude model RR (SE) [CI]	Adjusted model (total effect) [a] RR (SE) [CI]
Age (n = 257)		
10–19	1 (reference)	1 (reference)
20–29 [b]	1.6 (0.3) [1.2–2.2]	1.4 (0.3) [1.0–2.0]
30–39	1.9 (0.3) [1.3–2.7]	2.1 (0.4) [1.4–3.0]
40–49	1.8 (0.4) [1.2–2.7]	1.9 (0.4) [1.3–2.9]
50–59 [b]	2.4 (0.4) [1.8–3.3]	2.6 (0.5) [1.9–3.6]
≥ 60 [b]	2.1 (0.4) [1.4–3.1]	2.3 (0.5) [1.5–3.5]
Nail type (n = 257)		
FITBONE	1 (reference)	1 (reference)
PRECICE	0.7 (0.1) [0.5–0.9]	0.9 (0.1) [0.7–1.3]
Etiology (n = 257)		
Unknown	1 (reference)	
Congenital	1.1 (0.3) [0.7–1.7]	
Acquired/ developmental	1.3 (0.3) [0.9–2.0]	
Short stature	1.8 (0.4) [1.2–2.8]	
Bone (n = 257)		
Femur	1 (reference)	1 (reference)
Tibia	1.7 (0.2) [1.4–2.1]	1.7 (0.2) [1.4–2.0]
Primary osteotomy correction (n = 257)		
No correction	1 (reference)	1 (reference
Correction	1.3 (0.2) [1.0–1.6]	1.2 (0.1) [0.96–1.5]
Femur nail approach (n = 208):		
Antegrade	1 (reference)	1 (reference)
Retrograde	1.3 (0.3) [0.8–2.0]	1 (0.2) [0.7–1.5]
Previously bone lengthening (n = 257)		
No lengthening	1 (reference)	1 (reference)
Per leg	1.2 (0.2) [0.8–1.8]	1.1 (0.2) [0.7–1.6]
Per bone	1.1 (0.2) [0.8–1.6]	1.1 (0.2) [0.8–1.6]
Total bone length gained (n = 254)		
Length gained per mm [CI]	1.01 (0.004) [1.0–1.02]	1.01 (0.004) [0.99–1.01]

SE: Standard error.
Sub-cohort of segments used is the group that by random selection ensures that every patient was represented by only 1 segment. Age was grouped into decades from 10 to 60, and > 60 when considering age as a risk factor. When adjusting for age, age was considered continuously to increase power. Dependent variable: complication yes or no for each included observation.
[a] In the adjusted model, Age and Bone were adjusted for etiology, Nail type was adjusted for age (continuously variable), bone, and hospital, Previous bone lengthening and Total bone length gained were adjusted for etiology and age (continuously variable), and Primary osteotomy correction and Femur nail approach were adjusted for hospital, etiology, and age (continuously variable).
[b] The 20–29 group had a reduction in RR of complication compared with the older age 30–39 (RR 0.7 [CI 0.5–1.0]), 40–49 (RR 0.8 [CI 0.5–1.2]), 50–59 (RR 0.6 [CI 0.4–0.8]), and ≥ 60 (RR 0.6 [CI 0.4–0.96]).

ranging from 40–100% increased risk, which is interpreted as a clinically important result (Table 7). For bone site, the complication per segment is higher for type I and II complications in the tibia compared with the femur but equal for type IIIA/IIIB (Table 8). The risk of complications was similar between an antegrade or a retrograde approach to the femur (adjusted RR 1 [CI 0.7–1.5]). Previous bone lengthening showed a 10% increase in risk estimate for complication compared with no previous intervention (RR 1.1 [0.8–1.6]). Acute deformity correction presents a 20% higher risk of complications compared with no deformity correction (adjusted RR 1.2 [CI 0.96–1.5]), which would be a clinically significant result but statistically not so. Type I and II complications occurred more often in acute correction osteotomies, but there was no difference for type III complications (Table 8). We found that the risk of complications increased by 1% (RR 1.01 [CI 1.00–1.02])

Table 8. Number of complications distributed on severity grading by nail type, bone, or osteotomy correction. Values are count and (fraction)

Factor	Segments n	Complications severity grade I	II	IIIA	IIIB	Sum	Complication per segment
Nail type							
FITBONE	234	72 (0.3)	121 (0.5)	7 (0.03)	24 (0.1)	224	1
PRECICE	80	14 (0.2)	23 (0.3)	2 (0.03)	6 (0.08)	45	0.6
Bone							
Tibia	63	25 (0.4)	54 (0.9)	1 (0.02)	7 (0.1)	87	1.4
Femur	251	61 (0.2)	90 (0.4)	8 (0.03)	23 (0.1)	182	0.7
Osteotomy correction							
Yes a	80	44 (0.6)	78 (1)	7 (0.1)	21 (0.3)	150	2
No	234	42 (0.2)	66 (0.3)	2 (0.01)	9 (0.04)	119	0.5

[a] Correction is in frontal or sagittal plane.

for every mm lengthened, which is clinically interesting as most patients are lengthened by a minimum of 20 mm, starting with a 20% risk of complication. However, the total effect calculated by adjustment provides no evidence that lengthening increases the risk of complications.

Discussion

This consecutive series of 314 internal lengthening nails represents to our knowledge the largest cohort to date in examining complications of the FITBONE and PRECICE nails. The main finding was that 53% of the patients had 1 or more complications, which is higher than previously reported (10). Device-related complication was the leading cause of complications. The study by Frommer et al. found complications in 76% of the 90 patients with PRECICE femur lengthening, which is in accordance with our findings (24).

The joint was the 2nd most frequent origin of complications (23% of segments) with contracture as the most prevalent (16% of segments) joint complication. This is in line with temporary joint contractures of 20% reported by Frommer et al. and of 46% reported by Calder et al. (24,25). Joint complications are still an important complication even when the soft-tissue-tethering effect from external fixation has been eliminated. Muscle group imbalance was advocated by Paley as a reason for joint problems in bone lengthening (26).

Age had a high influence on complications with an approximately double risk of complications in the age groups above 30 years. Frommer et al. reported that age above 16 years did not increase the risk of unplanned surgery, but this finding might be due to the low median age (15 years) and small spread of age (14 to 17 years) in their study (24). Zak et al. did not find a risk of advanced age (above 45 years) on bone healing or complication rate when performing bone lengthening with the PRECICE nail; however, the study population was limited to 19 patients (27). The limitations of Frommer et al. and Zak et al. offer a plausible explanation for the differences between their and our results, as our study has larger cohort size, wider age spread, and model substantiated estimate.

Acute deformity correction followed by gradual limb lengthening has been reported to increase complication rates ranging from 15% to 45% (11,28,29). In our model, acute deformity correction showed an RR of 1.2 (CI 0.96–1.5) and we can therefore neither confirm nor reject the findings, even though the point estimate supports the 3 studies.

The tibia showed a 70% increased risk of complication compared with the femur, which is supported by 3 studies on bone-lengthening nails that disclose an increased complication risk of 50–82% (24,30,31).

In the crude model, the risk of total bone length gained showed a significant estimate of 1% increased risk per mm, which was insignificant in the adjusted model. This model of total bone length gained is a pendant to earlier models of increased risk of complication associated with the relative bone lengthening that has been shown for both children and adults (32,33).

Our study is subject to the limitations of the observational nature and retrospective design, which could lead to underreporting, lack of precision in reporting, and only demonstrating associations and not showing causality (34). A retrospective assessment of complications is, however, needed to perform the complication severity grading (9,35). The use of a severity grading standardizes our results, making them easier to assess and compare with others. When comparing our results, it became evident that the area of complication is lacking the gold standard for reporting complications. We have encountered 4 different severity gradings (Paley, Black et al., Dahl et al., Dinçyürek et al.) in studies on bone lengthening nails but many use a descriptive approach and some without defining complications (9,26,36-39). The comparison of complication rates between studies is compromised due to the lack of uniform reporting.

We partly accommodated the risk of observer bias by assigning a researcher not involved in the patient treatment to perform the patient chart evaluation and complication grading. However, bias might have occurred due to imprecise reporting of the complications in the patients' charts. Bias could also be introduced because the treating physicians participated in the data interpretation. The dominant risk of bias for this study is selection bias, as bone lengthening with external fixators was applied to the most severe cases treated in the same period. These biases would tend to underestimate the true incidence of complications with intramedullary bone-lengthening nails. Only 1% (4/318) of segments were lost to follow-up, which reduces the risk of transfer bias. The lack of interobserver reliability assessment of the applied complication classifications system is a study weakness. However, the complication classification system was

tested with an excellent result by 2 raters as reported by Frost et al. (10,40). At AAUH, multiple surgeons have been involved in the treatment for a long period as opposed to NCH, where the same surgeon treated all patients. FITBONE nails and tibial lengthening were performed only at AAUH.

Conclusion

This study showed complications in 53% of patients lengthened with intramedullary bone-lengthening nails. Device-related complications were most frequently seen with 0.3 complications per segment, followed by joint complications with 0.2 complications per segment. There was a higher relative risk for complications in the tibia compared with the femur and age groups above 30.

Supplementary material

Tables showing Disease etiology (18) and Complication origin (10) are available in the Supplementary material file on the article page, doi: 10.2340/17453674.2023.8479

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Appendix

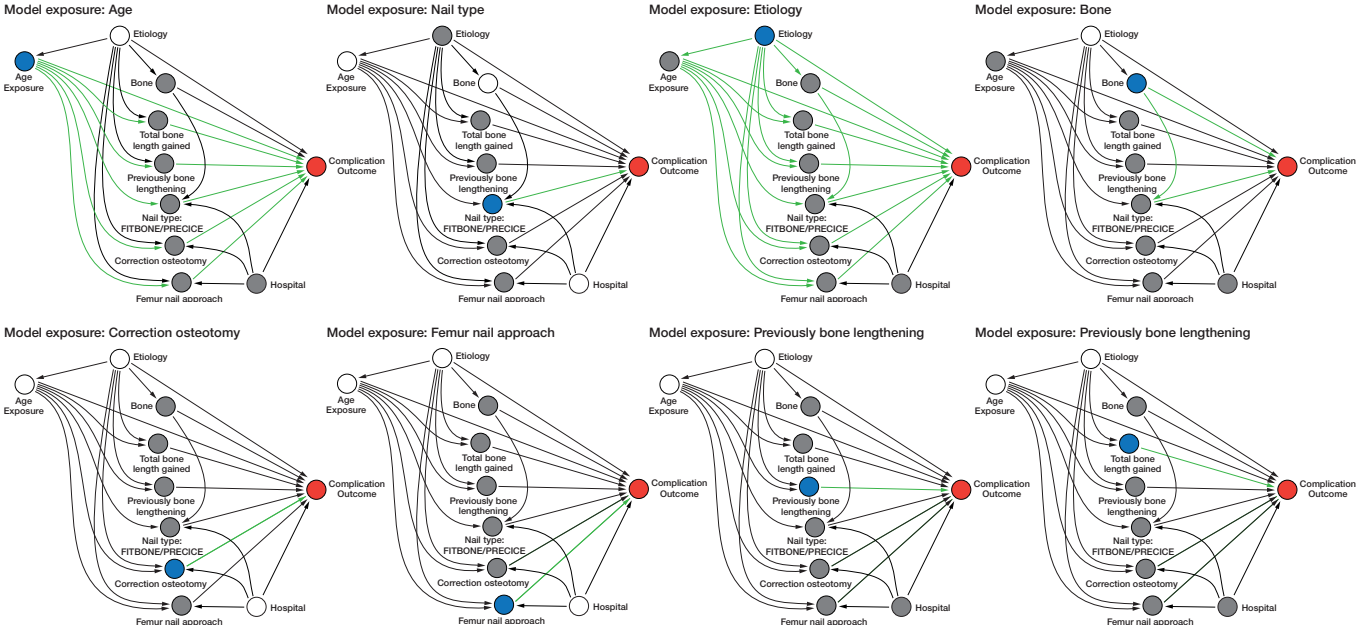

Figure 1. The 8 directed acyclic graphs (DAG) of models used for risk assessment of complication. ●: Exposure. ●: Outcome. ●: Covariates with unknown value/not included in the model. ○ Covariates use to reduce bias. → represent the total effect described by the DAC model.

Table 2. Estimate and covariate estimates in adjusted models of relative risk (RR) with standard error (SE), and confidence intervals (CI) of the 8 regression models

Model	RR (SE) [CI]
Age model: covariate: etiology	
10–19	1 (reference)
20–29	1.4 (0.3) [1.0–2.0]
30–39	2.1 (0.4) [1.4–3.0]
40–49	1.9 (0.4) [1.3–2.9]
50–59	2.6 (0.5) [1.9–3.6]
≥ 60	2.3 (0.5) [1.5–3.5]
Etiology (covariate)	
Congenital	1 (reference)
Short stature	1.5 (0.3) [1.0–2.3]
Acquired/ developmental	0.9 (0.2) [0.6–1.3]
Unknown	0.8 (0.2) [0.5–1.3]
Model Nail type: covariate: age (continuously variable), bone, and hospital	
FITBONE	1 (reference)
PRECICE	0.9 (0.1) [0.7–1.3]
Age (covariate)	1.01 (0.003) [1.006–1.01]
Bone (covariate)	
Tibia	1 (reference)
Femur	0.68 (0.07) [0.5–0.8]
Hospital (covariate)	
AAUH	1 (reference)
NCH	0.57 (0.2) [0.3–1.1]
Model Bone: covariate: etiology	
Femur	1 (reference)
Tibia	1.7 (0.2) [1.4–2.0]
Etiology (covariate)	
Congenital	1 (reference)
Short stature	1.6 (0.3) [1.1–2.3]
Acquired/ developmental	1.3 (0.2) [0.9–1.7]
Unknown	1.0 (0.2) [0.6–1.6]
Model Correction osteotomy: age (continuously variable), etiology and hospital	
No correction	1 (reference)
Correction	1.2 (0.1) [0.96–1.5]
Age (covariate)	1.02 (0.004) [1.008–1.02]
Etiology (covariate)	
Congenital	1 (reference)
Short stature	0.9 (0.2) [1.1–2.1]
Acquired/developmental	0.9 (0.2) [0.7–1.3]
Unknown	0.8 (0.2) [0.5–1.2]
Hospital (covariate)	
AAUH	1 (reference)
NCH	0.5 (0.2) [0.3–1.0]

Model	RR (SE) [CI]
Model Previously bone lengthening: age (continuously variable), etiology	
No lengthening	1 (reference)
Per leg	1.1 (0.2) [0.8–1.6]
Per bone	1.1 (0.2) [0.7–1.6]
Age (covariate)	1.02 (0.004 [1.01–1.03]
Etiology (covariate)	
Congenital	1 (reference)
Short stature	1.7 (0.3) [1.1–2.4]
Acquired/developmental	1.0 (0.2) [0.7–1.4]
Unknown	0.9 (0.2) [0.5–1.4]
Model Femur nail approach: age (continuously variable), etiology and hospital	
Antegrade	1 (reference)
Retrograde	0.99 (0.2) [0.7–1.5]
Age (covariate)	1.02 (0.004) [1.01–1.03]
Etiology (covariate)	
Congenital	1 (reference)
Short stature	1.7 (0.4) [1.0–2.8]
Acquired/developmental	1 (0.2) [0.6–1.5]
Unknown	0.9 (0.2) [0.5–1.4]
Hospital (covariate)	
AAUH	1 (reference)
NCH	0.6 (0.2) [0.3–1.2]
Model Total bone length gained: age (continuously variable), etiology	
Length gained	1.01 (0.004) [0.99–1.01]
Age (covariate)	1.02 (0.004) [1.01–1.03]
Etiology (covariate)	
Congenital	1 (reference)
Short stature	1.4 (0.3) [0.9–2.1]
Acquired/developmental	0.9 (0.2) [0.7–1.3]
Unknown	0.9 (0.05) [0.2–0.4]