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Comparison of Early Fatigue Failure of the TFNa and Gamma 3 Cephalomedullary Nails in the United States From 2015 to 2019

Matthew L. Klima, DO

Objectives: To compare reports of implant fatigue failure submitted to the FDA of 2 commonly used cephalomedullary nails.

Methods: In total, 2724 medical device reports from the FDA's MAUDE database from Jan 2015 to Oct 2019 were reviewed for the Trochanteric Femoral Nail–Advanced (TFNa) and Gamma 3 implants.

Results: Data from 342 implant failures included in the MAUDE database were analyzed. TFNa and Gamma 3 had 183 and 159 reported fatigue failures, respectively. All failed implants fractured in the same location through the proximal screw aperture. Time from implantation to failure was on average 2 months shorter for TFNa implants that were reported fractured than for Gamma 3 implants reported, a difference that was statistically significant ($P < 0.05$). In total, 100 implants were reported to have failed within the first 4 months (53 and 47 for TFNa and Gamma 3, respectively). For Gamma 3 implants that failed in the first 4 months, almost all of the available manufacturers' inspection reports revealed implant notches at the point of failure from drilling. For TFNa implants that failed early, only one reported notch was noted in the available inspection reports.

Conclusions: In contrast to other studies regarding fatigue failure, reported failures in both TFNa and Gamma 3 occurred earlier than can be attributed to delayed or nonunion. The reported failures of the TFNa in the MAUDE database occurred earlier than did those of the Gamma 3. Early failures of the Gamma 3 seemed to be the result of iatrogenic implant notching.

Key Words: fatigue failure, implant failure, cephalomedullary nails, TFNa, gamma 3, mechanical failure, cutout, MAUDE database, nail breakage, proximal femur fracture, intertrochanteric femur fracture, subtrochanteric fracture, hip fracture, nail breakage

Level of Evidence: Therapeutic Level III. See instructions for authors for a complete description of levels of evidence.

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INTRODUCTION

Mechanical failure after fixation of proximal femur fractures with cephalomedullary nails has been well described in implant "cut out" from the femoral head. However, few studies have described implant fatigue failure because of its rare occurrence.[1–9] Most studies on fatigue failure have examined a relatively small cohort of 16–22 patients, limiting the study validity because of low statistical power.[10] With limited data on in vivo performance to guide clinicians regarding implant survival, uncertainty exists regarding the longevity of the newest generation of cephalomedullary nails. Recent studies have questioned the reliability of the Trochanteric Femoral Nail–Advanced (TFNa) (Synthes, West Chester, PA) implant for use in unstable fracture patterns with early breakage noted in clinical settings.[11] Both the Gamma 3 (Stryker, Mahwah, NJ) and TFNa cephalomedullary nails include several new design features that involve not just instrumentation but also the size and shape of the implant itself. To date, there have been only 2 medical device recalls for Gamma3 and 5 medical device recalls for TFNa, none of which were attributed to manufacturing or design flaws.

In the United States, the Food and Drug Administration (FDA) is responsible for postmarket surveillance of medical devices. The Manufacturer and User Facility Device Experience, or MAUDE database, is a collection of reports submitted to the FDA regarding adverse events in medical devices. Although there is no formal universal orthopaedic implant registry in the United States, the FDA's MAUDE database is the largest available collection of data to judge implant performance. The FDA does not recommend using this data to compare failure rates between implants within the same category; however, other comparisons can be made regarding mode of failure.[12,13] Importantly for our purposes, the data can reliably be used to assess time to failure. To the best of our knowledge, this is the first study in the English literature to use MAUDE data for this objective.

The purpose of this study was to compare reports of implant fatigue failure with the FDA of 2 commonly used cephalomedullary nails, the TFNa and Gamma 3, to evaluate differences in time from implantation to failure, and to determine factors contributing to early failures.

MATERIALS AND METHODS

A search of the MAUDE database with problem code "break" and problem class "nail" was performed for a time

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interval from January 2015 to October 2019. All medical device reports (MDRs) for the TFNa and Gamma 3 implants that fit our search criteria were collected and organized by the FDA. Reports pertaining to breakage of instrumentation or implant components, such as an interlocking screw, were eliminated by the FDA. In addition, reports where the time of implantation was not specifically included in the data were also removed by the FDA. Time to implant failure in days was calculated by the FDA by subtracting the redacted date of explant from the redacted date of implant. For reports in which date of explant was not specifically included, the date of the report submission was used as the date of explant. Per the FDA, MDR reports are submitted to the FDA 0–2 weeks on average after the actual date of adverse events. Individual field reports from the FDA were then reviewed after filtering. Duplicate reports and reports that were miscategorized were removed by the investigator from the data set before statistical analysis.

An analysis of time from implantation to failure for the fractured implants in the database was performed using a Kaplan–Meier Curve. The log-rank test was used for testing the differences in time to implant failure among different groups to determine the statistical significance.

RESULTS

From January 2015 to October 2019, 2724 total MDRs were submitted to the FDA regarding Gamma 3 and TFNa (1651 and 978, respectively). TFNa comprised 350 reports coded "break" that included the implants, instrumentation, or implant components such as distal interlocking screw. Only 191 of 350 reports contained the date of implantation in the report. After the FDA provided individual 191 MDRs for the TFNa, 8 additional reports were removed by the investigator after being identified as duplicate or miscategorized, leaving 173 reports for analysis. Gamma 3 comprised 360 reports coded "break," but only 170 were determined by the FDA to contain the date of implantation. Eleven additional reports were removed by the investigator after being identified as a duplicate or miscategorized for the Gamma 3 data set, resulting in 159 reports for analysis. For both implants, the 2 most common categories of reports were implant fatigue failure with 342 reports and femoral head cutout with 334 reports. All implant fractures occurred in the same location through the proximal screw aperture. Implant demographics and timeline of failures are outlined in Table 1 and Figure 1, respectively.

Analysis of time from implantation to failure for the fractured implants in the database was performed using a Kaplan–Meier Curve. The mean time from implantation to failure among our cohort for the Gamma 3 was 278 days [95% confidence interval (CI), 151–207 days; median, 181 days] and 213 days for the TFNa (95% CI, 164–191 days; median, 180 days). The differences between the curves were subjected to a log-rank test and were observed to be statistically significant at $P = 0.04$ (Fig. 2). Implant diameter, length, and femoral neck angle had no impact on time from implantation to failure through the log-rank test.

Individual device reports were reviewed for the TFNa. In total, 25 implants were returned to the manufacturer for inspection with an available report. Only 2 of the inspections detailed "radial scuff marks" and "burrs" located along the lateral margin of the proximal screw aperture made by contact with a drill that accelerated fatigue. For the Gamma3, 68 inspections of the fractured implants were completed by the manufacturer with published reports. Of these, 51 inspection reports observed similar drill marks along the anterior or posterior proximal screw aperture that the report attributed to accelerated fatigue failure at that location.

DISCUSSION

Fatigue failure of cephalomedullary nails has uniformly been described by many studies as a late complication, resulting from delayed or nonunion occurring after at least 6 months.[14–24] Early fatigue failure, defined as failure before 4 months, is alarming because it occurs earlier than can be attributed to delayed union.[9,16,18,24]

There were several key findings in our study. The time from implantation to failure was on average 2 months shorter for the TFNa implants that were reported fractured than the Gamma 3 implants reported, a difference that was statistically significant with $P < 0.05$. Of the 342 implants sampled, all fractured in the same location through the proximal screw aperture. Concerning were the number of early fatigue failures or implant fractures before 4 months observed for both the TFNa and the Gamma 3 implants (53 and 47, respectively). For the TFNa implants that failed, more than half of the 183 failures occurred within the first 6 months. Considering host factors such as bone quality, fracture type/stability, pathologic fracture, and surgeon factors such as reduction quality all exert their effect on fatigue failure after 6 months through delayed union; many of the failures reported in this study remain unexplained.

TABLE 1. Implant Demographics for Implants Included in the Cohort

	TFNa <4 mos	Gam3 <4 mos	TFNa	Gamma 3
Total	53	47	183	159
9 cm	1	0	14	0
10 cm	13	3	52	28
11 cm	16	43	56	119
12 cm	13	N/A	45	N/A
13 cm	N/A	1	N/A	2
14 cm	6	N/A	10	N/A
120 degree	N/A	3	N/A	9
125 degree	11	38	54	114
130 degree	38	6	123	26
Short	7	11	31	38
Intermediate	6	14	19	37
Long	36	22	130	74

Separate columns are included for the early failures that occurred before 4 months. Not all reported failures documented the size of the failed implant.

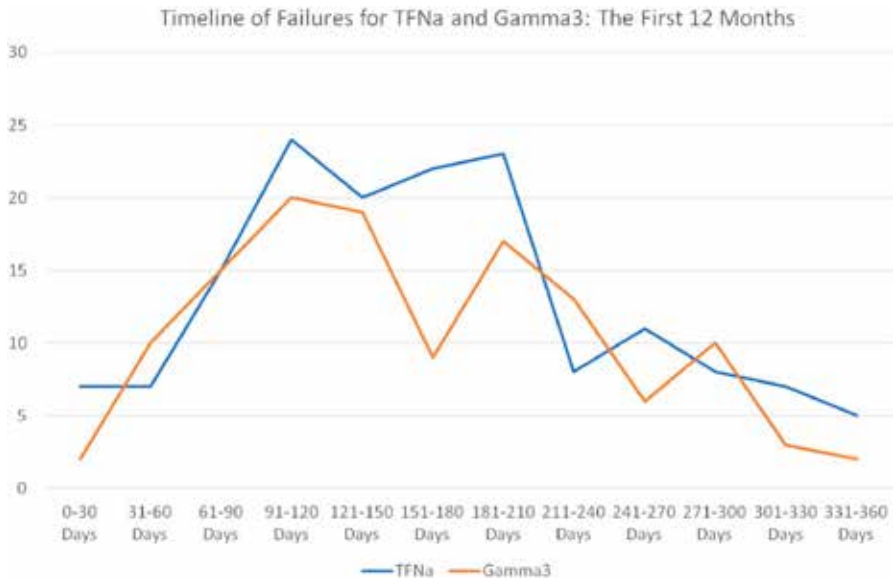

FIGURE 1. Time to failure for implants that failed plotted as the number of failures (y axis) found per time interval in days post-operatively (x axis). Depicted are only reported failures that occurred during the first 12 months post–implantation.

For the early failures, it was hypothesized that the fatigue strength of the implants may have been compromised by damage from the reaming drill before lag screw/blade insertion. As the lateral implant wall is exposed to the highest tensile forces in this same key location, notches can be devastating for the ability of the implant to resist fatigue.[17] A reduction in fatigue strength by 50% has been reported in finite element studies of notched titanium nails.[25] For the Gamma 3 implants that failed in the first 4 months, almost all of the published manufacturer's inspection reports (19 of 21) discovered notches in the implant at the point of failure from drilling (Fig. 3). For the TFNa implants that failed early, there was only one reported notch in the available inspection reports, which suggests that fatigue failures as early as 2 or 3 months are occurring in the TFNa without implant damage. This finding is consistent with the other published cohort of atypical implant fractures in the TFNa where early failures occurred without compromise of the implant from notching.[11]

Implant "notching" occurs when the targeting device has been damaged, when the targeting device has been improperly assembled, or when bending forces are applied to the drill/targeting device during insertion. To prevent notching, the technique guide for the Gamma 3 also recommends predrilling the lateral cortex of the femur before K-wire insertion for lag screw placement.[26] Predrilling will help avoid deflection of the K wire on hard cortical bone forcing the wire away from the center of the proximal screw aperture into a more eccentric position. An eccentrically placed K wire will be closer to the implant wall resulting in wall contact by the reamer and notching. Design differences in the targeting devices themselves may also contribute to insertional notching. The technique guide for the TFNa recommends against overtightening the compression mechanism on the aiming arm to avoid additional deforming forces from being applied to the guidewire resulting in notching.[27] Not all notches are attributed to the stepped reamer, as a helical blade inserted over an eccentrically placed guidewire can still cause minor notches or abrasions in titanium that compromises fatigue strength.[16,25,28] If significant clinical suspicion exists for implant notching during insertion, immediate implant removal and exchange would be indicated.

There have been several changes in the design of the proximal TFNa and Gamma 3 implants which could account for some of the key findings in our study. The weakest portion of the cephalomedullary nail is at the proximal screw aperture where the implant's cross-sectional area is reduced by almost 75 percent.[29] This key region was made even thinner in both the Gamma 3 and TFNa with reduced proximal diameters from 17 to 15.5 and 15.66 mm, respectively. Further reduction in the proximal diameter, in some cases down to 13.4 mm, is noted in the TFNa because of the design of the "lateral relief cut." The effect of the lateral relief cut on the implant wall surrounding the proximal screw aperture is best demonstrated radiographically. Radiographic survey of the Gamma 3, TFN, and TFNa does reveal an additional key change in lateral wall thickness of the TFNa that could theoretically result in increased implant failures (Fig. 4) Identified in Figure 4 is an area of sharp transition in the thickness of the lateral wall distal to the proximal screw aperture. Compared with both TFN and Gamma 3 implants, the TFNa lateral wall thickness is markedly thinner in this region. Furthermore, the threads on the implant in the cannulation below the proximal screw aperture would contribute to poor stress distribution on the region of the nail that is subjected to the highest tension forces.[17,30–33] The novel Ti-15Mo (TiMo) titanium alloy used in the TFNa has a lower tensile strength in smooth tensile testing compared with the Ti-6Al-4v (TAV) titanium alloy found in other cephalomedullary nails.[34] Simply stated, an implant with a thinner lateral wall subjected to tension forces made of an alloy with a lower smooth tensile strength would likely fail faster.

The changes in design of TFNa could also result in implant failures that seem atypical in location and morphology. During the first phase of fatigue failure, initial crack

Gamma3: Summary Statistics for Time Variable Days

Quartile Estimates				
	Point	95% Confidence Interval		
Percent	Estimate	Transform	[Lower	Upper)
75	299.00	LOGLOG	254.00	387.00
50	181.00	LOGLOG	151.00	207.00
25	105.00	LOGLOG	91.00	125.00

Mean	Standard Error
278.10	24.76

TFNa: Summary Statistics for Time Variable Days

Quartile Estimates				
	Point	95% Confidence Interval		
Percent	Estimate	Transform	[Lower	Upper)
75	278.00	LOGLOG	238.00	317.00
50	180.00	LOGLOG	164.00	191.00
25	113.00	LOGLOG	98.00	134.00

Mean	Standard Error
213.80	10.97

Summary of the Number of Censored and Uncensored Values					
Stratum	Nail	Total	Failed	Censored	Percent Censored
1	Gamma3	159	159	0	0.00
2	TFNa	183	183	0	0.00
Total		342	342	0	0.00

The SAS System

The LIFETEST Procedure

Testing Homogeneity of Survival Curves for Days over Strata

Rank Statistics	
Nail	Log-Rank
Gamma3	-18.331
TFNa	18.331

Covariance Matrix for the Log-Rank Statistics		
Nail	Gamma3	TFNa
Gamma3	80.5848	-80.5848
TFN	-80.5848	80.5848

Test of Equality over Strata			
Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.170	1	0.041

FIGURE 2. Results of Logrank test for significant differences between the Kaplan-Meier curves of the TFNa and Gamma 3 Implants.

formation, secondary fracture lines could extend distally below the proximal screw aperture into the thinner lateral wall because of the poor stress distribution and alloy

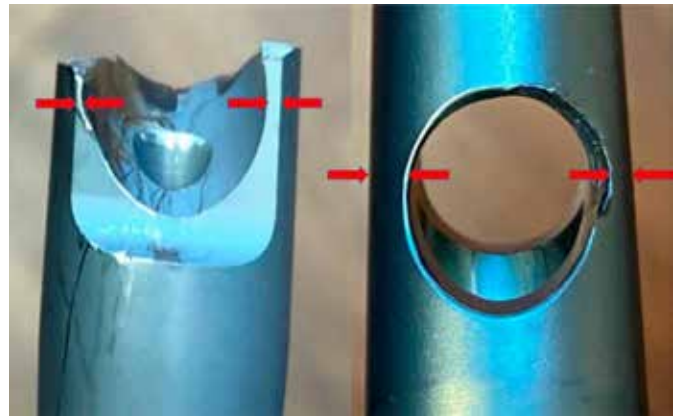

FIGURE 3. Pictured left: distal portion of fractured Gamma 3 implant looking at the lateral aspect of the proximal screw aperture. Arrows outline borders of implant walls in this region. Decrease in wall thickness on the left side of the aperture can be appreciated by comparing the distance between the opposing arrows. A large notch contributed to fatigue failure at 5 months. Other factors contributing to fatigue in this case were delayed union of subtrochanteric femur fracture and BMI >40. Pictured right: differences in lateral implant wall thickness of the proximal screw aperture of a notched TFN are marked by arrows. All 342 failed implants fractured in proximity to this area.

properties described.[21,33,34] This break pattern and location correlates with the atypical failures of the TFNa observed by Lambers et al with additional implant fragments and cracks noted surrounding the point of failure along the proximal screw aperture. Typical fatigue failure of cephalomedullary implants results in the formation of 2 implant pieces, and therefore, secondary fragmentation of the implant at the point of failure would be unusual.[16,21,28,29,35] Descriptions of this secondary fragmentation of the TFNa at the point of failure were noted in the manufacturer's inspection reports available in the MAUDE data pool as well. Formal finite element analysis to quantify the changes in structure and their potential impact on fatigue failure would be required to adequately describe the differences observed.

There were several limitations with the utilization of the MAUDE database for this study. Although 95% of the reports in the MAUDE database are submitted by the manufacturer, there is no standardization in the type of data that should be included in the reports.[12,13] Key information is often missing in the reports, which affects both the quality and validity of the data. Of the 360 break reports submitted to the FDA for the TFNa, only 191 reports contained the actual date of implantation for analysis. Similar reporting patterns were noted with the Gamma 3, where only 170 of 370 reports contained the date of implantation. One possible explanation for this missing data is that the actual date of implantation may not have been deemed relevant to device failure. Late implant breakages, such as fatigue failure in the setting of a prolonged nonunion, are expected and not likely to be due to manufacturing defects. Under these circumstances, the date of implantation would be less likely to be included among the details in the MDR. This could have contributed to the

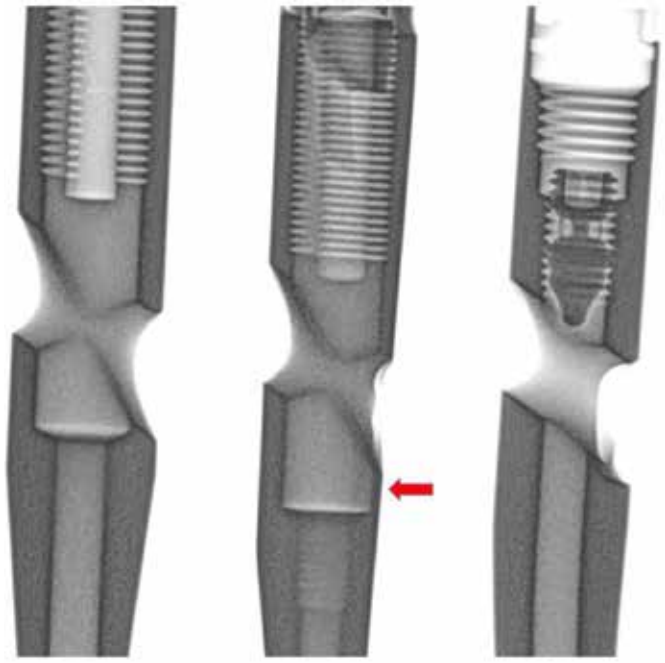

FIGURE 4. X-ray of 12 mm TFN, 10 mm TFNa, and 10 mm Gamma 3 implants from left to right. Single arrow identifies the lateral wall of TFNa implant just inferior to the proximal screw aperture in a region of sharp transition in wall thickness that is new compared with previous design of TFN. Wall thickness in this key region seems to be narrowest in the TFNa partially because of the design of the "lateral relief cut," which not only decreases proximal implant circumference but results in a markedly thinner implant wall laterally compared with the opposite wall medially. It is important to note that the tensile forces subjected to the implant during bending are highest in this same region. In the Gamma 3 implant of equivalent size pictured on the far right, there seems to be minimal difference in medial/lateral wall thickness in this region.

asymmetric distribution of the early failures compared with the late failures observed for both the TFNa and Gamma 3. As data for both the TFNa and Gamma 3 related to time to implantation were filtered exclusively by the FDA, and the authors of the study were blinded to the complete data set, minimal bias was incurred as a result of the filtering process.

Outside of incomplete dates, additional reports in the study were eliminated for redundancy. The Maude database is organized by the problem code. Searching the database with "break" as the problem code will provide all break events for the implants, their components, and their instrumentation. For cephalomedullary nails, the list of broken implants would include a list of broken nails, broken distal interlocking screws, broken helical blades, broken guidewires, broken drill bits, broken stepped reamers, and broken locking mechanisms. Separate and redundant reports are issued for each component involved (such as nail and interlocking screw), such that up to 4 reports can be generated per "event." This requires each report to be carefully reviewed and filtered to eliminate these redundancies. Most of the duplicate reports were eliminated concordantly with reports that lacked date of implantation by the FDA before being provided to the investigator. From the initial data set provided by the FDA, only 8 additional reports were eliminated by the investigators for the TFNa, and 11 reports were eliminated for the Gamma 3 after determining that they were redundant or that involved implant component/instrumentation and not the nail itself. Because the authors were blinded to the data before most filtering, the chances of selection bias were minimized.

As almost all reports are submitted by the medical device manufacturers, protected patient information can also be missing from the reports. Therefore, the effect of confounding variables such as fracture reduction, fracture stability, patient age, bone quality, patient weight, or presence of pathologic fractures on implant failure cannot be adequately studied. With limited data to describe the homogeneity of the patient populations among compared implants, the possibility of sampling bias among the data pool exists. Because the confounding variables mentioned all exert their effects on implant fracture after 6 months, they likely do not play a role in explaining the failures of the TFNa and Gamma 3 observed before 4 months in our study. Despite the limitations outlined above, the MAUDE database represents the largest collection of data pertaining to medical device failures in the United States. It is mandatory that implant manufacturers report all known medical device failures and adverse events to the FDA. Failure to do so can result in penalties. As such, one strength of the database is its ability to capture as many events as possible. There is variability in the content of the reports which does limit the scope of investigation in many circumstances. The validity of the data is enhanced with a rigorous filtering process that ensures only the best quality information is used for analysis. Because the authors of the study were blinded from most of the filtering, the selection bias was minimized as a result of the filtering. Information that is selectively excluded in the reports may represent an omission bias on behalf of the medical device companies. A concerning issue was the MDRs and manufacturers' inspection reports submitted to the FDA that attributed medical device fracture to nonunion/delayed union before 4 months. A formal implant registry would eliminate some of these issues and enable more accurate performance evaluation of orthopedic implants. Another limitation of the study lies in establishing the exact date of implant fracture. Implant fracture can be a subtle finding on routine radiographs. In some MDRs, implants may have broken sooner than reported. This would likely have a larger effect on the data for the late failures. Furthermore, if the company's representative is not present at the extraction procedure, as can occur when a different manufacturer's device is reimplanted, the event may pass unreported as observed in a case at our own institution. In conclusion, of the 342 implants sampled all fractured in the same location through the proximal screw aperture. The time from implantation to failure was on average 2 months shorter for the TFNa implants that were reported fractured than the Gamma 3 implants reported, a difference that was statistically significant with $P < 0.05$. In contrast to other studies regarding fatigue failure, many implant fractures in both the TFNa and Gamma 3 occurred earlier than can be attributed to delayed or nonunion. The TFNa implant exhibits atypical behavior compared with the

Gamma 3 implant with failures before 4 months arising without implant notching. Establishing a formal implant registry in the United States would allow for more accurate performance evaluation of orthopaedic implants.

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