

# Precice Stryde® Magnetic Internal Lengthening Nail does not Impair Bone Healing Despite Radiographic and Clinical Symptoms

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## ABSTRACT

**Aims:** The Precice Stryde® internal magnetic lengthening nail allowed many patients a full weight-bearing experience during femur and tibia lengthening, but concerns over corrosion, pain and radiographic changes led to the implant's recall. Despite the recall, it is important to understand the rate of these occurrences and their influence on the overall success of the lengthening procedure. We aimed to investigate radiographic changes, patient-reported symptoms and bone healing indices for our cohort of Stryde lengthening.

**Materials and methods:** Our surgical database and electronic medical record system were used to review and document patient demographics, indications for lengthening, length achieved, bone healing index (BHI), location and type of radiographic changes, time until radiographic changes were first visible, presence of pain symptoms (not attributable to surgery or distraction), time to implant removal and if the pain symptoms resolved following implant extraction.

**Results:** From January 2019 to February 2021, 90 Stryde nails (78 femur and 12 tibia) were implanted in 63 patients. The cohort included 48 males and 15 females. The average length [ $\pm$  standard deviation (SD)] achieved was  $58.4 \pm 22.7$  mm. The 66 bones (73%) developed radiographic changes and were found to be 58/78 (74%) femurs and 8/12 (67%) tibias. The average time to initial radiographic changes was  $168 \pm 108.1$  days (femur) and  $276 \pm 126.8$  days (tibia). Late-onset pain developed in 10 femur lengthening (11.1% of all nails) surgeries across eight patients (12.7% of all patients). All patients' pain resolved; three instances prior to nail removal and the remaining seven after nail removal. No patients were re-presented with worsening pain or radiographic changes following implant removal. Radiographic or symptomatic abnormalities did not impair bone formation. The BHI for femurs with ( $29.6 \pm 16.6$  days/cm,  $n = 58$ ) vs without ( $29.4 \pm 17.9$  days/cm,  $n = 20$ ) radiographic or symptomatic irregularity were nearly identical ( $p = 0.961$ ). The difference between BHI for tibias with ( $39.3 \pm 7.8$  days/cm,  $n = 8$ ) vs without ( $86.1 \pm 38.2$  days/cm,  $n = 4$ ) radiographic changes was influenced by outliers and underpowered to draw a conclusion.

**Conclusion:** Bone lengthening with the Stryde nail was associated with high rates of radiographic abnormalities, but symptoms were uncommon and resolved with explantation. The radiographic changes did not affect bone healing in the femur.

### Clinical significance:

- Radiographic changes including bone hypertrophy and osteolysis were common after bone lengthening with the Stryde nail, but the development of pain following consolidation was rare and resolved with implant removal.
- The BHI in femurs was not affected by radiographic changes.

**Keywords:** Distraction osteogenesis, Limb lengthening, Limb reconstruction, Precice nail.

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## INTRODUCTION

In the early 1950s, Ilizarov established the foundation of modern limb-lengthening surgery through his discovery of distraction osteogenesis. This concept—that gradual distraction creates tension stresses which stimulate the formation of bone—paved the way for early limb lengthening surgery using circular external fixation.<sup>1</sup> Although external fixators have long served as an invaluable tool in limb lengthening and complex deformity correction, they are prone to numerous drawbacks that pose significant challenges to patients and surgeons.<sup>2</sup> To avoid the shortcomings associated with external fixation, multiple different internal lengthening nails have been developed. Among the most widely used is the intramedullary, telescopic, magnetically controlled Precice® nail, introduced in 2011 (NuVasive, San Diego, California, USA). The first generation had structural weaknesses which were resolved by the second generation's improved manufacturing techniques.<sup>3</sup> Multiple subsequent investigations have shown the Precice to

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have a favourable healing profile, excellent accuracy and precision, high patient satisfaction and low complication rates.<sup>3-6</sup> A notable

**Table 1:** Indications for lengthening with the Precice Stryde nail

| Indication                        | Number of nails (% of all nails)<br>[% of indication] |
|-----------------------------------|---|
| Stature lengthening               | 57 (63%)  |
| Femur                             | 49 (54%) [86%]  |
| Tibia                             | 8 (9%) [14%]  |
| Post-traumatic                    | 12 (13%)  |
| Femur                             | 10 (11%) [83%]  |
| Tibia                             | 2 (2%) [17%]  |
| Congenital leg length discrepancy | 8 (9%)  |
| Femur                             | 8 (9%) [100%]   |
| Tibia                             | 0 (0%) [0%]   |
| Other                             | 13 (14%)  |
| Femur                             | 11 (12%) [85%]  |
| Tibia                             | 2 (2%) [15%]  |

limitation of the Precice is the recommended weight-bearing limit of 30–70 pounds (~15–30 kg), which restricts many patients, especially those undergoing bilateral lengthening, to wheelchairs, walkers or crutches for prolonged periods after surgery before bone healing is sufficiently robust.

To overcome the weight-bearing limitation, the Precice Stryde® nail (NuVasive, San Diego, California, USA) was introduced in 2018. Made of a stainless-steel alloy (Biodur 108) instead of titanium, it increased weight-bearing up to 250 pounds (113 kg) while maintaining the same surgical techniques and patient user experience as the original Precice.<sup>4</sup> To avoid confusion, this article uses “Precice” to refer to the titanium version, and “Stryde” to refer to the stainless-steel version. The Stryde nail showed early clinical success but was recalled in 2021 following concerns regarding pain, radiographic bone abnormalities at the interface between the telescoping nail segments and nail corrosion.<sup>3,7</sup> In light of the recall, it is important to understand the rate of these occurrences and their influence on the overall success of the lengthening procedure.

This investigation of our patient cohort that had lower extremity lengthening using Stryde nails has three equally important aims. First, to report the incidence and frequency of radiographic bone abnormalities. Second, to profile the patient-reported symptoms. Third, to calculate the bone healing indices.

## MATERIALS AND METHODS

Following institutional review board approval, we reviewed our surgical database for patients who had a Stryde implanted. Inclusion criteria were lower extremity surgery for lengthening, unilateral or bilateral implantation and subsequent implant removal. Upper extremity patients, those whose Stryde had not been removed and those with surgery for bone shortening were excluded. From January 2019 to February 2021, 110 Stryde nails were implanted. Three nails were excluded for shortening, and 17 nails were excluded because they remained *in situ*. 90 Stryde nails (78 femur and 12 tibia) were implanted with subsequent retrieval in 63 patients. The cohort included 48 males and 15 females. Indications for lengthening are outlined in Table 1. The odd number of stature-lengthening nails is explained by a patient who had one nail removed and one nail retained at the time this study was conducted. The average length (± SD) achieved was 58.4 ± 22.7 mm.

**Table 2:** Type and location of radiographic changes

| Radiographic change           | Number of nails (% of 90)<br>[femur (% of 78), tibia (% of 12)] |
|-------------------------------|---|
| Osteolysis                    | 26 (29%) [22 (28%), 4 (33%)]                                    |
| Telescopic junction           | 13 (14%) [11 (14%), 2 (17%)]                                    |
| Inner segment screws          | 13 (14%) [11 (14%), 2 (17%)]                                    |
| Bone hypertrophy              | 55 (61%) [48 (62%), 7 (58%)]                                    |
| Telescopic junction           | 12 (13%) [9 (12%), 3 (25%)]                                     |
| Inner segment screws          | 43 (48%) [39 (50%), 4 (33%)]                                    |
| Osteolysis + bone hypertrophy | 5 (6%) [5 (6%), 0 (0%)]   |
| Telescopic junction           | 2 (2%) [2 (3%), 0 (0%)]   |
| Inner segment screws          | 3 (3%) [3 (4%), 0 (0%)]   |

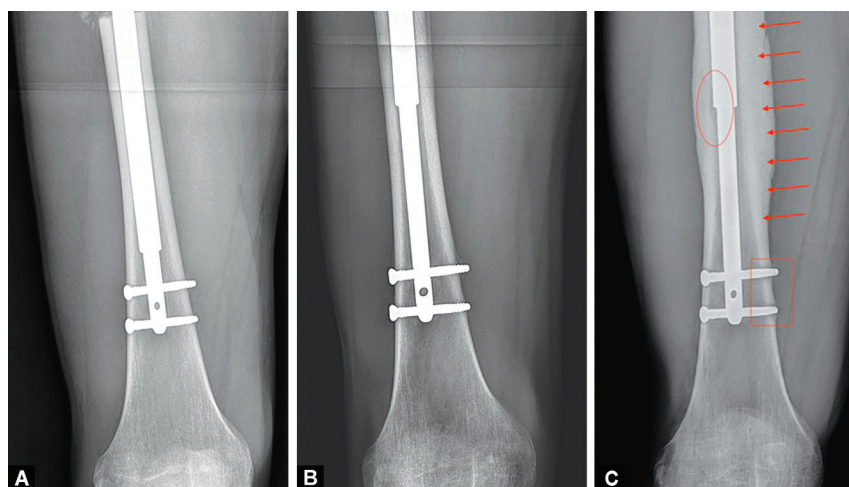
The review included patient demographics, indications for surgery, length achieved, bone healing index (BHI), the occurrence, location and type of radiographic changes, time until the first radiographic changes were evident, presence of pain symptoms (not attributable to surgery or distraction), time to implant removal and if the pain symptoms resolved following implant removal.

The preoperative patient evaluation included a detailed history, a thorough lower extremity physical exam, a standing bilateral hip-to-ankle radiograph with blocks to level the pelvis as needed and orthogonal radiographs of the indicated bone. Surgical details, major risks and postoperative routines were reviewed with the patient prior to surgery. Details of our surgical approach and postoperative protocol have been outlined previously.<sup>3,8</sup> All surgeries were performed at a single institution by fellowship-trained orthopedic surgeons. Postoperative evaluation including radiographic interpretation was performed in-person biweekly during distraction and in-person or via telemedicine monthly during consolidation. Consolidation was considered achieved when at least three cortices displayed confluent bridging bone at least 2-mm thick. Nail removal was offered after complete consolidation and remodelling of all four cortices and at least nine months following implantation. Patient evaluation occurred 2–3 weeks following nail removal and then as needed for new symptom development.

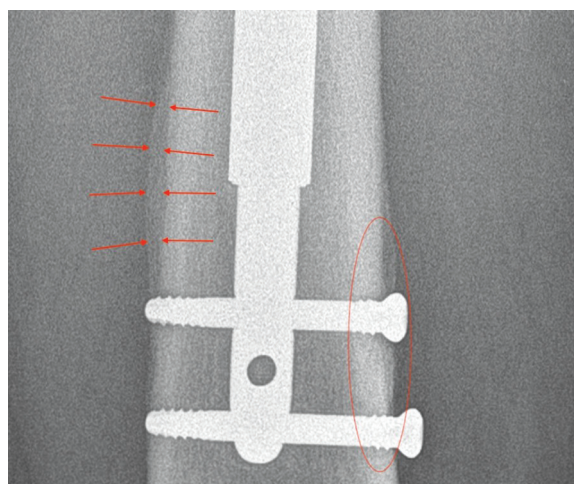
Descriptive statistics were used to summarise data, Fisher’s exact tests were used to compare frequencies and Student’s *t*-tests compared means. These tests were performed using Microsoft Excel 2019 (Redmond, WA). Significance was set as *p* < 0.05. It deserves to be noted that we did perform a statistical comparison of the tibial patients vs the femoral patients, despite the number of tibias (12) being much smaller than the number of femurs (78). We acknowledge the limitations of performing statistical comparisons of the small number of 12 events, especially against a much larger number, but believe this comparison was still valuable.

## RESULTS

The incidence, frequency, type and location of radiographic changes are summarised in Table 2. Sixty-six bones (73%) developed radiographic changes, including 58 femurs (74% of all femurs) and 8 tibias (67% of all tibias, *p* = 0.727). Twenty bones developed radiographic changes at both the telescopic junction and inner segment screws, meaning those 20 nails were counted twice in Table 2. Examples of radiographic changes in our study cohort can be visualised both in Figure 1 and in Figure 2. The average time



**Figs 1A to C:** The anterior–posterior (AP) radiographs of the distal femur. (A) Three-weeks postoperative; (B) Seven-months postoperative; (C) Fifteen-months postoperative of a 19-year-old male who gradually developed pain and radiographic changes after Stryde nail implantation for an 8-cm stature lengthening. This patient experienced osteolysis at the telescopic junction (identified with a red oval), bone hypertrophy at the telescopic junction (identified with red arrows), and bone hypertrophy at the inner segment screws (identified with a red rectangle)



**Fig. 2:** The 6-month postoperative AP radiograph of a femur in a 22-year-old male who experienced hypertrophy at the telescopic junction (identified with red arrows) and inner segment screws (identified with a red oval) after Stryde nail implantation for correction of an 18 mm leg length discrepancy. The patient did not report any pain or discomfort throughout treatment beyond acute immediate postoperative pain

( $\pm$  SD) to initial radiographic changes was  $168 \pm 108.1$  days in the femur and  $276 \pm 126.8$  days in the tibia ( $p = 0.051$ ). No radiographic changes were associated with the outer segment (other than at the junction of the segments). All radiographic changes either appeared the same or improved/diminished on post-removal radiographs taken two to three weeks following extraction.

The adverse symptoms reported by patients were exclusively that of late-onset pain. This occurred in 10 femur lengthening (11.1% of all nails) surgeries in eight patients (12.7% of all patients), and none in the tibia. Three instances of pain resolved prior to nail removal, and the remaining seven instances resolved completely after nail removal. No patients re-presented with worsening pain or new radiographic changes following implant removal. The mean weight of patients developing a radiographic or symptomatic

abnormality was  $68.8 \pm 14.7$  kg vs  $68.6 \pm 11.5$  kg for those that did not ( $p = 0.961$ ).

The mean BHI was calculated separately for femurs and for tibias, as the bones have substantially different biological capacities for healing.<sup>2</sup> The BHI was not statistically different, and indeed nearly identical, for femurs that developed a radiographic or symptomatic abnormality ( $29.6 \pm 16.6$  days/cm,  $n = 58$ ) vs femurs that did not develop radiographic or symptomatic abnormalities ( $29.4 \pm 17.9$  days/cm,  $n = 20$ ,  $p = 0.961$ ). For tibias, there was a clinically relevant, but not statistically significant, difference in BHI between tibias that developed a radiographic or symptomatic abnormality ( $39.3 \pm 7.8$  days/cm,  $n = 8$ ) and those that did not ( $86.1 \pm 38.2$  days/cm,  $n = 4$ ,  $p = 0.093$ ), but it is re-emphasised that the small number of tibias limits the confidence in these comparisons. Radiographic and/or symptomatic events did not impact the average time until implant removal:  $462 \pm 179.9$  days for 66 bone segments with events, vs  $458 \pm 178.3$  days for 24 bone segments without events ( $p = 0.929$ ).

## DISCUSSION

The most important finding of this investigation is that the BHI is not altered by the occurrence of radiographic or painful symptoms, at least in the femur. This finding is meaningful because, despite the radiographic bone abnormalities and low frequency of reported pain, it is likely that there is no actual impairment of healing. The BHI of  $\sim 1$  month/cm is very similar to values published for Precice nail.<sup>9</sup> While there was a clinically relevant (but not statistically significant) difference for the tibias, our tibial cohort (12 patients; 8 with symptoms and 4 without) is too small to be confident in this comparison.

It was further identified that the majority (73.0%) of patients who received a Stryde internal lengthening nail developed radiographic changes at the telescopic junction and/or locking screws in the inner segment. No radiographic changes occurred in relation to the outer segment. Late-onset pain occurred much less frequently (11.1% of implants), and resolved either prior to or following implant removal, and no patients were represented with pain following removal. Further, patient weight did not appear

to impact the occurrence of radiographic changes or pain. The remainder of this discussion will compare these results to previously reported Stryde outcomes and consider the Stryde's obstacles in the context of other similar devices.

The first group to identify concerns with Stryde was Iliadis et al.<sup>10</sup> They reported osteolysis and periosteal reaction at the nail junction in 9 of 13 (69.2%) Stryde implants, and noted that 5 of 8 (62.5%) patients reported localised pain and swelling. Rölfing et al. performed a cross-sectional analysis of all 30 limbs treated with Stryde nails across Denmark. They observed radiographic changes in 21 out of 30 limbs (70%), and prominent late-onset pain in eight out of 27 (29.6%) patients. Also, 15 out of the 30 analysed nails had not yet been removed and were at potential risk of developing complications.<sup>11</sup> Hothi et al. found cortical thickening and osteolysis around the junction of six of ten (60%) retrieved Stryde nails.<sup>12</sup> Frommer et al. investigated the rates of osteolysis around the nail's telescopic junction and found that 20 of 57 (35.1%) segments experienced osteolytic changes around this area. During distraction, 16 out of 50 (32%) patients reported pain on the operative side that did not resolve with NSAIDs taken up to 4 times a day. During consolidation, 14 out of 50 (28%) patients reported rest and ambulation pain on the operative side.<sup>13</sup> All of these studies demonstrated the majority of patients develop radiographic changes, consistent with our experience, however, our rate of late-onset pain was lower (11.1%).

Although this study did not involve an analysis of retrieved nails, multiple studies have performed macroscopic, mechanical and biochemical analyses of retrieved Stryde nails that provide a deeper understanding of the various underlying causes of clinical and radiographic symptoms. Iliadis et al. removed 4 femoral nails and 2 tibial nails from their cohort of 13 implants and found evidence of corrosion at the telescopic junction in four out of 6 implants. Histological analysis of tissue samples obtained during implant removal was consistent with the effects of focal metallic wear debris.<sup>10</sup> Jellesen et al., who investigated the same 30-nail cohort as Rölfing et al., noted visible signs of corrosion at the telescopic nail junction in 20 out of 23 retrieved nails, and observed mechanically assisted crevice corrosion at the locking screws and screw holes in 20 out of 23 nails. They also noted biological material inside the nail and oozing from the junction in two nails. These results led to the conclusion that the nails were not hermetically sealed and that despite being composed of a corrosion-resistant alloy, the Stryde nail is susceptible to mechanically exacerbated crevice corrosion at sites such as the bushing, locking screws and screw holes.<sup>14</sup> The radiographic analysis of 10 retrieved nails, conducted by Hothi et al., also included a macroscopic analysis that revealed at least some corrosion at the telescopic junction or screw holes in all ten nails. Energy dispersive X-ray spectroscopy showed surface deposits to be chromium rich with one patient demonstrating elevated chromium in their blood prior to nail removal. Quite notably, all patients who experienced cortical thickening around the nail junction also experienced severe corrosion around the junction, while patients who did not experience cortical thickening at the junction experienced mild or no corrosion around this area.<sup>12</sup> In the 57-nail analysis conducted by Frommer et al., 20 of 24 retrieved nails demonstrated macroscopic corrosion at the nail's telescopic junction, and energy dispersive X-ray analysis revealed chromium as the main metallic element of corrosion.<sup>13</sup> These studies strongly suggest an association between nail corrosion and radiographic changes, but more investigation is necessary to determine the

specific biologic mechanisms leading to the observed bone changes.

The concern of implant corrosion and its potential or actual impact on patient health is not unique to the Stryde. In fact, Jones et al. published their experience with a modular stainless-steel nail in 2001, which is strikingly reminiscent of the Stryde experience.<sup>15</sup> Of 27 patients treated for femoral fracture or non-union, 23 (85.2%) had osteolysis, periosteal reaction or cortical thickening localised to one or both modular junctions, and retrieved modular nails had signs of fretting corrosion as well as stainless-steel corrosion products adherent to the junction where the osteolysis occurred. Chromium levels were also significantly elevated vs patients with solid intramedullary nails or control patients without internal fixation devices. However, 26 (96.3%) achieved union and no catastrophic events occurred. Very relevant to this, elevated serum chromium levels have not been shown to correlate with systemic symptoms in the much larger metal-on-metal total hip population.<sup>16</sup> More substantial negative effects of device wear in the local tissues have been demonstrated for certain total hip replacement implants, such as at the neck–stem junction in modular stem designs or between the femoral and acetabular components on metal-on-metal designs.<sup>17–19</sup> However, these implants are meant to be permanent, so adverse soft tissue reactions are more problematic than a nail designed to be *in situ* for approximately one year and then removed.

While some patients may be light enough for non-Stryde options<sup>8</sup> or more easily accommodate weight-bearing limitations, many patients will have trouble adjusting work, school or parenting commitments to protect more fragile lengthening nails. External fixators can support the full weight of many children and adults and can provide more complex corrections than intramedullary nails,<sup>20–23</sup> but external fixators are physically inconvenient, require substantial maintenance from patients, are prone to infectious events,<sup>24,25</sup> and can be psychologically burdensome.<sup>26</sup> With the Stryde nail unavailable, the Fitbone (Orthofix Medical Inc, Lewisville, TX) and Precice nails are likely the most common alternative internal lengthening devices.<sup>27</sup> Although radiographic changes in the Fitbone and Precice nails are extremely uncommon when compared to the Stryde nail,<sup>28</sup> they, of course, have complications and limitations which have been accepted by patients and surgeons. The Fitbone nail is driven by an electric-powered motor and has had documented instances of backtracking, in which thousands of repetitive micromovements at the nail's junction lead to shortening of the nail and early consolidation.<sup>27,29</sup> Additionally, the Fitbone nail has also shown some signs of corrosion and may lead to pain around the nail's telescopic junction.<sup>27</sup> The Precice nail, which is the current internal lengthening nail of choice in our practice, has also had documented complications. In a 2017 study investigating the benefits and limitations of different lengthening nails (Intramedullary Skeletal Kinetic Distractor [Orthofix, Valley, Germany], Precice generation one and Precice generation two) in lower extremity lengthening, 23 of 46 (50%) segments lengthened with Precice generation two nails experienced device-related complications.<sup>30</sup> In a 2021 systematic review of 983 lower extremity segments lengthened with Precice or Fitbone nails, 1 out of every 3 segments suffered a complication, and 1 out of every 4 segments suffered a complication that leads to a substantial change in treatment, failure to achieve lengthening goal, introduction of a new pathology or permanent sequelae.<sup>31</sup> In our Stryde cohort, no patients had their overall care or outcome compromised because of radiographic or pain symptoms, and all pain symptoms resolved

before or following removal. There are always relevant benefits and limitations for any implant, and understanding them is important in optimizing the prioritised outcomes for each individual patient.

Given bone lengthening is still months-long process, the goal of providing patients the most tolerable and convenient care should not be overlooked. While radiographic changes, corrosion and pain are important to consider, and a device recalls the safest response in this case, the Stryde did provide greater weight-bearing tolerance than other internal lengthening devices. The benefit of weight-bearing conferred by the Stryde nail (or a future weight-bearing lengthening nail) to the patient experience of bone lengthening deserves further study since intuitively and anecdotally patients prefer to be ambulatory during the process.

This study has limitations to recognise. The most relevant is the retrospective design, which has inherent limitations vs a prospective design, including identifying patient pain symptoms, and the low number of tibias. While no patients presented with ongoing pain or complication following nail extraction, it is possible this occurred at another institution and was not reported to us. Our study also has notable strengths. The number of bone segments (90) and patients (63) are the most reported in any article focusing on Stryde complications. Further, this analysis featured only patients whose implants had been removed, minimizing the possibility that potential implant-associated events would be underreported. Most importantly, our study is the only one which focuses on the primary orthopaedic concern regarding the Stryde: What is the impact on the bone's capacity to lengthen and heal? This is the only study which compared the BHI (the most appropriate benchmark outcome metric) between patients who did and did not have radiographic and symptomatic concerns.

## CONCLUSION

In summary, our experience corroborated the existing literature's reported rates of radiographic and clinical abnormalities but found no evidence that these situations impaired bone healing or prevented the achievement of the intended surgical goals.

## Clinical Significance

- Radiographic changes including bone hypertrophy and osteolysis were common after bone lengthening with the Stryde nail, but the development of pain following consolidation was rare and resolved with implant removal.
- The BHI in femurs was not affected by radiographic changes.

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