■ GENERAL ORTHOPAEDICS

Radiographs of 366 removed limb lengthening nails reveal differences in bone abnormalities between different nail types

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Aims

Limb lengthening nails have largely replaced external fixation in limb lengthening and reconstructive surgery. However, the adverse events and high prevalence of radiological changes recently noted with the STRYDE lengthening nail have raised concerns about the use of internal lengthening nails. The aim of this study was to compare the prevalence of radiological bone abnormalities between STRYDE, PRECICE, and FITBONE nails prior to nail removal.

Methods

This was a retrospective case series from three centres. Patients were included if they had either of the three limb lengthening nails (STYDE, PRECICE, or FITBONE) removed. Standard orthogonal radiographs immediately prior to nail removal were examined for bone abnormalities at the junction of the telescoping nail parts.

Results

In total, 306 patients (168 male, 138 female) had 366 limb lengthening nails removed. The mean time from nail insertion to radiological evaluation was 434 days (36 to 3,015). Overall, 77% of STRYDE nails (20/26) had bone abnormalities at the interface compared with only 2% of FITBONE (4/242) and 1% of PRECICE nails (1/98; $p < 0.001$). Focal osteolysis in conjunction with periosteal reaction at the telescoping interface was only observed in STRYDE nails.

Conclusion

Bone abnormalities at the interface of telescoping nail parts were seen in the majority of STRYDE nails, but only very rarely with FITBONE or PRECICE nails. We conclude that the low prevalence of radiological changes at the junctional interface of 242 FITBONE and 98 PRECICE nails at the time of nail removal does not warrant clinical concerns.

Introduction

Intramedullary lengthening nails provide an alternative to external fixation for patients requiring bone lengthening and deformity correction. Excellent short-term results have been demonstrated in large case series for both the FITBONE and the PRECICE intramedullary lengthening nails.[1-4] The FITBONE nail (Wittenstein Intens, Germany) is made of stainless steel 316 and the PRECICE (NuVasive Specialized Orthopaedics, USA) nail has two designs: one titanium PRECICE P2.2 and one stainless steel, which is known as STRYDE, and was released in 2018. STRYDE is constructed specifically from Biodur 108 alloy stainless steel (ASTM F2229) which increases the overall strength and allows patients to accelerate their postoperative weightbearing.[5] However, two recent publications have reported adverse radiological changes and patient symptoms of localized pain and swelling related to the STRYDE nail.[6,7] A nationwide Danish cross-sectional study of 27 patients who had 30 STRYDE nails inserted showed radiological changes in the area of the junction between telescoping nail parts, in 21 of the 30 lengthened bone segments.[6] Furthermore, Iliadis et al[7] reported that osteolysis and periosteal reaction at the junction of the telescopic nail was evident in nine out of 14 STRYDE nails

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Table I. Patient demographic data presented with the distribution on three limb lengthening nails.

Variable	Total	FITBONE	PRECICE	STRYDE
Evaluated nails, n	366	242	98	26
Patients, n	306	202	82	22
Patients with multiple nail removals, n (%)	39 (13)	28 (14)	8 (10)	3 (14)
Sex, n (%)				
Female	138 (45)	89 (44)	35 (43)	14 (64)
Male	168 (55)	113 (56)	47 (57)	8 (36)
Mean age, yrs (range)	27 (10 to 79)	28 (14 to 73)	25 (10 to 79)	23 (13 to 66)
Mean LLD, cm (range)	3 (0 to 14)	3 (0 to 14)	4 (0 to 13)	2 (20 to 7)
LLD aetiology, n (%)				
Congenital	121 (40)	82 (41)	28 (34)	11 (50)
Post-traumatic	94 (31)	73 (36)	19 (23)	2 (9)
Developmental	47 (15)	20 (10)	22 (27)	5 (23)
Short stature	26	20 (10)	3 (4)	3 (14)
Mean time from insertion to evaluation, days (range)	434 (36 to 2,372)	481 (36 to 2,372)	357 (58 to 1,095)	292 (107 to 593)
Mean time to removal, days (range)	507 (55 to 2,372)	557 (57 to 2,372)	426 (55 to 1,095)	343 (107 to 609)

LLD, limb-length discrepancy.

Table II. Distribution of nail sites, nail approaches, nails with blocking screws, and number of blocking screws.

Variable	Total	FITBONE	PRECICE	STRYDE
Bone segment, n (%)				
Femur	292 (80)	194 (80)	80 (82)	18 (69)
Tibia	68 (19)	45 (19)	15 (15)	8 (31)
Humerus	6 (2)	3 (1)	3 (3)	0 (0)
Nail approach, n (%)				
Antegrade femur	64 (17)	7 (3)	39 (40)	18 (69)
Retrograde femur	228 (62)	187 (77)	41 (42)	0 (0)
Antegrade tibia	68 (19)	45 (19)	15 (15)	8 (31)
Antegrade humerus	6 (2)	3 (1)	3 (3)	0 (0)
Nails with Poller screws, n (%)	103 (28)	63 (26)	34 (35)	6 (23)
Total Poller screws, n	134	79	48	7

Table III. Bone abnormalities at the interface of the telescoping nail segments.

Abnormality	Total (n = 366)	FITBONE (n = 242)	PRECICE (n = 98)	STRYDE (n = 26)
Total, n (%)	25 (7)	4 (2)	1 (1)	20 (77)
Focal osteolysis, n (%)	2 (1)	1 (0)	1 (1)	0 (0)
Periosteal reaction, n (%)	2 (1)	0 (0)	0 (0)	2 (8)
Cortical hypertrophy, n (%)	7 (2)	3 (1)	0 (0)	4 (15)
Focal osteolysis, periosteal reaction, n (%)	3 (1)	0 (0)	0 (0)	3 (12)
Cortical hypertrophy and periosteal reaction, n (%)	5 (1)	0 (0)	0 (0)	5 (19)
Focal osteolysis, periosteal reaction, cortical hypertrophy, n (%)	6 (2)	0 (0)	0 (0)	6 (23)

inserted. These adverse events and radiological changes noted with the STRYDE nail are of concern.[8] Further investigations are required to see whether similar changes also occur with the other commercially available intramedullary limb lengthening devices, namely the stainless steel FITBONE and titanium PRECICE P2.2 nails. We therefore conducted a retrospective analysis of radiographs of all limb lengthening nails that had been removed at our three centres. The aim was to compare the prevalence of radiological bone abnormalities between STRYDE, PRECICE, and FITBONE nails prior to nail removal. The primary aim was to evaluate the presence of bone abnormalities (osteolysis, periosteal reaction, and/or cortical hypertrophy) at the telescoping interface, and the secondary aim was to describe bony changes at the sites of interlocking screws/pegs and Poller screws.

Methods

This study was performed as retrospective case series from three centres. Institutional approval was obtained at each institution (Nationwide Children's Hospital, Columbus, Ohio, USA, and Aalborg University Hospital and Aarhus University Hospital, Denmark). Patients were included if they had either of the three limb lengthening nails (FITBONE, PRECICE, or STRYDE) removed at one of the three centres. All PRECICE nails were PRECICE P2.2 nails. Bone transport nails and stump lengthening nails were excluded. Nail removals were performed between January 2017 and December 2020 at Nationwide Children's Hospital, between January 2006 to 2021 at Aalborg Univeristy Hospital, Denmark, and between 2016 to 2021 at Aarhus University Hospital, Denmark. Patient charts were reviewed to identify patient demographic details (Table I). Aetiology was classified as congenital, developmental, post-traumatic, or short stature. Patients who had multiple nail removals represented patients with either sequential bone lengthening of the same segment or bone lengthening of multiple segments.

Nail removals were categorized regarding: site (femur/tibia/humerus); nail approach (antegrade/retrograde); nail type (FITBONE, PRECICE, STRYDE); and number of Poller screws.

Standard orthogonal radiographs immediately prior to nail removal were examined for bone abnormalities at the junction of the telescoping nail ends and in the area of interlocking and blocking screws/pegs. Bone abnormalities were categorized as osteolysis, periosteal reaction, cortical hypertrophy, or others. Where cortical thinning at the junction of the telescoping nail ends was observed, additional radiographs were evaluated in order to determine if this was due to the development of osteolysis over time, or if this was due to intramedullary reaming during nail insertion.

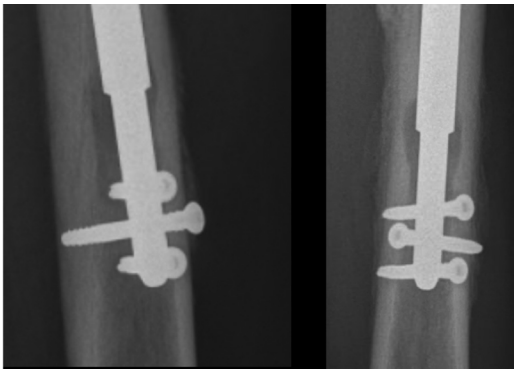

Fig. 1

Example of a STRYDE nail with focal osteolysis and periosteal reaction at the interface of telescoping nail segments.

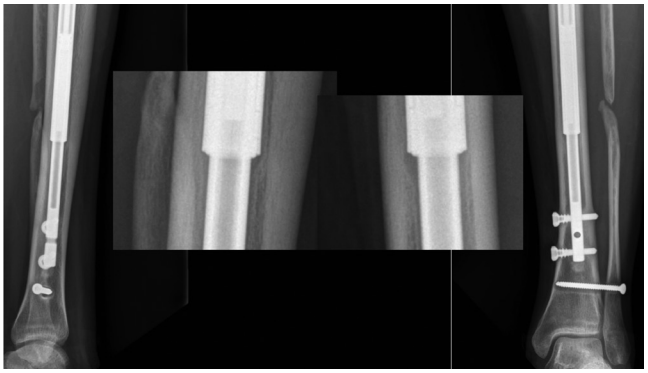

Fig. 2

The one PRECICE nail with bone abnormality (minimal osteolysis) at the interface of telescoping nail segments.

A total of 19 of the 26 radiological evaluations of the STRYDE nails reported in the current study have also been reported in a Danish nationwide cross-sectional study.[6]

Statistical analysis. Study data were collected and managed at each site. Microsoft Excel 2019 v. 16.45 (Microsoft, USA) was used for anonymized data fusion and descriptive analysis. Demographic data were described with absolute number (percentage) or means (standard deviation (SD) or range). A chi-squared test of independence was performed to examine the relation between nail type and the occurrence of bone abnormalities at the interface of the telescoping nail ends, and the relation between nail type and the occurrence of bone reaction at the locking screws. Degrees of freedom were 2, n = 366. The level of significance was set to 0.05.

Results

In total, 306 patients had 366 limb lengthening nails removed (44 at Nationwide Children's Hospital, 279 at Aalborg University Hospital, 43 at Aarhus University Hospital) and 366 radiographs prior to nail removals were examined in the present study. A total of 267 patients had one nail removal, while 39 patients accounted for 99 nail removals (two to six removals per patient). The demographic data are summarized in Table I. The mean time from nail insertion to radiological evaluation was 434 days (SD 381; 36 to 3,015), and for each of the examined nail types: FITBONE 481 days (SD 442; 36 to 3,015); PRECICE 357 days (SD 200; 58 to 1,095); STRYDE 292 days (SD 1,144; 107 to 593). The majority of the nails were FITBONE and the femur was the most predominant lengthened segment (Table II). One or more Poller screws were used in approximately one-third of the cases.

Table III highlights the differences in observed bone abnormalities at the interface of telescoping nail between the three different types of limb lengthening nails. Overall, 77% of STRYDE nails (20/26) had bone abnormalities at the interface compared with only 2% of FITBONE (4/242) and 1% of PRECICE nails (1/98; $p < 0.001$). In addition, the extent of bone abnormalities was more pronounced in the STRYDE nails compared with the other nails. For example, focal osteolysis at the interface was accompanied by periosteal reaction in many of the STRYDE nails (Figure 1; Table III). In contrast, osteolysis, which was observed in one PRECICE nail (Figure 2) and one FITBONE nail (Figure 3), was not accompanied by any other bone abnormalities at the interface.

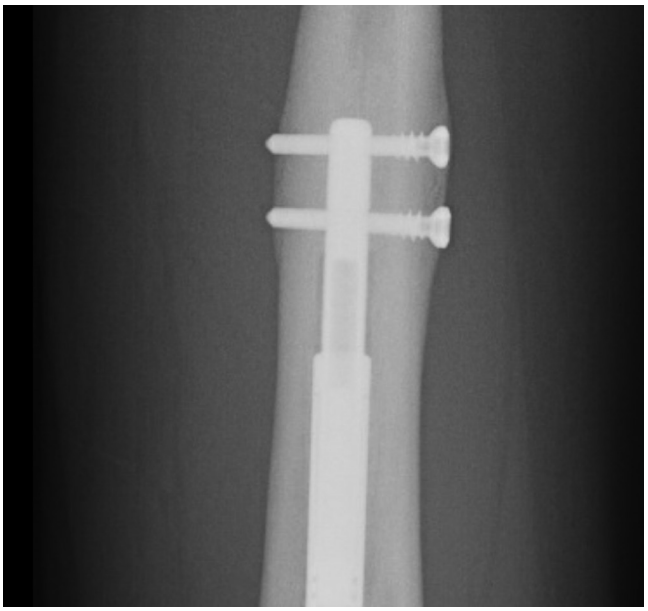

Fig. 4

PRECICE nail with cortical hypertrophy seen at the locking screw in the thin part of the nail.

The bone reaction around the interlocking screws/pegs occurred at the interlocking screw/peg in the thin part of the nail. The reaction was mainly cortical hypertrophy (Figures 3 and 4) and the frequency of bone reaction at the interlocking screw/peg was significantly higher for the FITBONE nail ($p = 0.035$, Table IV). In many of the patients bony overgrowth covering the interlocking screws/pegs were noticed. However, we did not observe any bone abnormalities related to Poller screws.

Discussion

In this retrospective analysis of 366 removed lengthening nails, a statistically significant difference was found between three

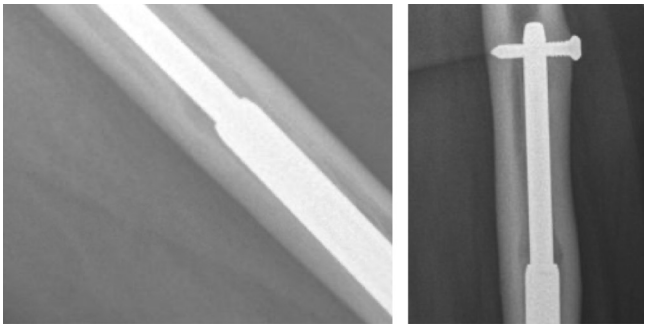

Fig. 3

The one FITBONE with bone abnormality (osteolysis) at the interface of telescoping nail segments. In addition, cortical hypertrophy is seen at the locking screw in the thin part of the nail.

of telescoping nail ends. Instead of a toxic reaction, cortical hypertrophy around the interlocking screws/pegs is likely to be caused by mechanical load stressing the bone as the load is transferred through the interlocking screw/peg. This hypothesis is supported by the fact that the FITBONE nail with only one interlocking screw, which often is situated in the diaphysis of the long bone, had cortical hypertrophy in 44% of patients (106/242) compared with 30% (29/98) with the PRECICE nail with more interlocking screw/peg options. The clinical implication of this cortical hypertrophy might be related to difficulties in removing these interlocking screws/pegs at the time of nail extraction due to bony overgrowth.

In a recent systematic review investigating complications with FITBONE or PRECICE lengthening nails, 122 device-related complications were found in 983 lengthened segments.[10]

Table IV. Bone reaction around the locking screw(s).

Bone reaction around locking screw(s)	Total (n = 366)	FITBONE (n = 242)	PRECICE (n = 98)	STRYDE (n = 26)
Total, n (%)	144 (39)	106 (44)	29 (30)	9 (35)
Cortical hypertrophy at the locking screw(s) in the thin part of the nail, n (%)	143 (39)	106 (44)	29 (30)	8 (31)
Focal osteolysis and periosteal reaction at the locking screw(s) in the thin part of the nail, n (%)	1 (0)	0 (0)	0 (0)	1 (4)

internal limb lengthening nails with regards to the presence of bone abnormalities at the interface of telescoping nail segments. Furthermore, the recently described bone abnormalities of osteolysis in conjunction with periosteal reaction at the interface of the STRYDE limb lengthening nail was not found in either FITBONE or PRECICE.[6,7] The reason why the combined osteolysis and periosteal reactions are confined to STRYDE is likely to be related to corrosion of the Biodur 108 alloy. In a recent retrieval study 20 out of 23 STRYDE nail showed visible signs of corrosion with micro-CT-verified corrosion attacks in 12 out of 12 scanned bushings.[9] Of clinical importance, the radiological osteolysis has been associated with the onset of pain and the presence of localized swelling.[6,7] Furthermore, the response of the bone showing intramedullary osteolysis and periosteal reaction was preceded by pain in patients. This resulted in a sudden loss of ability to fully weight-bear after solid consolidation had occurred.[6] In our study we found that one of 248 FITBONE nails, and one of 98 PRECICE nails, demonstrated osteolysis at the interface of the telescoping nail segments. The reasons for these radiological changes are speculative. Even though no periosteal reaction was seen, these osteolytic changes could be due to either infection or a toxic reaction to the nails. No retrieval studies were available for the FITBONE nail but despite the use of stainless steel, there might be a risk of corrosion. A retrieval analysis of the PRECICE intramedullary limb lengthening system has demonstrated internal corrosive debris of the early generation P1 designs, but no internal corrosion debris for the P2.2 designs, which were used in our study.[9]

In contrast to the high variation in bone abnormalities occurring at the interface of telescoping nail ends, the variation of cortical hypertrophy around the interlocking screws/pegs was less pronounced between the different nail types. This could indicate that different mechanisms are responsible for the bone reactions around the interlocking screw/peg and at the interface

None of the device-related complications were attributed to bone abnormalities at the interface of the lengthening nails. Other papers focusing on complications of limb lengthening nails do not report this complication.[4,11–13] Iliadis et al[7] reviewed radiologically 192 patients undergoing limb lengthening with the PRECICE nail at three and six months following lengthening and at full regenerative consolidation. These authors were unable to find evidence of osteolysis or cortical thickening at the sliding junction at any of the radiological timepoints.[7] For the STRYDE nail, radiological changes primarily occurred during the consolidation time.[6,7]

To our knowledge, our study is the first to evaluate the radiological changes with the FITBONE nail, and it is unknown at what timepoint potential changes would occur. We have evaluated the radiological appearances around lengthening nails at the time of nail removal, as this allowed us to examine the longest possible effect of the nail on the bone. We would suggest that it is unlikely that the radiological changes of osteolysis and periosteal reaction occurring at any time of nail treatment would disappear spontaneously prior to the final radiograph at the time of nail removal. We also chose only to report on the radiological appearances, in this large retrospective series, where nail removals occurred as early as 2006. It is only recently that we have become aware of the possibility of bone abnormalities at the interface of the telescoping nail ends, and over the last 15 years we have not looked for more subtle symptoms of pain or swelling related to such radiological changes. This constitutes the major limitation of our study. Nonetheless, the large number of evaluated radiographs of limb lengthening nails (n = 366 (242 FITBONE + 98 PRECICE + 26 STRYDE)), followed up until removal is unprecedented in the literature and reflects the strength of our study. Overall, 19 out of the 26 STRYDE nails in our review have previously been reported in

a nationwide Danish cross-sectional study.[6] In the current study, the 19 nails were all followed up to nail removal, allowing us to make comparisons between different nail designs. In particular, the centre in the USA reported similar observations regarding STRYDE, which compared favourably with the previous observations at Danish centres and one large UK centre, thus externally validating the findings of those studies.[6,7]

It is clear that the accuracy of the estimated incidence of radiological changes depends on the number of evaluated nails. The estimates are thus most accurate for FITBONE and slightly less accurate for PRECICE, due to the lower number of evaluated nails. From a clinical perspective, we recommend careful evaluation of the radiographs of all limb lengthening nails in the outpatient clinic. In line with previous studies, our study adds to the body of evidence reporting high numbers of osteolysis and periosteal reaction with the STRYDE nail.[6,7] Our results regarding PRECICE P2.2 also highlight the generalizability of the recent study by Iliadis et al[7] reporting no signs of osteolysis or periosteal reaction with PRECICE nails in 192patients from a single centre. Out of 98 PRECICE nails at the three centres in the present study, one PRECICE nail demonstrated minimal osteolysis without periosteal reaction. Out of 242 FITBONE nails at two centres in our study, one FITBONE nail demonstrated minimal osteolysis without periosteal reaction. However, bone abnormalities at the interface of telescoping nail parts were seen in the majority of STRYDE nails, but only in 1% to 2% of FITBONE or PRECISE nails. Also, in the latter two lengthening nails, no combination of osteolysis and perosteal reaction was observed.

Hence, based both on the current literature and on our findings, the observed radiological changes at the telescoping junction and clinical safety concerns regarding the use of the STRYDE nail do not apply to the other evaluated limb lengthening nails.[6,7] We therefore conclude that the low prevalence of radiological changes at the junctional interface of 242 evaluated FITBONE and 98 evaluated PRECICE nails at the time of nail removal does not warrant clinical concern.

Take home message

- Bone abnormalities at the interface of telescoping nail parts were seen in the majority of STRYDE nails.
- In contrast, the low prevalence of radiological changes at the junctional interface of 242 evaluated FITBONE and 98 evaluated PRECICE nails at the time of nail removal does not warrant clinical concern.

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