

### PUBLISHED EVIDENCE ON THE RATES OF BONE ABNORMALITIES WITH THE USE OF FITBONE™ TAA WITH RESPECT TO STRYDE™

The scope of this document is to analyse the complications reported in the peer-reviewed literature related to bone abnormalities (osteolysis, periosteal reaction, cortical hypertrophy/thickening) following the application of the Fitbone TAA, Precice, and Stryde intramedullary lengthening nails (ILNs).

Systematic searches were conducted on different databases, focusing on bone abnormalities with the use of Fitbone TAA, Precice and Stryde, with no filters applied.

Table 1 presents a summary of the studies published to date reporting bone abnormalities with the Stryde ILN<sup>1, 2, 3, 4, 5, 6, 7</sup>.

**TABLE 1**

Author, year	Number of STRYDE nails	Mean age (range)	Percentage of bone abnormalities (focal osteolysis, periosteal reaction, cortical hypertrophy)
Frommer, 2021 <sup>1</sup>	57	16.5 (10.1-49.8) Y	<b>35%</b> (osteolytic changes at telescopic junction)
Iliadis, 2021 <sup>2</sup>	14	33 (14-65) Y	<b>64%</b> (osteolysis and periosteal reaction at telescopic junction)
Sax, 2022 <sup>3</sup>	57	15.6 (10-18) Y	<b>39%</b> periosteal reaction; <b>26%</b> osteolysis
Röfing, 2021 <sup>4</sup>	30	20 (11-65) Y	<b>70%</b> (osteolysis, periosteal reaction, cortical hypertrophy at telescopic junction)
Vogt, 2023 <sup>5</sup>	48	Median 16 (IQR: 13-19) y	<b>65%</b> (osteolysis next to the telescopic junction) <sup>†</sup>
Hothi, 2021 <sup>6</sup>	10	29.5 (14-64) Y	<b>60%</b> (cortical thickening and osteolysis around the junction)
Radler, 2022 <sup>7</sup>	2	32 (18-72) Y <sup>‡</sup>	<b>50%</b> (osteolysis at the male-female junction)

Jellesen et al.<sup>8</sup> performed a metallurgical analysis on the Stryde nails (n=23) removed (reported in Röfing et al.<sup>4</sup>). The main findings of the study were:

- 87% of Stryde nails had visible signs of corrosion at the telescopic junction and at the locking screws and screw holes
- Stryde nails were not hermetically sealed (i.e., biological material and corrosion were found inside the nail)

Findings of this study correlate with the radiographic changes (i.e., junctional osteolysis, periosteal reaction, cortical hypertrophy) noted in Röfing et al.<sup>4</sup> within the same cohort. Authors' hypothesis is that: "[...] *internal and junctional corrosion and its products cause a toxic environment leading to osteolysis. [...]*"

Correlation between Stryde nails corrosion and radiographic changes (i.e., cortical thickening and osteolysis) are also reported by Hothi et al.<sup>6</sup>

The study of Iobst et al.<sup>9</sup> (retrospective analysis of 366 nails, from three different centres, from 2006 to 2021) focuses on the comparison between Stryde, Precice® and Fitbone TAA ILNs<sup>5</sup>.

Variable	STRYDE	PRECICE	FITBONE TAA
Number of nails	26	98	239
Mean age (range)	23 (13-66) y	25 (10-79) Y	28 (14-73) y
Bone abnormalities at the interface of the telescopic nail segment (focal osteolysis, periosteal reaction, cortical hypertrophy)	<b>77%</b> (focal osteolysis, periosteal reaction, cortical hypertrophy)	<b>1%</b> (focal osteolysis)	<b>2%</b> (focal osteolysis, periosteal reaction)

<sup>†</sup> This study analyses also 91 Precice nails of which 1 nail was associated to the presence of osteolysis (1%).

<sup>‡</sup> Mean age of the study population including also 32 patients treated with Precice nails.

<sup>5</sup> The study comprises application of Fitbone TAA on femur, tibia, and humerus, but only on-label data on femur and tibia were considered for the purpose of this document.

In the study by Teulières et al.<sup>10</sup>, which focuses on the outcomes of Fitbone application (n=34; 30 Fitbone TAA and 4 Fitbone SAA) in posttraumatic limb lengthening surgery, the following findings are reported: "[...] *even though it was not the primary objective of the present study, we evaluated the latest radiographs and found no osteolysis and no periosteal reaction at the telescoping junction in our prospective cohort of 34 patients that were operated from 2010 until 2019. Moreover, we did not observe a significant amount of corrosion on the retrieved FITBONE nails [...]*".

Considering all the other peer reviewed articles published on Fitbone TAA (data on file, retrieved from systematic searches conducted on Fitbone TAA) **no complications related to bone abnormalities have been reported in literature.**

# Fitbone™

## Intramedullary Lengthening System

### References:

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