



■ GENERAL ORTHOPAEDICS

Focal osteolysis and corrosion at the junction of Precice Stryde intramedullary lengthening device

PRELIMINARY CLINICAL, RADIOLOGICAL, AND METALLURGIC ANALYSIS OF 57 LENGTHENED SEGMENTS

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Aims

This study aims to enhance understanding of clinical and radiological consequences and involved mechanisms that led to corrosion of the Precice Stryde (Stryde) intramedullary lengthening nail in the post market surveillance era of the device. Between 2018 and 2021 more than 2,000 Stryde nails have been implanted worldwide. However, the outcome of treatment with the Stryde system is insufficiently reported.

Methods

This is a retrospective single-centre study analyzing outcome of 57 consecutive lengthening procedures performed with the Stryde nail at the authors' institution from February 2019 until November 2020. Macro- and microscopic metallographic analysis of four retrieved nails was conducted. To investigate observed corrosion at telescoping junction, scanning electron microscopy (SEM) and energy dispersive x-ray spectroscopy (EDX) were performed.

Results

Adjacent to the nail's telescoping junction, osteolytic changes were observed in bi-planar radiographs of 20/57 segments (35%) after a mean of 9.5 months (95% confidence interval 7.2 to 11.9) after surgery. A total of 8/20 patients with osseous alterations (40%) reported rest and ambulation pain of the lengthened segment during consolidation. So far, 24 Stryde nails were retrieved and in 20 (83%) macroscopic corrosion was observed at the nail's telescoping junction. Before implant removal 11/20 radiographs (55%) of lengthened segments with these 20 nails revealed osteolysis. Implant retrieval analysis by means of SEM showed pitting and crevice corrosion. EDX detected chromium as the main metallic element of corrosion.

Conclusion

Patients are exposed to the risk of implant-related osteolysis of unclear short- and long-term clinical consequences. The authors advocate in favour of an early implant removal after osseous consolidation.

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Article focus

■ Preliminary clinical, radiological, and metallurgic analysis of 57 segments lengthened with the Precice Stryde (Stryde) system.

■ Investigation of implant-related osteolysis and corrosion of the Stryde nail.

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Key messages

- To date, 24/57 Stryde nails (42%) have been removed and macroscopic signs of corrosion were identified in 20/24 implants (83%).
- Implant-specific osteolysis was found in 20/50 patients (40%); 8/20 patients with osteolysis (40%) complained about persistence or new onset of rest and ambulation pain during the consolidation period.
- Patients are exposed to the risk of implant-related osteolysis of unclear short- and long-term clinical consequences.

Strengths and limitations

- First single-centre study that provides clinical and radiological findings as well as metallurgical implant retrieval analysis after 57 consecutive lengthenings with the Stryde nail.
- At the time of submission, not all Stryde nails were explanted and only a small number of implants had undergone metallographic analysis.
- The exact mechanisms involved in the corrosion process remain to be identified.

Introduction

Intramedullary lengthening nails (ILNs) for bone lengthening have undergone a striking development in recent years and have become an established alternative to external fixators.^{1,2} While primary ILNs relied on mechanical distraction mechanisms,^{3,4} motorized drive systems have been developed.⁵⁻⁷ In particular, magnetically driven ILNs have become increasingly popular over the last decade.⁸⁻¹³ The Precice Stryde (Stryde) nail (NuVasive Specialized Orthopedics, USA) was approved by the USA Food and Drug Administration in April 2018 and received European CE certification in February 2019. The major difference in comparison to precedent implants such as the second-generation Precice ILN (P2) (NuVasive Specialized Orthopedics),¹⁴ the intramedullary skeletal kinetic distractor (Orthofix, USA),⁴ or the Fitbone nail⁵ (Orthofix) lies in the change of implant design and material. The Stryde nail is composed of Biodur stainless steel (Fort Wayne Metals Research Products Corp, USA) and designed with a modified distraction mechanism to enable full weightbearing during lengthening.¹⁵ However, there is a lack of studies which have analyzed treatment with the Stryde nail in large patient cohorts. In January 2021, the manufacturer took the Stryde system off market and released a field safety notice since issues of biocompatibility and implant-related complications were observed. Safety concerns were raised by medicine and healthcare product regulatory agencies in Europe and the UK.^{16,17}

Corrosion of the Stryde nail and implant-related osteolysis have recently been reported.^{18,19}

To further investigate these observations, this study provides clinical and radiological information about treatment with the Stryde nail supported by metallographic analysis. Potential causes of corrosion were analyzed by means of scanning electron microscopy (SEM) and energy dispersive x-ray analysis (EDX).

Methods

Patients and indications. All patients treated with the Stryde nail from April 2019 until November 2020 at the authors' institution were retrospectively analyzed. A total of 50 patients (19 female) with a median age at time of surgery of 16.5 years (range 10.1 to 49.8) were identified. There were 57 Stryde nails (38 femoral, 19 tibial) implanted (Table I) of which 43 operations (30 femoral, 13 tibial) were conducted for correction of leg length discrepancy (LLD). In seven patients with disproportionate short stature (DSS), bilateral treatments (four femoral, three tibial) were performed (Table II). To date 24/57 nails (42%) have been explanted. The median follow-up period was 12.2 months (range 3 to 22). No patient was lost to follow-up.

Clinical and radiological evaluation. Clinical information was acquired from the hospital records. All treatment-related radiographs were analyzed. This included biplanar radiographs taken every second week under distraction and anteroposterior long standing radiographs obtained preoperatively and after consolidation. Besides the type and frequency of oral analgesics pain was assessed on the numeric rating scale (NRS) (0 = no pain, 10 = worst pain). The following limb lengthening parameters were determined as previously described: LLD, distraction index, consolidation index, reliability, accuracy, and precision.^{6,10,12} All measurements were conducted on calibrated radiographs with the picture archiving and communication system (PACS) system (GE Healthcare, USA).

Surgical technique. The surgical technique is described in the supplementary file of this manuscript. Details about implant features are listed in Table III.

Implant analysis. In 20/24 retrieved Stryde nails (83%), macroscopic corrosion was observed mainly at the nail's telescoping junction but also at the bolts and corresponding locking holes (Figures 1 to 3, Table IV). To further investigate these findings, the following analysis of the retrieved implants was conducted.

Macroscopic classification of corrosion at the Stryde nail's telescoping junction. All explanted implants were intraoperatively analyzed by the first and senior authors (AF and BV), and changes at the Stryde nail's junction were subclassified as depicted in Figure 1.

Microscopic analysis. In three implants with (patients no. 3, 12, and 39) and in one nail without macroscopic evidence of corrosion (patient no. 47), a Sony α 58 camera (Sony AG, Japan) was used for standardized documentation and microscopic analysis was performed using a KEYENCE VHX-600 digital microscope (Keyence, Japan)

Table 1. Patient demographics and parameters of distraction osteogenesis.

Variable	LLD			DSS			LLD + DSS		
	Femur	Tibia	Total	Femur	Tibia	Total	Femur	Tibia	Total
No. of patients	30	13	43	4	3	7	34	16	50
Sex (male/female), n	19/11	8/5	27/16	3/1	1/2	4/3	22/12	9/7	31/19
Median age, yrs (range)	14.8 (10.1 to 49.8)	19.2 (13.3 to 45.0)	16.3 (10.1 to 49.8)	18.5 (17.4 to 22.6)	18.3 (16.2 to 26.1)	18.3 (16.2 to 26.1)	15.1 (10.1 to 49.8)	18.8 (13.3 to 45.0)	16.5 (10.1 to 49.8)
Mean body height, cm (95% CI)	165.9 (140 to 188)	172.4 (155 to 198)	167.8 (140 to 198)	151.8 (140 to 158)	149.0 (142 to 160)	150.6 (140 to 160)	164.2 (140 to 188)	168.0 (142 to 198)	165 (162 to 169)
Median body weight, kg (range)	63.5 (32 to 85)	65.0 (42 to 137)	65.0 (32 to 137)	55.5 (40 to 82)	53.0 (45 to 62)	53.0 (40 to 82)	62.5 (32 to 85)	61.0 (42 to 137)	62.0 (32 to 137)
Median BMI, kg/m ² (range)	22.1 (16.3 to 27.1)	23.5 (17.4 to 41.8)	22.8 (16.3 to 41.8)	23.5 (20.0 to 32.8)	24.2 (21.4 to 26.3)	24.2 (20.0 to 32.8)	22.1 (16.3 to 32.8)	23.7 (17.4 to 41.8)	22.8 (16.3 to 41.8)
No. of lengthened segments / implanted nails	30	13	43	8	6	14	38	19	57
Median LLD before surgery, mm (range)	35 (20 to 80)	47 (24 to 94)	37 (20 to 94)	n/a	n/a	n/a	35 (20 to 80)	47 (24 to 94)	37 (20 to 94)
Median gained leg length in DSS, mm (range)	n/a	n/a	n/a	61.5 (55 to 65)	50.0 (47 to 50)	55.0 (47 to 65)	60.8 (55 to 65)	49.0 (47 to 50)	55.0 (47 to 65)
Median planned distraction distance, mm (range)*	35.0 (20 to 65)	50.0 (30 to 65)	36.0 (20 to 65)	60.0 (60 to 65)	50.0 (50 to 65)	60.0 (50 to 65)	41.0 (20 to 65)	50.0 (30 to 65)	47.5 (20 to 65)
Median achieved distraction distance, mm (range)*	36.0 (20 to 67)	49.0 (27 to 66)	36.5 (20 to 67)	61.5 (55 to 65)	50.0 (47 to 50)	55.0 (47 to 65)	41.0 (20 to 67)	50.0 (27 to 66)	46.0 (20 to 67)
Median distraction period, days (range)*	42.5 (27 to 81)	78.5 (40 to 134)	51.5 (27 to 134)	75.0 (55 to 98)	85.0 (77 to 113)	75.0 (55 to 113)	49.0 (27 to 98)	83.0 (40 to 134)	55.5 (27 to 134)
Mean distraction index, mm/day (95% CI)*	0.81 (0.77 to 0.85)	0.58 (0.51 to 0.65)	0.74 (0.69 to 0.79)	0.84 (0.72 to 0.95)	0.56 (0.48 to 0.64)	0.72 (0.62 to 0.82)	0.82 (0.78 to 0.86)	0.57 (0.52 to 0.62)	0.74 (0.69 to 0.78)
No. of segments finished distraction (%)*	28 (93)	12 (92)	40 (93)	8 (100)	6 (100)	14 (100)	36 (95)	18 (95)	54 (95)
No. of segments with complete osseous consolidation (%)†	27 (90)	11 (85)	38 (88)	6 (75)	5 (83)	12 (86)	33 (87)	16 (84)	49 (86)
Median consolidation period, days (range)†	101.0 (68 to 220)	139.0 (86 to 221)	103.5 (68 to 221)	195.0 (118 to 262)	200.0 (157 to 239)	195.0 (118 to 262)	109.0 (68 to 262)	157.0 (86 to 239)	118.0 (68 to 262)
Median consolidation index, days/cm (range)†	27.9 (16.2 to 59.0)	29.0 (26.0 to 55.7)	28.4 (16.2 to 59.0)	32.5 (19.7 to 43.7)	40.0 (31.4 to 47.8)	32.5 (19.7 to 47.8)	28.1 (16.2 to 59.0)	31.5 (26.0 to 55.7)	30.4 (16.2 to 59.0)
Median LLD at final follow-up, mm (range)	-0.5 (-22 to 30)	2.5 (-12 to 46)	0 (-22 to 46)	n/a	n/a	n/a	-0.5 (-22 to 30)	2.5 (-12 to 46)	0 (-22 to 46)
No. of explanted nails (%)	14 (47)	6 (46)	20 (47)	0 (0)	4 (67)	4 (29)	14 (37)	10 (53)	24 (42)
Median follow-up, mths (range)†	11.5 (3 to 21)	9.8 (3 to 22)	12.2 (3 to 22)	8.7 (7 to 17)	15.5 (7 to 21)	12.1 (7 to 21)	12.3 (3 to 21)	10.5 (3 to 22)	12.2 (3 to 22)

*Calculations only for segments that finished distraction with the lengthening nail in situ (54/57 segments (95%)).

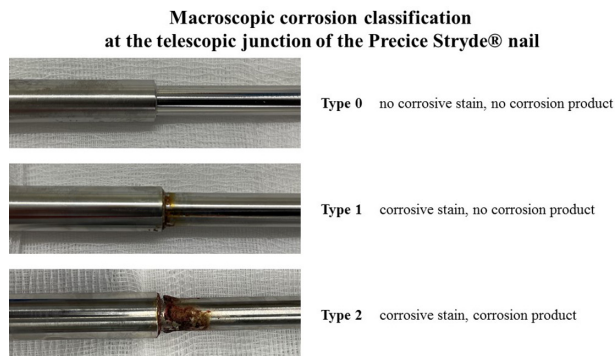
†Calculations only for segments that consolidated with the lengthening nail in situ (49/57 segments (86%)).

CI, confidence interval; DSS, disproportionate short stature; LLD, leg length discrepancy; n/a, not applicable.

Table II. Aetiologies of the study cohort.

Aetiology	Data (n = 50)
LLD, n	43
Idiopathic, n (%)	11 (26)
Congenital, n (%)	12 (28)
Acquired, n (%)	20 (47)
DSS, n	7
Idiopathic, n (%)	5 (71)
Congenital, n (%)	2 (29)

DSS, disproportionate short stature; LLD, leg length discrepancy.

**Fig. 1**

This classification system aims to standardize reporting of corrosion at the junction of the Stryde nail and can be employed immediately after implant removal. It is based on obvious macroscopic features.

up to a magnification of 50× and an EVO MA10 Scanning Electron Microscope (Carl Zeiss Microscopy, Germany) up to a magnification of 4000×.

Additional SEM analysis was conducted in one device with macroscopic evidence of corrosion (patient no. 3) with an accelerating voltage of 20 kV and a working distance (distance from the final pole piece of the lens to the sample when the image is in focus) of 12.5 mm, 12.0 mm, or 9.5 mm.

First, analysis of the explanted Stryde nails was performed without destructive preparation. In a second step, the region of interest at the telescopic junction was cut open, while meticulous caution was given to avoid changes of microstructure due to heat generation. Analysis was performed with a safe margin to the cutting surfaces to guarantee results without preparational influence. In a third step, the cross-section of the area with corrosive attack was metallographically mounted, ground, and polished prior to further microscopic analysis.

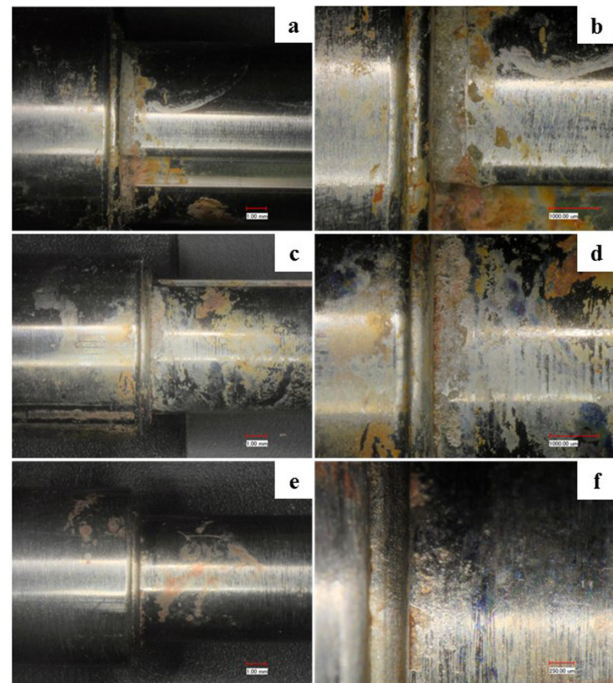
Energy dispersive x-ray analysis. The elemental composition of the corrosion product at the Stryde nail's telescopic junction was assessed via EDX using a XFLASH 6|10 detector (Bruker, USA).

Statistical analysis. All statistical tests were conducted using SPSS v27 (IBM, USA). Normal distribution of the

Table III. Implant information.

Femur	LLD	DSS	Total	Tibia	LLD	DSS	Total
PS10.0-50D235	13	0	13	PS10.0-50S 235	6	4	10
PS10.0-65D250	2	0	2	PS10.0-80S 265	2	0	2
PS10.0-80D265	3	6	9	PS11.5-50S 235	3	0	3
PS10.0-80D280	1	0	1	PS11.5-80S 265	1	2	3
PS10.0-80D305	1	0	1	PS11.5-80S 280	1	0	1
PS11.5-50D235	5	0	5				
PS11.5-80D335	0	2	2				
PS13.0-50D235	5	0	5				
Total	30	8	38	Total	13	6	19

DSS, disproportionate short stature; LLD, leg length discrepancy.

**Fig. 2**

Images of the corrosive attack at the nail's telescopic junction taken with digital microscope at 20× (left column) and 50× magnification (right column). The retrieved implants from: a) and b) patient no. 12; c) and d) no. 47; and e) and f) no. 39 are depicted. All analyzed implants revealed a corrosive attack at the telescopic junction of the nail.

measurements was verified by the Shapiro-Wilk test. Descriptive statistics were performed using mean and 95% confidence interval (CI) for normally distributed and median and range (minimum/maximum) for non-normally distributed continuous variables. Numbers and percentages are presented for binary variables.

Results

Lengthening parameters. At the time of manuscript submission, distraction was completed in all treated segments (57/57, 100%). The lengthening procedure was finished with the Stryde nail remaining in situ until the end of distraction in 54/57 segments, showing a reliability of 95%. The median LLD reduced from 37 mm (range 20 to 94) before surgery to 0 mm (range -22 to



Fig. 3

Corrosion of the a) distal locking holes and b) corresponding bolts of patient no. 39. Osteolysis was observed in bi-planar radiographs six months after surgery. The patient reported rest and ambulation pain during the consolidation period.

46) after surgery. In DSS patients, the median gain in leg length measured 55 mm (range 47 to 65). The median achieved distraction distance was 46 mm (range 20 to 67). Accuracy and precision of distraction were calculated at 96% and 93%, respectively. The mean distraction index was 0.74 mm/day (95% CI 0.69 to 0.78). Osseous consolidation has been documented in 49/57 segments (86%). The median consolidation index was 30.4 days/cm (range 16.2 to 59.0) (Table I). A total of 6/57 nails (11%) were prematurely explanted due to osteomyelitis ($n = 2$) and nail dislocation ($n = 1$) during distraction, and due to nonunion ($n = 3$) during consolidation. To date, 18/57 nails (32%) were routinely removed according to the treatment plan after complete consolidation. **Clinical and radiological outcome.** A total of 19/50 patients (38%) completed the course of treatment without clinical or radiological peculiarities. They reported no or moderate pain (NRS 0 to 3) of the lengthened segment which was relieved by oral non-steroidal anti-inflammatory drugs (NSAIDs) taken once or twice per week during distraction. Symptoms fully regressed after osseous consolidation (Table V).

Newly occurring and persistent limitation of range of motion of the knee or ankle joint after distraction was observed in 4/50 patients (8%). While range of motion was restored by conservative treatment in two patients, the two other patients required retraction of the nail or premature abrupture of distraction, respectively.

Revision surgery was necessary in 10/57 lengthened segments (18%) (Table VI). In 2/50 patients (4%) implant

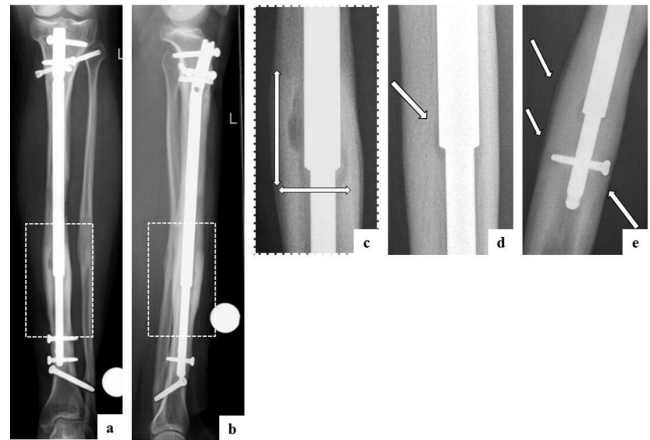


Fig. 4

a) Anteroposterior (AP) and b) lateral radiographs of the left tibia of patient no. 3 (female 16 years, postoperative at 11 months), who presented with pain and new lytic-hypertrophic osteolysis adjacent to the telescopic junction of the Stryde nail nine months after the end of distraction. c) Close-up of the geographical osteolysis on an AP radiograph with calibrated measurement of 30 mm × 17 mm and thickening of the cortical bone. d) and e) AP radiographs of different cortical reactions: d) lytic only (patient no. 20, male, 16 years, postoperative at 18 months) and e) periosteal reaction and thickening distally level with the locking bolts (patient no. 6, male, 18 years, postoperative at nine months).

removal, application of external fixators, and antibiotic treatment were required due to osteomyelitis. The desired amount of lengthening was achieved in both patients via external fixator. In three patients with nonunion, the lengthening nail was exchanged to a trauma nail. To date, complete osseous consolidation has been documented in both segments with previous infection and in 2/3 segments (67%) with previous nonunion.

Pain. During distraction, 16/50 patients (32%) reported pain of the lengthened segment which was not relieved by oral NSAIDs taken up to four times a day (NRS 1 to 3: $n = 9$; NRS 4 to 7: $n = 5$; NRS 8 to 10: $n = 2$). Out of this subgroup 2/16 patients (13%) presented for consultation out of the planned routine (reported pain 5 and 8 on NRS) and bi-planar radiographs revealed osteolytic changes adjacent to the nail's telescoping junction during distraction (Table IV).

During consolidation, 14/50 patients (28%) were found with persistent (8/14, 57%) or newly occurring (6/14, 43%) rest and ambulation pain of the lengthened segment (NRS 1 to 3: $n = 6$; NRS 4 to 7: $n = 6$; NRS 8 to 10: $n = 2$). This led to presentation in the outpatient department and additional unplanned radiographs. In 8/14 patients (57%), osteolytic alterations of the bone were detected in bi-planar radiographs next to the Stryde nail's telescopic junction (NRS 1 to 3: $n = 2$; NRS 4 to 7: $n = 4$; NRS 8 to 10: $n = 2$). A total of 5/16 patients (31%) with suspected osteomyelitis due to detected osteolysis at the telescopic junction were treated with oral antibiotics, which did not help to relieve symptoms. Finally, implant removal led to immediate pain relief in all affected patients.

Table IV. Clinical, radiological, and metallographic data of patients with osteolysis and/or implant removal. Patients who did not complete lengthening with the Stryde nail in situ are listed in parentheses.

No.	Sex	Age, years	Body height, cm	Body weight, kg	Indication	Achieved distraction, mm	Distraction index, mm/day	Consolidation index, mths/cm	Type of osteolysis	Time between osteolysis and implantation, mths	Time between osteolysis and end of distraction, mths	Pain during distraction	Pain during consolidation	Full weight bearing during distraction	Full weight bearing during consolidation	Time between removal and implantation, mths	Time between removal and consolidation, mths	Type of corrosion	Serum levels of metal ions	Type of membrane biology
2	m	19.5	168	54	LLD	50	0.66	44.2	lytic only	11	8	no	yes	yes	yes	12	5	1	n/a	n/a
3*	f	16.2	145	45	DSS	47	0.59	31.4	lytic-hypertrophic	11	9	yes	yes	no	no	12	7	2/2	n/a	n/a
4	m	13.2	177	80	LLD	45	1.18	19.0	none	n/a	n/a	no	no	yes	yes	19	16	1	n/a	n/a
5	f	16.3	155	42	LLD (49)	30	n/a	n/a	osteomyelitis	n/a	n/a	yes	(no)	yes	(yes)	3	n/a	2	n/a	n/a
6	m	17.6	180	79	LLD	30	0.75	34.3	lytic only	9	8	no	yes	yes	yes	10	6	1	n/a	positive
7	m	15.0	180	85	LLD (68)	30	n/a	n/a	osteomyelitis	n/a	n/a	yes	(no)	no	(yes)	5	n/a	1	n/a	positive
8	f	13.0	152	40	LLD	43	0.75	27.3	none	n/a	n/a	no	no	yes	yes	9	5	1	n/a	n/a
10†	f	26.1	142	53	DSS	50	0.65	47.8	none	n/a	n/a	yes	no	no	yes	21	13	0/0	normal	1/1
11	f	41.4	165	65	LLD	48	0.75	28.6	none	n/a	n/a	yes	yes	no	no	13	8	1	n/a	n/a
12††	m	39.0	175	75	LLD	36	0.74	28.1	lytic-hypertrophic	20	18	yes	yes	no	no	20	16	2	normal	1
13	m	18.4	185	78	LLD	37	0.68	30.4	none	n/a	n/a	yes	no	yes	yes	11	9	1	n/a	n/a
14	m	18.9	162	62	LLD	26	0.76	29.2	none	n/a	n/a	no	no	yes	yes	14	12	1	n/a	n/a
15	f	13.8	162	55	LLD	23	0.81	40.4	lytic-hypertrophic	10	9	no	no	yes	yes	11	8	1	n/a	n/a
16†	m	12.0	140	32	LLD	45	0.82	21.6	lytic only	13	11	no	no	yes	yes	20	16	1	normal	1
17	m	17.4	154	63	DSS	60	0.79	19.7	lytic-hypertrophic	8	5	no	no	yes	yes	n/a	n/a	n/a	n/a	n/a
20†	m	15.8	165	73	LLD	21	0.66	35.2	lytic-hypertrophic	18	17	no	no	yes	yes	19	16	1	normal	1
21	m	13.8	162	50	LLD	24	0.74	39.6	lytic-hypertrophic	14	13	no	no	yes	yes	n/a	n/a	n/a	n/a	n/a
22	f	14.9	160	50	LLD	65	0.80	25.4	lytic only	12	9	no	no	yes	yes	n/a	n/a	n/a	n/a	n/a
24	m	13.3	165	50	LLD	30	0.83	26.7	lytic-hypertrophic	12	11	yes	yes	no	no	12	10	1	n/a	n/a
27†	m	29.8	165	67	LLD	48	0.75	26.0	lytic-hypertrophic	17	14	yes	yes	no	no	17	12	2	normal	1
28†	f	23.3	169	65	LLD	50	0.62	27.8	lytic only	9	6	yes	no	no	yes	15	11	1	normal	1
30	f	12.3	164	52	LLD	28	0.82	27.9	lytic-hypertrophic	3	1	no	no	no	yes	n/a	n/a	n/a	n/a	n/a
32	m	19.0	185	75	LLD	25	0.78	52.0	lytic only	4	3	no	no	yes	yes	n/a	n/a	n/a	n/a	n/a
34†	m	37.9	180	102	LLD	66	0.64	28.8	none	n/a	n/a	no	no	no	yes	10	4	0	normal	1
35	f	14.7	160	56	LLD	36	0.80	n/a	none	n/a	n/a	yes	yes	no	no	7	n/a	1	n/a	n/a
36	f	22.6	140	40	DSS	63	0.81	n/a	lytic only	1	-1	yes	yes	yes	yes	n/a	n/a	n/a	n/a	n/a
39*,†	f	14.0	168	67	LLD	50	0.89	39.0	lytic-hypertrophic	7	5	no	yes	no	no	7	1	2	normal	1
41	m	16.5	181	137	LLD	55	0.46	29.0	lytic-hypertrophic	6	1	no	no	no	yes	n/a	n/a	n/a	n/a	n/a
46	f	19.2	168	54	LLD	30	0.58	26.9	lytic only	2	0	no	no	no	no	n/a	n/a	n/a	n/a	n/a
47*	m	34.7	145	45	LLD (60)	60	n/a	n/a	none	n/a	n/a	no	(no)	yes	(no)	3	n/a	0	n/a	n/a
50	f	13.3	155	65	LLD	43	0.88	16.2	lytic only	4	2	no	no	yes	yes	n/a	n/a	n/a	n/a	n/a

*Documentation using a Sony camera (Sony AG, Japan) and microscopic analysis using a KEENCE VHX-600 digital microscope (Koence, Japan) up to a magnification of 50x. †Serum analysis (cobalt, chromium, and manganese) as well as histological analysis from intramedullary reaming obtained during nail explanation. DSS, disproportionate short stature; LLD, leg length discrepancy; n/a, not applicable.

Table V. Clinical, radiological, and implant-related outcomes.

Outcome parameter	Osteolysis, n (%) (n = 20)	Osteomyelitis, n (%) (n = 2)	No osseous alteration, n (%) (n = 35)	Total, n (%) (n = 57)
Pain during distraction	6 (30)	2 (100)	8 (23)	16 (28)
Pain during consolidation	8 (40)	0 (0)	6 (17)	14 (25)
Full weightbearing during distraction	11 (55)	1 (50)	14 (40)	26 (46)
Full weightbearing during consolidation	16 (80)	2 (100)	21 (60)	39 (68)
Additional analgetic medication	6 (30)	2 (100)	3 (9)	11 (19)
Additional antibiotic medication	4 (20)	2 (100)	1 (3)	7 (12)
Additional radiological imaging	7 (35)	2 (100)	4 (11)	13 (23)
Hardware failure	6 (30)	0 (0)	2 (6)	7 (12)

Table VI. Reasons for revision surgery per lengthened segment.

Type of complication	Data (n = 57)
Dislocation of proximal tibiofibular screw	2 (4)
Dislocation of the nail	1 (2)
Delayed consolidation/nonunion (exchange to trauma nail)	3 (5)
Premature consolidation	2 (4)
Osteomyelitis	2 (4)

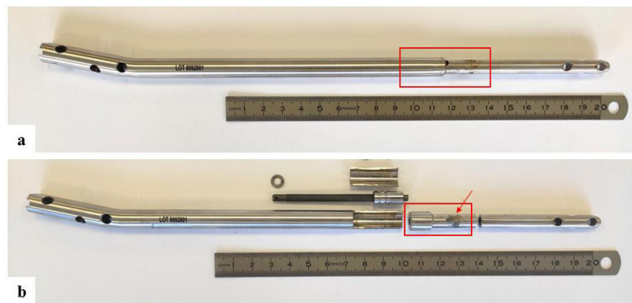


Fig. 5

a) Explanted Stryde nail (patient no. 3). The red box indicates the area affected by corrosive changes at the telescopic junction. b) Disassembled Stryde nail with cut sections at the telescopic junction. The red box indicates the region of interest for further microscopical analysis. The red arrow points at the corrosive material loss, which is shown in Figures 6 to 8 in higher magnification (b). Images taken with a Sony α58 camera (Sony AG, Japan).

Osseous alterations in bi-planar radiographs. Newly occurring osteolytic changes level with the Stryde nail’s telescoping junction were found in 20/57 lengthened segments (35%) (Figure 4).

The incidence and different types of osteolytic changes (lytic only, lytic-hypertrophic) are depicted in Tables IV and VII. These osseous alterations were seen postoperatively after a mean of 9.5 months (95% CI 7.2 to 11.9) and a mean of 7.1 months (95% CI 4.9 to 9.4) after the end of distraction (Tables IV and VII).

Inflammatory blood parameters. Under distraction CRP and white blood cell count were available in 15/50 patients (30%). They were elevated in the two patients with osteomyelitis but found within physiological ranges in the other 13/15 patients (87%) (Table IV). In 9/13 patients (69%) osteolytic changes were observed (Table IV).

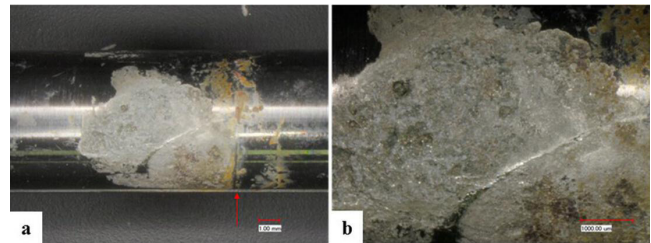


Fig. 6

Images of the corrosive attack at the nail’s telescopic part taken with digital microscope at a) 20× and b) 50× magnification, respectively (patient no. 3, female, 16 years). The red arrow indicates the position of the telescopic junction prior to lengthening. Absence of corrosion in the area not connected to the crown. The nail was removed after osseous consolidation 12 months postoperatively.

Implant retrieval analysis. At the time of manuscript submission, 24/57 Stryde nails (42%) had been removed. Macroscopic signs of corrosion were observed in 20/24 explanted Stryde nails (83%), especially at the nail’s telescopic junction, the distal locking holes, and corresponding bolts (Figures 1 to 3). Before implant removal, 11/20 radiographs (55%) of lengthened segments with these 20 nails revealed implant-related osteolysis.

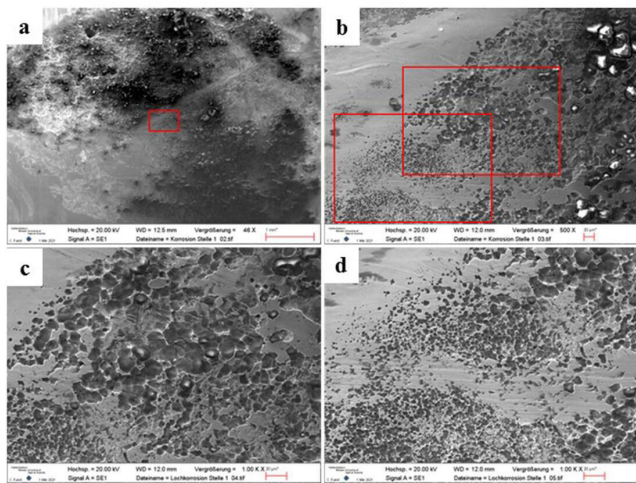
Digital macro- and microscopy, scanning electron microscopy, and energy dispersive x-ray analysis. So far, four Stryde nails were analyzed (patients no. 3, 12, 39, and 47). Figures 2, 5 and 6 illustrate that all analyzed implants are subjected to a comparable corrosive attack even if the extent might vary.

Three nails showed macro- and microscopic signs of corrosion at the telescopic junction and partially corrosive-like material loss at the piston distal or close to the junction (Figures 2 and 6). In one nail corrosion was only detectable by microscopic examination (Figures 2e and 2f). The implant of patient no. 3 was chosen for further metallographic analysis. A higher magnification illustrated that the area is subject to a corrosive attack with typical trough-shaped loss of material (Figures 6 to 8). The cross-section depicts that this loss of material is caused by the corrosive attack since the corrosion product was detected on the Biodur 108 surface (Figure 9). EDX analysis detected chromium as the main metallic element of the corrosion deposits. No intercrystalline corrosive attack took place along the grain boundaries.

Table VII. Osteolytic changes adjacent to the Stryde nail's telescopic junction observed in biplanar radiographs.

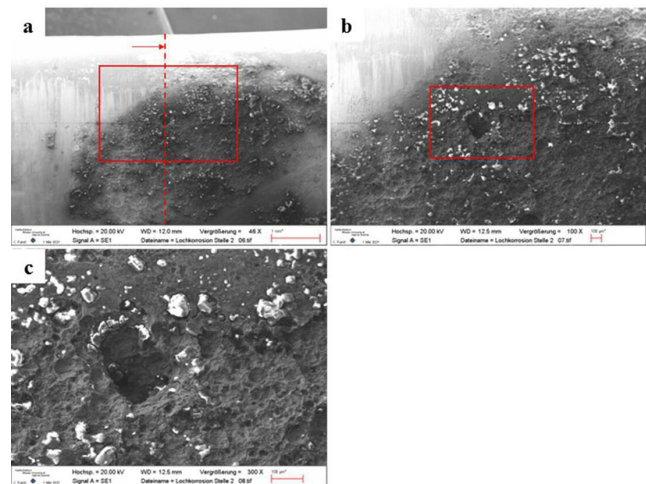
Variable	LLD			DSS			LLD + DSS		
	Femur	Tibia	Total	Femur	Tibia	Total	Femur	Tibia	Total
Osteolysis, n (%)	12 (40)	5 (38)	17 (40)	2 (25)	1 (17)	3 (21)	14 (37)	6 (32)	20 (35)
Mean time period from surgery to osteolysis, mths (95% CI)	11.1 (7.8 to 14.4)	7.4 (4.2 to 10.5)	10.0 (7.4 to 12.6)	4.5 (-1.8 to 10.7)	11.3	6.8 (1.0 to 12.5)	10.2 (7.0 to 13.3)	8.0 (5.1 to 10.9)	9.5 (7.2 to 11.9)
Mean time period from end of distraction to osteolysis, mths (95% CI)	9.6 (6.3 to 12.8)	4.8 (1.5 to 8.2)	8.2 (5.5 to 10.8)	2.0 (-1.6 to 5.5)	8.5	4.2 (0.6 to 7.7)	7.7 (4.6 to 10.7)	5.9 (3.2 to 8.5)	7.1 (4.9 to 9.4)

CI, confidence interval; DSS, disproportionate short stature; LLD, leg length discrepancy; n/a, not applicable.

**Fig. 7**

Corrosive attack at the nail's telescopic part (see Figure 6). Images taken by scanning electron microscopy (SEM). a) 46× magnification with marked area that is shown at 500× magnification in image b). The marked areas of image b) are shown at 1000× magnification in images c) and d). The effect of corrosion can be observed in the trough-shaped loss of material at the nail's telescopic part. Image a) was taken at a working distance of 12.5 mm and b-d) at a working distance of 12.0 mm.

Serum analysis of metal ions and histology report. Serum analysis of metal ions (cobalt, chromium, and manganese) and histological analysis of intramedullary tissue samples obtained by reaming after Stryde nail explantation were available from six patients with (patient no. 12, 16, 20, 27, 28, and 39) and two patients (patient no. 10 and 34) without detected osteolytic changes next to the nail's junction. In all eight patients serum concentrations were found unobtrusive, and histology reports revealed synovial-like interface membranes Type 1 according to the Krenn consensus classification (Figure 10, Table IV).²⁰ In the six patients with osteolysis, the Stryde

**Fig. 8**

Corrosive attack at the nail's telescopic part with visible trough-shaped loss of material and corrosion product. Images taken by scanning electron microscopy (SEM). Image a) was taken at a 46× magnification (working distance 12.0 mm) and the area marked with the red box is shown in image b) at a 100× magnification (working distance 12.5 mm). c) The area of the precedent image b) at a 300× magnification (working distance 12.5 mm). The dashed red line in image a) indicates the position of the cross-section and the arrow indicates the orientation, as shown in Figure 9.

nail remained in the bone for a mean 16.2 months (95% CI 12.3 to 20.0). The other two patients were treated for post-traumatic LLD with pre-existing pseudarthrosis and DSS, respectively. They required exchange nailing with premature Stryde nail removal due to nonunion ten and 21 months postoperatively, and no osseous alteration level with the telescoping junction was detected before removal.

Discussion

Since its introduction in 2011, the Precice limb lengthening system has become the most frequently applied ILN for treatment of LLD and DSS.²¹ Since crown breakage remained an issue of the first generation Precice devices

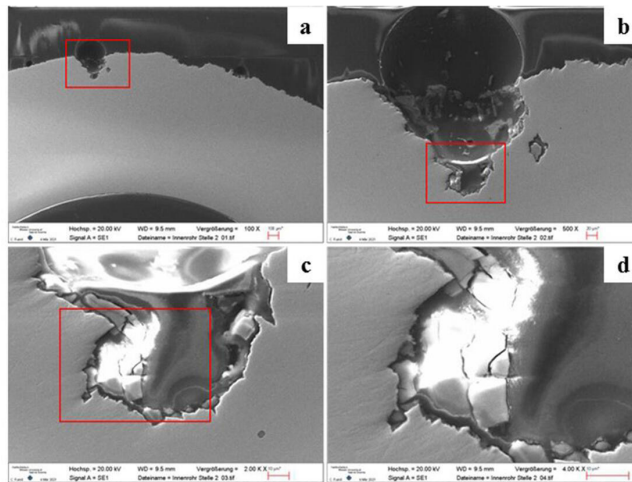


Fig. 9

Images taken by scanning electron microscopy (SEM). a) Metallographically prepared cross-section of the position marked in Figure 8a at 100 \times magnification. b) to d) illustrate the areas marked by the red box of the respective precedent image at a higher magnification ((b) = 500 \times , (c) = 2000 \times , (d) = 4000 \times). The elliptical and wide shallow pits were formed as a result of corrosive attack. The corrosion product can be seen at the edges of the pit. No intercrystalline corrosion was detectable. All images were taken at a working distance of 9.5 mm.

such as the P1, P2, P2.1 nails the implant design was modified.¹⁴ In 2015, the P2.2 nail made of titanium alloy was released and has been successfully employed as an established alternative to external fixators with lower complication rates.^{1,2,22} Several previous studies have found limb lengthening with magnetically driven motorized ILNs to be safe and reliable.^{10,12,13,23}

During lengthening with the P2.2 nail only partial weightbearing is possible due to the implant design. The Stryde nail made of Biodur 108 alloy stainless steel was developed to enable full weightbearing during distraction. The main components include manganese (21% to 24%) and chromium (19% to 23%).¹⁵

In February 2021 NuVasive Specialized Orthopedics issued a Field Safety Notice due to the observation of osteolysis and corrosion associated with the Stryde nail, and since then the nail is not allowed for use in a clinical setting.¹⁶ However, according to the manufacturer about 2,400 Stryde nails have been implanted worldwide ever since its introduction in 2018. More than 50% of the implants were used in 2020 and 2021.²⁴ The exact amount of implants which still remain in the patients is unclear. Most likely a very notable proportion of all the 2,400 implanted Stryde nails is still in patients, since removal is usually scheduled one to two years after consolidation.

To date, outcome of treatment with the Stryde nail is insufficiently reported in research journals. A review of PubMed-listed articles revealed that the few studies

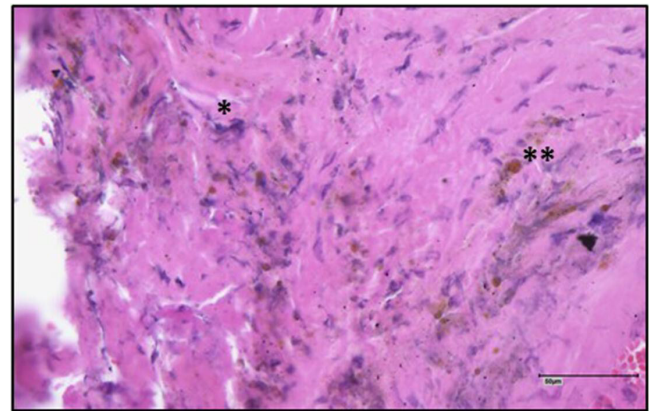


Fig. 10

Haematoxylin and eosin stains of intramedullary tissue samples obtained by reaming after removal of a Stryde nail with macroscopic signs of corrosion at the junction and osteolysis of the treated segment (patient no. 39). Infiltrate of macrophages and multinuclear giant cells (*) indicate acute and chronic inflammation (Type 1 synovial-like interface membrane according to the Krenn consensus classification).²⁰ Macrophages containing brown metallic particles were detected (**). Images were taken at a 100 \times magnification.

reporting treatment with Stryde nail only included small numbers of patients.^{18,19,25-27}

In accordance with our findings, Rölfing et al¹⁹ (n = 27 patients) and Iliadis et al²⁷ (n = 9 patients) recently reported osteolysis detected by radiological analysis in 63% and 69% of lengthened segments, respectively. They also observed pain associated with implant related osteolysis in 30% and 56% of patients, respectively.^{19,27} Contrary to these observations, Robbins and Paley¹⁵ reported their first results of lengthening with the Stryde nail in a non-PubMed-listed journal and found a similar outcome compared to treatment with the P2 nail. The authors concluded that “there have been no issues of biological incompatibility with the Biodur 108 alloy stainless steel”, “there was no corrosion seen in the few nails that were removed”, and that “immediate full weight-bearing with the Stryde nail is safe during limb lengthening”. The mean follow-up, the number of removed implants, and serum or histological analysis were not provided.¹⁵

In May 2021, Galal et al²⁸ reported a retrospective comparison of treatment with Stryde and Precice nails without mention of implant-related osteolysis. It is unclear if this was not a primary outcome parameter or if the authors really did not encounter osteolysis adjacent to the telescopic junction.

Previous studies have analyzed serum metal concentrations in patients treated with growing rods for early-onset scoliosis. Elevated serum levels of metal ions were found and are possibly explained by the long treatment period over several years with implants remaining in situ.^{29,30} In contrast to growing rods for early-onset scoliosis, ILNs for limb lengthening remain in the patient for a shorter time as they are usually removed after osseous consolidation.²¹ This might explain why serum levels of cobalt, chromium, and manganese were not elevated in the

studied cohort. However, more investigation is required since serum analysis of metal ions was only available from eight patients in this study at the time of submission.

In more than 80% of the explanted Stryde nails macroscopic signs of corrosion were found in this study. Macroscopic patterns of corrosion were comparable even if the extent varied. The crown at the nail's telescopic junction and the distal locking holes were particularly susceptible to corrosion. Similar observations were recently published by Rölfling et al,¹⁹ Iliadis et al,²⁷ Johnson et al,¹⁸ and Jellesen et al³¹ with signs of corrosion at the telescopic junction.

Based on microscopic analysis, a corrosive attack can be inferred from the visible troughs at the telescopic part of all analyzed implants. The reason for corrosion cannot conclusively be determined due to the current lack of information on all materials involved in the corrosion system. However, one can preclude that corrosive attack took place as an intercrystalline type of corrosion. Interestingly, corrosive attacks at the nail's junction were only evident on sections of the male part that were localized inside the female part of the nail before distraction. The ambient medium might have entered the small gap between the crown and the male part of the implant and may have led to a corrosive attack, presumably crevice corrosion caused by resulting differences in the concentration of the electrolyte. This hypothesis is supported by previously published implant retrieval analysis of the first and second generation titanium alloy Precice nails, which revealed corrosion after treatment and fluid as well as biological ingress within the nails.³² The corrosive process might have been enhanced by friction during extension of the nail and micromovement during weightbearing, which potentially leads to fretting at the telescopic junction and the screw nail-hole interface. This mechanism might also explain the corrosion observed on the bolts and corresponding nail-holes. It might have been accelerated by micromovement and friction during full weightbearing under distraction.

Another alarming finding of this study is the observed osteolysis adjacent to the nail's telescopic junction, which might have led to onset of rest and ambulation pain after a previously uncomplicated course of treatment. This has not yet been reported in treatment with any precedent type of motorized ILN.^{5,8,9,14,21} Interestingly, from a radiological point of view, almost identical focal osteolysis has been described previously after treatment with a stainless modular trauma nail. Just like in this study, the authors identified chromium as a corrosion product.³³ Chromium corrosion is known for its capacity to induce osteolysis via macrophages and metal debris, which can stimulate osteoclast activity leading to bone resorption.³³⁻³⁶

Osteolysis adjacent to the nail's telescopic junction observed in this study was generally detected after several months (average nine months after surgery and seven months after end of distraction). The actual rate of osteolysis might be higher than the calculated rate of 32%, as only 62% of the patients to date reached a follow-up, which is longer than the mean time from surgery to the occurrence of osteolysis.

In accordance with Rölfling et al,¹⁹ this study reveals that bony alterations level with the nail's telescopic junction were mainly (18/20, 90%) observed during the consolidation period. The authors hypothesize that this might be caused by the static position of the junction during consolidation, possibly leading to a locally increased concentration of the corrosion product, which could be causative of the observed osteolysis.

In accordance with recent investigations by Rölfling et al¹⁹ and Jellesen et al,³¹ this study suggests that mechanically assisted crevice corrosion level with the telescopic junction can lead to osteolysis and new onset of rest and ambulation pain in patients treated with the Stryde nail.

Further investigations are needed for reliable conclusions about the cause and nature of the corrosive attack of the Stryde nail. These should include detailed analyses of the corrosion system, all involved materials, and the ambient conditions.

This study has several limitations and the authors acknowledge that most explanations for the observed osseous alterations at the nail's telescopic junction are hypothetical at the moment. Another major limitation of the study is that to date not all ILNs have been explanted yet. Due to limitation of time and resources so far only a limited number of implants have been analyzed by SEM or EDX. Bias might also be sustained by the heterogeneous study population in terms of the operative approach and underlying conditions. The patients and compared groups were not randomized and exclusively retrospective clinical and radiological analysis was conducted. This study does not provide any comparison to treatments with other types of ILNs. Matched pair study designs and more clinical investigation (i.e. blood sampling during treatment and after implant removal, tissue sampling, and analysis during implant removal) are needed. The available samples for histological analysis were obtained from reaming of the entire medullary canal and the tissue is not only representative for the localization of the osteolysis. Specific transcortical sampling at the level of the osteolysis would be helpful to further investigate this matter. However, one should be aware of the reduction of stability caused by transcortical sampling. Despite the mentioned limitations, we believe that it is crucial to report potential implant-related adverse effects as soon as possible to increase patient safety and alert orthopaedic surgeons to this specific observation, since more than 2,000 Stryde nails have been implanted worldwide.

In conclusion, this is the first single-centre study that provides clinical and radiological findings as well as metallurgic implant retrieval analysis after treatment with the 57 consecutive lengthenings with the Stryde nail. The results are preliminary and more clinical investigation as well as *in vitro* implant testing are required to identify the exact mechanism leading to corrosion and osteolysis.

Patients in whom the nail has not been removed yet are exposed to the risk of new onset of pain and implant-related osteolysis with unclear short- and long-term clinical consequences. Therefore, the authors advocate in favour of an

early implant removal after osseous consolidation to possibly prevent harm caused by implant corrosion. In patients with osteolysis-related pain, before full consolidation premature implant removal and conversion to a standard trauma nail should be considered.

More than 2,000 Stryde nails have been implanted worldwide and implant retrieval rates are unclear. Therefore, we urgently encourage surgeons who have applied the Stryde lengthening system to report their experiences. We hope that the introduced macroscopic classification of corrosion at the junction can help to standardize terminology in upcoming investigations.

Supplementary material



Details about the surgical technique and postoperative protocol.

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Ethical review statement:

- The study was approved by the Research Ethics Committee of the Chamber of Physicians of Westfalen-Lippe of the University of Münster and conducted according to the principles of the World Medical Association Declaration of Helsinki from 1964.

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