# A Cross-sectional Analysis of “182” Complications for Femoral Neck System from Medical Device Reports Maintained by the United States Food and Drug Administration.

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INTRODUCTION:

The Femoral Neck System (FNS), which received Food and Drug Administration (FDA) approval in 2018, was created to theoretically offer high resistance against angular instability and femoral head rotation while concurrently remaining minimally invasive in order to reduce the number of reoperations. While a limited number of studies have demonstrated the efficacy and potential benefits of the FNS, there is a lack of robust analysis examining the short and long-term complications which can help clinicians decide when FNS should be used. Therefore, this study demonstrates the complication profile of FNS in real-time in order to assess the risk-benefit of this device.

METHODS:

The Manufacturer and User Facility Device Experience (MAUDE) nationwide database was used to identify complications related to the FNS between 1/1/2018 and 1/1/2022. Data collected included the date the reports were received by the FDA, the type of complication, event description, and the source of the report. The complication event description was utilized to determine the completion of the investigation, whereas, entries with insufficient information were excluded. Complications were further divided into two categories, device and non-device related. This, to assure complications captured were filtered to give a consistent representation of implant-associated complications. Complications were then numbered, categorized, and ranked overall.

RESULTS:

Of the identified FNS cases within the MAUDE database, 182 total complication entries were reported.

A formal investigation into the complication complaint was completed in 98.9% (n = 180) of the cases. According to the entry data, 67.5% (n = 123) of the complications were related to the FNS and 31.8% (n = 81) were not. While the most common device problem was listed as “Adverse Event Without Identified Device or Use Problem” (n = 97), other device problems included: “Migration” (n = 36); “Device-Device Incompatibility” (n = 30); “Break” (n = 8); “Patient Device Interaction Problem” (n = 2); “Failure to Align” (n = 1); and “Device Slipped” (n = 1). The remaining entries were listed as “No Apparent Adverse Event” (n = 7). When analyzing the “event type”, 94.5% (n = 172) were classified as an injury and 5.5% (n = 10) were classified as a malfunction. The most common reported type of complication was periprosthetic fracture (25.8%; 47 entries), of which, 36 entries were specified as subtrochanteric fracture. Twenty entries cite a fall being the cause of the periprosthetic fracture, with 13 of these specified as subtrochanteric. The remaining most common type of complications are: screw failure–cut out (38 entries, 20.9%); avascular necrosis (25 entries, 13.7%); non-union (17 entries, 9.3%); varus collapse (16 entries, 8.8%); implant failure (14 entries, 7.7%); and pain (14 entries, 7.7%).

DISCUSSION AND CONCLUSION:

While a few, small studies have demonstrated the efficacy of the FNS citing potential benefits such as decreased femoral neck shortening postoperatively, and complication rates comparable to controls receiving cannulated screw fixation, there is a lack of robust analysis examining the short and long-term complications. Knowing the complication profile of any device is critical to optimizing patient outcomes. This is the first study to summarize, in real time, the current complication profile of this relatively new device. With periprosthetic fracture, in particular atraumatic subtrochanteric fractures being the commonest reported complication, it is reasonable to conclude that the implant may be capable of causing a stress riser in the subtrochanteric region. This yields important information as orthopaedic surgeons may want to scrutinize the subtrochanteric region to ensure that an adequate cortical environment exists when selecting patients to be implanted with this device in the future.

Figure 1. Summary of Reported Type of Complications

| Complication | Number |
|---|---|
| **Periprosthetic (PP) Fracture Total** | 47 |
| Subtrochanteric Fracture | 36 |
| **Screw Cut Out** | 38 |
| **Avascular Necrosis** | 25 |
| **Nonunion** | 17 |
| **Varus Collapse** | 16 |
| **Pain** | 14 |
| **Implant Failure** | 14 |
| Hardware Fracture Post Op | 8 |
| Screw Cold Weld | 4 |
| Unknown | 2 |
| **Insertion Of Device Problem** | 7 |
| **Traumatic Hip Dislocation** | 2 |
| **Stress Riser** | 1 |
| **Infection** | 1 |
| **Total** | 182 |
| Device Related Yes | 123 |
| No | 58 |
| Incomplete | 2 |

Figure 2. Total Complication Distribution of Femoral Neck System

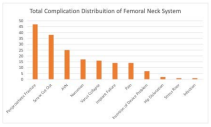


Figure 3. Traumatic versus Atraumatic Periprosthetic and Subtrochanteric Fractures

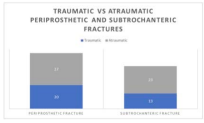


Figure 4. Reported Implant Failure of Femoral Neck System