

# Defining Cephalomedullary Nail Breakage Rates: A Systematic Review and Meta-Analysis

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**Objective:** To establish the background rate of breakage of cephalomedullary nails.

**Data Sources:** MEDLINE, PubMed, and Web of Science were searched on April 3, 2023.

**Study Selection:** All English-language studies that examined trochanteric with or without subtrochanteric fractures and identified cephalomedullary nail breakage as an outcome measure and a breakage rate could be derived were included. Implants captured were predominantly the TFNA, TFN, and PFN by DePuy Synthes, various versions of the Gamma nail by Stryker, the Zimmer Natural Nail by Zimmer Biomet, and the Intertan by Smith and Nephew.

**Data Extraction:** The author, year of publication, dates of implant insertion, study design, method of detection of breakages, implant used, number of implant breakages, number of implants inserted, breakage rate, and follow-up were extracted.

**Data Synthesis:** Meta-analysis of included studies used descriptive nonparametric statistics and a noncomparative proportion for the pooled result. Differences in results between study design types were compared using the mean breakage rate per study design.

**Conclusions:** Cephalomedullary nail breakage is a rare complication with a median reported rate of 0.6% and a pooled result rate of 0.4%. Ninety-five percent of studies had a breakage rate of 1.3% or less, which sets a benchmark from the reported literature for future studies. There is wide variability in rates of breakage reported

between different types of study designs with single-center review studies reporting breakage rates nearly 4-fold greater than large-scale administrative database reviews. The rate of implant breakage should not be used in isolation to judge an implant's performance.

**Key Words:** intramedullary nail, cephalomedullary nail, proximal femur fracture, breakage rate, mechanical failure, implant failure

**Level of Evidence:** Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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## INTRODUCTION

Treatment of proximal femur fractures often uses a cephalomedullary nail to achieve osteosynthesis. As described by Gaebler et al,<sup>1</sup> they are “a temporary implant characterized by a limited life expectancy under continuous dynamic stress.” After sufficient cyclical loads any implant will undergo fatigue failure if the fracture does not heal and the fatigue limit of the implant is surpassed during activity cycles. Risk factors for cephalomedullary nail breakage include low American Society of Anaesthesiologists score, unstable fracture types (pathologic, reverse oblique, subtrochanteric), younger age, poor reduction quality, loss of post-eromedial support, prior radiotherapy, and a large offset from nail to medial blade/screw tip.<sup>2–5</sup> Implant damage at insertion may also play a role, as discussed by Klima et al.<sup>6</sup> Thus, the implant at risk of breakage is one that is poorly supported biomechanically (unstable fracture pattern, pathologic lesions) for an extended period of time (nonunion or delayed union for more than 4 months) and placed in an active (younger, healthier) patient who will put the device through many load cycles. Breakages that occur early (during the expected fracture healing time) are unusual and do not fit this paradigm of delayed healing resulting in fatigue failure of the implant. Although time to implant breakage is deliberately excluded in this study to focus on rates of breakage instead, previous authors have demonstrated that cephalomedullary nail breakage usually occurs at a mean of 9 months after insertion.<sup>7</sup>

The breakage rate of a cephalomedullary nail is the number of implant breakages (numerator) divided by the total number of implants inserted (denominator). This is different from the overall “failure rate” that may include other causes of mechanical failure such as loss of fixation or cut out, which may be as high as 5%–6%.<sup>8</sup> A standard reference rate for cephalomedullary nail breakage in the literature is lacking with reported rates varying between 0% and 8%.<sup>3,4,9–11</sup>

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Ethical Review Committee Statement: As a meta-analysis this research is exempt from ethical review.

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There are several challenges constructing the numerator and the denominator in a breakage rate. Without registries or mandatory reporting, implant breakage detection in institutional studies generally relies on re-presentation to the same hospital for treatment of implant breakage with appropriate documentation or coding to capture the event. Patients with failures may not present to the same institution as their index procedure and would then be missed. Laboratory repositories are another detection method, and our research group based in Perth, Western Australia is fortunate to work alongside a state-wide biomedical engineering department that collects and analyses broken implants. This involves hospitals returning faulty or broken implants after removal from the patient to a central government-funded and independent repository. Biomedical engineers undertake review of the prostheses, produce a report and store the implants in case later additional review is required. This system is unique and is not observed in other states of Australia. Although voluntary, contribution rates are high and this combined with an isolated, urban population provides high-quality data. This resource facilitated the reporting of a series of breakages recently, which has led to numerous studies in response, looking into the poorly-investigated topic of cephalomedullary nail breakage.<sup>12</sup>

To increase participant numbers, some authors have interrogated large-scale US health care databases.<sup>13–16</sup> These are considered administrative rather than clinical databases, because the information is typically compiled from billing information and is not recorded primarily for clinical research purposes.<sup>17</sup> Administrative databases that use the International Classification of Diseases (ICD) codes to capture implantation or breakages rely on accurate translation of records and operation reports by health information managers who may not understand the differences between implant types or revision procedures. Schneble et al<sup>18</sup> demonstrated that accuracy in ICD coding for proximal femur fracture diagnosis was consistently poor. Breakage detection in these studies also relies on searching for the appropriate queries to include all the various treatments. These include nonoperative treatment (which most detection methods will miss altogether), isolated implant removal, revision nailing, arthroplasty (resection, partial or total), proximal femur replacement, and extramedullary osteosynthesis.<sup>19</sup>

Although administrative databases have the advantage of enrolling a higher number of patients, these studies often lack specific critical clinical information in the data. A quality study on implant breakage should include a subgroup analysis and specify the types of fractures treated in their study population. Studies that look at pathologic (8%), subtrochanteric (5%), or reverse obliquity (4%) fractures in isolation demonstrate higher breakage rates than others.<sup>3,4,11</sup> In addition, time to failure, and the location of the implant breakage are clinically relevant pieces of information that should be included in any comprehensive study on implant breakage. To maintain a focus on failure rates in this study, the location of the failures has been omitted, and is well published elsewhere.<sup>10</sup>

The primary aim of this study is to identify a reference rate of cephalomedullary nail breakage reported in the literature. A secondary aim was to assess and explore the

variability in breakage rates calculated between different study designs. It was hypothesized that there would be significant variability between studies, large-scale databases searches would under-report breakage rates, and the breakage rates would remain low across studies.

## METHODS

### Inclusion and Exclusion

English-language studies were identified through a systematic review conducted on the April 3, 2023, using Ovid MEDLINE (Wolters Kluwer), PubMed (National Library of Medicine) and Web of Science Core Collection (Clarivate, St. Helier, Jersey, United Kingdom). The bibliographies of published studies were reviewed, and additional studies were included where relevant. The systematic review was guided by the standards of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) Statement.<sup>20</sup>

The search terms used are listed below. Medical Subject Heading (MeSH) terms were used when available (Ovid MEDLINE and PubMed).

*Ovid MEDLINE:* Bone Nails/and Femoral Fractures/ and (“nail breakage” or “nail fracture” or “Nail rupture” or “broken nail” or “Implant Failure” or “Implant Breakage” or “Implant Fracture”).

*PubMed:* (bone nails[MeSH Terms]) AND (femoral fractures[MeSH Terms]) AND (“nail breakage”[Text Word] OR “nail fracture”[Text Word] OR “Nail rupture”[Text Word] OR “broken nail”[Text Word] OR “Implant Failure”[Text Word] OR “Implant Fracture”[Text Word] OR “Implant Breakage”[Text Word]).

*Web of Science:* (TS = (intramedullary nail OR cephalomedullary nail)) AND TS = (“nail breakage” OR “nail fracture” OR “Nail rupture” OR “broken nail” OR “Implant Failure” OR “Implant Breakage” OR “Implant Fracture”) AND TS = (“femur” OR “femoral”).

### Study Eligibility Criteria

Eligibility criteria was based on the Population Intervention Comparators Outcomes Study design framework. Studies were included that met the following criteria:

*Population:* Studies with human adult participants aged 18 years and over. Studies had to specifically mention implant breakage, failure, or rupture as an outcome in the abstract, methods, or results sections. Implantation needed to occur during or after 1989 (chosen as the year of release of the first Gamma nail).

*Interventions/Comparators:* Treatment with a cephalomedullary nail for a proximal femur fracture. The fracture type had to include trochanteric fractures with or without subtrochanteric fractures, if specified. Studies or subgroups containing solely pathologic fractures were excluded. Having some pathologic fractures in the study cohort was not an exclusion criterion.

*Outcome:* Number of broken and total number of cephalomedullary nails able to be derived.

*Study Design:* No restrictions.

## Outcomes and Prioritization

The primary outcome of interest was the implant breakage rate expressed as a percentage. These were used to collate and compare breakage rates according to study design and calculate a pooled breakage rate.

## Screening and Data Extraction

Screening was conducted by the lead author (A.L.) in 3 stages. Stage 1 involved the 3 database searches using the specific search terms listed, combining the results with any additional references, and removing duplicates. Stage 2 involved screening of full abstracts. At stage 3, full-text articles were retrieved and assessed against the eligibility criteria. A risk of bias assessment was not performed because the review involved cohort studies screening for the same outcome, without comparator groups.

Data extraction was performed by the same author (A.L.) and included the author, year of publication, dates of implant insertion, study design, method of detection of breakages, implant used, number of breakages, number of implants inserted, breakage rate, and follow-up. Follow-up was recorded as it was found in the publications as a mean, minimum, or range.

## Approach to Evidence Synthesis

Breakage rate was described individually for each study. Descriptive statistics were undertaken using Microsoft Excel (Microsoft, Redmond, WA). Nonparametric data were described using median and interquartile range. A pooled result for all studies was calculated by the sum of all breakages divided by all implanted cephalomedullary nails. The pooled analysis excluded the 2 systematic reviews because these had overlap with the other included studies and some studies included in the meta-analyses did not meet our strict inclusion criteria. Where more than one publication was available for a particular study design, the breakage rates were compared by study design as an average rate (the mean of each study design's rates).

## RESULTS

### Systematic Review

Database searches revealed 635 potential records with an additional 36 records identified through reference review. After duplicate removal, 407 records remained. After abstract review, 363 articles were excluded leaving 47 that were assessed by full-text review. Twenty-three further studies were excluded, leaving 24 studies included in the meta-analysis. The PRISMA flow diagram is shown in Figure 1.

### Individual Study Analysis

A total of 24 studies demonstrated a positively skewed nonparametric distribution of results as demonstrated in Figure 2. The median breakage rate was 0.6% with an interquartile range of 0.6% (0.3%–0.9%) and a range from 0.0% to 4.7%. The follow-up was greater than 6 months in all individual studies, although in 1 study, it was not specified.<sup>21</sup> Pooling the results, with the 2 meta-analyses excluded, a total

of 206 breakages were reported in 51,952 patients. This gives a pooled breakage rate across the cohorts of 0.4%. Table 1 summarizes the findings. There was one statistical outlier that reported a high implant breakage rate of 4.7%.<sup>21</sup> This study examining the TFNA implant had a mean time to failure of 10 months and 3 of the 6 implant breakages occurred in patients with a confirmed or suspected pathologic fracture. As also noted by Lambers et al,<sup>12</sup> there was a high prevalence of reverse oblique fracture patterns in this cohort.

## Study Designs

There were 2 meta-analyses, 1 prospective randomized trial, 2 multicenter retrospective reviews, 4 retrospective database reviews, and 15 single-center retrospective reviews. The mean breakage rate of all the studies for each study design is shown in Figure 2. The single prospective randomized trial had a cohort of 168 patients with no breakages reported and is not included in this chart.

## Detection of Breakage

Detection of breakage in the prospective study and in the retrospective single-center and multicenter studies occurred through hospital record review (usually a combination of patient notes and imaging). For database papers, 3 of the studies detected breakage by ICD code searches for “breakdown of internal device” AND (femur fracture repair OR device removal from femur) occurring in one hospital admission.<sup>14–16</sup> The fourth study detected revisions defined as any operation after index procedure in which a component was removed and/or replaced; however, it did not specify how the database was queried for that outcome.<sup>13</sup> Those patients then had a hospital record review.

## Implant Types

A range of manufacturers and designs were assessed. Heterogeneous studies and small subgroup numbers meant that a comparison of breakage rates between implants would be statistically invalid.

## DISCUSSION

This study is the first systematic review to summarize and pool results from the literature that specifically examines cephalomedullary nail breakage. The median breakage rate of 0.6% sits within the range outlined in other nonsystematic reviews (0.5% and 1.0%).<sup>9,10</sup> The narrow spread of results (interquartile range of 0.6%) is an improvement to the wide variation in rates previously reported by other studies, suggesting this is a more accurate estimate (Fig. 2). Ninety-five percent of the studies had a breakage rate of 1.3% or less. This serves as an upper limit for the standard breakage rate reported in studies against which to compare future results. It is important to note that breakage rates alone should not be used to determine implant effectiveness.<sup>36</sup> Revision for all causes, cost, union rates, and patient reported outcomes are other important tools for determining overall implant safety and performance.

There was a wide variability in rates of breakage reported between different types of study designs with

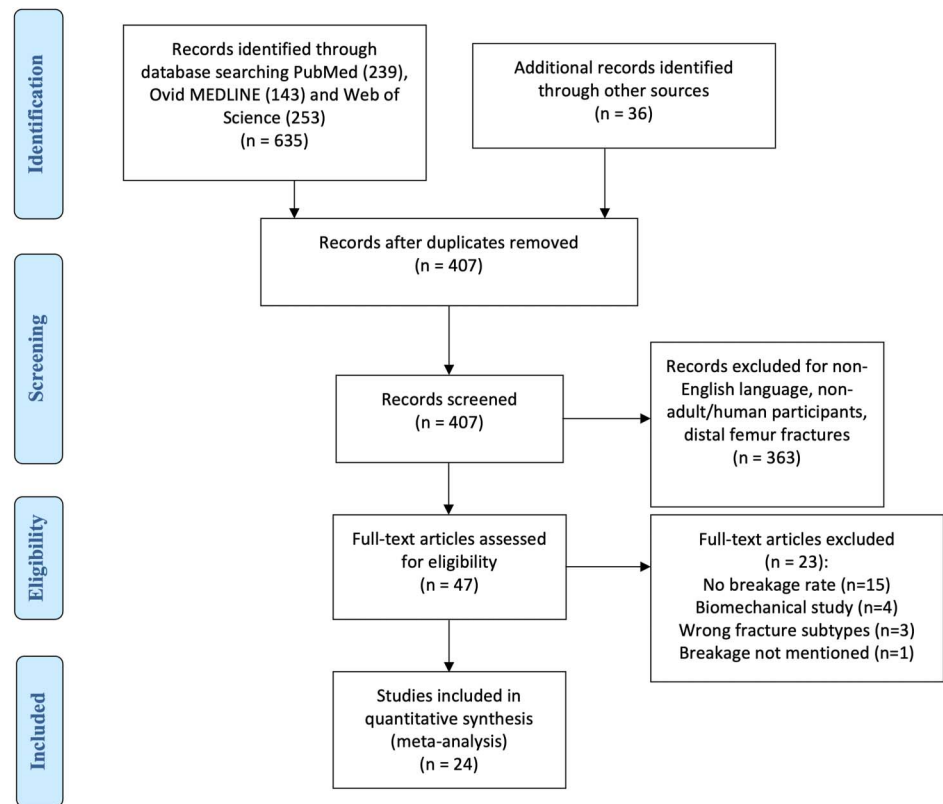


FIGURE 1. PRISMA flowchart.

single-center review studies reporting breakage rates that are nearly 4-fold greater than large-scale administrative database reviews. The rate was lowest among the large-scale administrative databases, and progressively increased from retrospective multicenter trials to meta-analyses, to retrospective single-center studies (Fig. 3). Two possible explanations for the higher rates in institution-level reviews include a relatively captive population with better detection rates for the numerator or missing patients in the denominator who have had implants placed, but were not captured correctly. Lower rates of breakage captured in large-scale administrative databases may be because of poor sensitivity in detection methods of breakage (such as not capturing certain revision procedure codes), or because of misclassification of the at-risk population to unintentionally increase its size (such as including additional nonintramedullary implants).

There could also be bias introduced from patient selection. The Medicare supplemental claims database as an example excludes patients younger than 65 years of age, and because young age is a risk factor for implant breakage, this dataset may underestimate breakage rates. Chitnis et al<sup>15</sup> derives 74% of its study population from the Medicare supplemental claims database. It is also worth noting that 3 of the 4 large-scale database searches were conducted by employees of a medical technology company that manufactured the implant it studied, which would have the potential to introduce bias from conflict of interest.<sup>14–16</sup> With no gold standard

reference, the true accuracy of all of the studies remains unknown.

The study designs also differed in their reported explanation of breakage. The administrative databases tended to explain implant breakages as a result of more general causes such as delayed union and early weight-bearing.<sup>13,16</sup> This was likely because the smaller single center institutional studies had access to more detailed data that could evaluate variables such as adequacy of reduction.

Despite large volumes of insertions, the implant breakage events were rare which makes the studies underpowered to draw meaningful conclusions in comparing performance between implants. For example, the Goodnough et al<sup>13</sup> study had a lower rate of breakage in the TFN compared with the TFNA group (0.06% vs. 0.2%); however, the events were only 2 and 5 breakages captured, respectively. None of the studies that specified 2 or more types of broken implants had more than 7 breakages of any 1 prosthesis type. Wallace et al<sup>16</sup> captured 56 breakages; however, it pooled the Zimmer Natural Nail and Gamma 3 Nail in their analysis without a breakdown of the numbers of each, preventing meaningful comparison.

The major strength of this systematic review is the strict inclusion criteria selecting studies that examined cephalomedullary nail breakage as an outcome. This ensures that breakage cases were at least examined even if they did not occur, and improves on 2 previous nonsystematic literature reviews.<sup>9,10</sup> The major limitations of the studies included the

TABLE 1. Summary of Systematic Review by Author

Author	Year	Study Design	Failure Capture	Dates	Nail	Nail Breakages	Nails	Rate	Follow-up
Alvarez et al <sup>22</sup>	2004	Retrospective Institutional: Single Center	Hospital Records Review	1990–2002	Gamma (Pre-Gamma 3)	5	843	0.6%	6–10 m
Appelt et al <sup>23</sup>	2007	Retrospective Institutional: Single Center	Hospital Records Review	2002–2003	PFN	0	178	0.0%	>6 m
Ballal et al <sup>24</sup>	2008	Retrospective Institutional: Single Center	Hospital Records Review	2000–2006	PFN	1*	160	0.6%	>6 m
Chitnis et al <sup>14</sup>	2020	Retrospective Database: Mercy Health Electronic Health Records	ICD code search	2016–2020	TFNA	0	733	0.0%	10 m
Chitnis et al <sup>15</sup>	2021	Retrospective Database: IBM MarketScan Commercial and Medicare Supplemental Claims	ICD code search	2016–2019	NS	73†	11,128	0.7%	<2 y
Cruz-Sanchez et al <sup>25</sup>	2015	Retrospective Institutional: Single Center	Hospital Records Review	2003–2012	Gamma 3 (7/1117), Affixus (0/52), LNS-GT (0/14) and PFN (1/63)	8‡	1180	0.7%	13 m
Docquier et al <sup>26</sup>	2002	Retrospective Institutional: Single Center	Hospital Records Review	1990–2000	Gamma (Pre-Gamma 3)	1	323	0.3%	10 m
Erez and Dougherty <sup>27</sup>	2012	Retrospective Institutional: Single Center	Hospital Records Review	2006–2008	Intertan	1	127	0.8%	14 m
Gaebler et al <sup>1</sup>	1999	Retrospective Institutional: Single Center	Hospital Records Review	1992–1996	Gamma (Pre-Gamma 3)	2	839	0.2%	NS
Gallagher et al <sup>28</sup>	2019	Retrospective Institutional: Multicenter (3 sites)	Radiographic Review Only	2002–2004	PFN	0	106	0.0%	4–7 y
Goodnough et al <sup>13</sup>	2022	Retrospective Database: Integrated Health-care System Hip Fracture Registry (35 sites)	Detection of revision (method NS) and Hospital Records Review	2014–2019	TFNA (5/3972) and TFN (2/4007)	7	7979	0.1%	3 y
Iwakura et al <sup>10</sup>	2013	Literature Review and Meta-analysis	NA	Various	Gamma (Pre-Gamma 3)	19	3761	0.5%	NA
Kasimatis et al <sup>29</sup>	2007	Retrospective Institutional: Single Center	Hospital Records Review	1991–2002	Gamma (Pre-Gamma 3)	4	412	1.0%	NS
Li et al <sup>7</sup>	2021	Retrospective Institutional: Single Center	Hospital Records Review	2008–2018	NS	6	785	0.8%	>12 m
Liu et al <sup>30</sup>	2013	Retrospective Institutional: Single Center	Hospital Records Review	2003–2009	TFN	2	223	0.9%	24 m
Nayar et al <sup>21</sup>	2021	Retrospective Institutional: Single Center	Hospital Records Review	2017–2020	TFNA	6	127	4.7%	NS
Rollo et al <sup>9</sup>	2018	Literature Review and Meta-analysis	NA	Various	Mixed use	58	5835	1.0%	NA
Schmitz et al <sup>31</sup>	2022	Retrospective Institutional: Single Center	Hospital Records Review	2011–2016	Gamma 3 (5/797) and TFNA (3/542)	8†	1339	0.6%	3 y
Shannon et al <sup>32</sup>	2019	Prospective: Randomized	Patient & radiographic review	2014–2017	TFNA (0/89), Gamma 3 (0/67) and Affixus (0/12)	0	168	0.0%	14 m
Swift et al <sup>33</sup>	2022	Retrospective Institutional: Single Center	Hospital Records Review	2014–2018	ZNN & TFN (breakdown NS)	4	662	0.6%	9 m

(continued on next page)

**TABLE 1.** (Continued) Summary of Systematic Review by Author

Author	Year	Study Design	Failure Capture	Dates	Nail	Nail Breakages	Nails	Rate	Follow-up
Tomás-Hernández et al <sup>19</sup>	2018	Retrospective Institutional: Single Center	Hospital Records Review	2010–2015	Intertan, TFN, IMHS (breakdown NS)	13	1481	0.9%	>12 m
von Ruden et al <sup>34</sup>	2015	Retrospective Institutional: Single Center	Hospital Records Review	2005–2013	Gamma 3	8	453	1.8%	>6 m
Wallace et al <sup>16</sup>	2021	Retrospective Database: Premier Healthcare Database (365 sites)	ICD code search	2014–2019	TFNA (27/14,370) and Gamma 3/ZNN combined (29/8260)	56	22,630	0.2%	18 m
Yee et al <sup>35</sup>	2020	Retrospective Institutional: Multicenter (2 sites)	Hospital Records Review	2015–2019	TFNA	1	76	1.3%	13 m

Follow-up is described as the mean, range or minimum according to the publication terminology. The literature review papers include some articles already listed separately in the table.

\*The pathologic fracture series in this publication is excluded.

†Nail breakages indirectly calculated from total nails and breakage rate.

‡Screw only breakages excluded from review.

NA, not applicable; NS, not specified.

accuracy and reliability of event capture in database and hospital record searches. For example, in cities with more than 1 hospital for trauma care, patients may be brought to a different hospital for the treatment of an implant breakage. These patients are typically missed in institutional review study designs. For database searches, the ICD codes used for detection of revisions appeared narrow and relied on a coding diagnosis of device removal or fracture repair at the time of revision. A conversion to arthroplasty that fails to code the implant removal or breakage would then be missed.

The population at risk decreases rapidly in hip fracture cohorts because of high postoperative mortality, and not taking this into account could falsely lower the breakage rate by exaggerating the size of the population at risk. Only 2 studies accounted for censoring of patients due to death.<sup>13,15</sup> In contrast, the rate could potentially be lower than reported, such as if breakages were diagnosed when they did not occur (coding or documentation errors) or partial capture of patients at risk (missing patients that had the implants inserted).

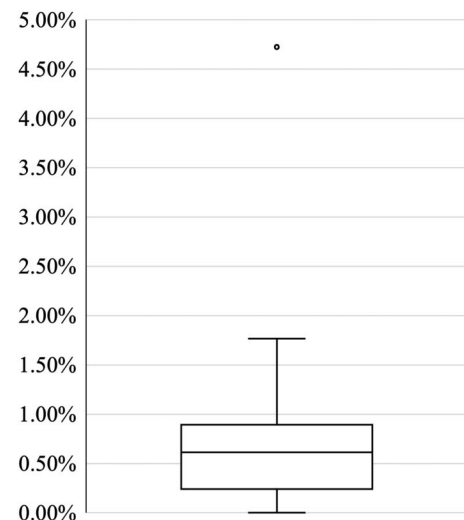
So which study design should be trusted to guide surgeons? None are completely accurate, although institution studies may have a closer estimation of true cephalomedullary nail breakage rates given the higher rate of breakage detection. These studies have the downside of smaller population sizes.

Future avenues for research include data linkage across health services for improving detection of breakages when care is transferred to another institution and comparative studies of breakage rates between different implant designs in prospective randomized controlled trials. The ideal study would accurately capture insertions and breakages with high sensitivity and specificity. Expanding ICD codes for detection of breakages to capture the broad variety of revision procedures could also improve the sensitivity of database searches and specificity could be maintained by careful record and imaging examination of those patients captured. Medical technology companies could consider assisting such research through directly providing access to data on implant insertion

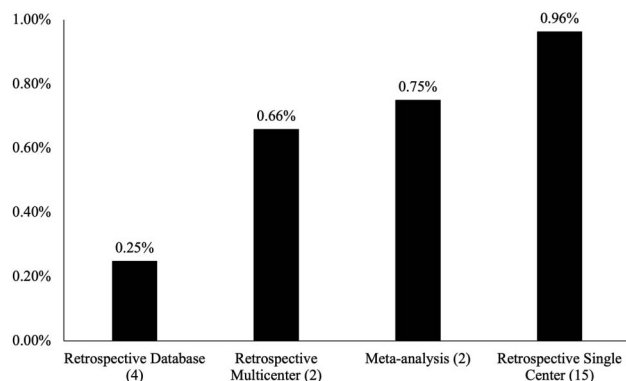
volume, which would make the denominator more robust. This typically does not occur because this company-derived information is considered commercial in confidence.

Further studies should consider reporting breakage rate not only as a simple equation of broken implants divided by inserted implants, but also account for incidents that remove the implant from the at-risk pool of patients. Incidents such as death or removal of unbroken implants would be censored and a cumulative percent revision reported. Given the great volume of hip fracture care worldwide, and the vulnerability of those who receive it, perhaps proximal femur fracture implants deserve the same scrutiny and performance documentation of their arthroplasty counterparts with large-scale national registries.

This systematic review and meta-analysis demonstrates that cephalomedullary nail breakage is rare with a median reported rate of 0.6% and a pooled result rate of 0.4%. Ninety-



**FIGURE 2.** Box plot of distribution of breakage rates.



**FIGURE 3.** Average nail breakage rate by study design (and number of studies).

five percent of studies had a breakage rate of 1.3% or less, which sets a benchmark from the reported literature for future studies. However, the rate of implant breakage should not be used in isolation to judge performance. There is wide variability in rates of breakage reported between different types of study designs with single-center review studies reporting breakage rates that are nearly 4-fold greater than large-scale administrative database reviews. Although there is variation between the study designs, none are without shortcomings and there is significant scope for further research in this area. Consideration should be given for improved trauma registries to assist with postmarket surveillance.

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## REFERENCES

- Gaebler C, Stanzl-Tschegg S, Tschegg EK, et al. Implant failure of the gamma nail. *Injury*. 1999;30:91–99.
- Johnson NA, Uzoigwe C, Venkatesan M, et al. Risk factors for intramedullary nail breakage in proximal femoral fractures: a 10-year retrospective review. *Ann R Coll Surg Engl*. 2017;99:145–150.
- Hao Y, Zhang Z, Zhou F, et al. Risk factors for implant failure in reverse oblique and transverse intertrochanteric fractures treated with proximal femoral nail antirotation (PFNA). *J Orthop Surg Res*. 2019;14:350.
- Willeumier JJ, Kaynak M, van der Zwaal P, et al. What factors are associated with implant breakage and revision after intramedullary nailing for femoral metastases? *Clin Orthop Relat Res*. 2018;476:1823–1833.
- Lee YK, Kim JT, Park CH, et al. Analysis of risk factor for nail breakage in patients with mechanical failures after proximal femoral nail antirotation in intertrochanteric fractures. *Medicine*. 2022;101:e29436.
- Klima ML. Comparison of early fatigue failure of the TFNA and Gamma 3 cephalomedullary nails in the United States from 2015 to 2019. *J Orthop Trauma*. 2021;35:e39–e44.
- Li P, Zhang Z, Zhou F, et al. Characteristics of intramedullary nail breakage in pertrochanteric femur fractures: a summary of 70 cases. *J Orthop Surg Res*. 2021;16:676.
- Klima ML. Mechanical complications after intramedullary fixation of extracapsular hip fractures. *J Am Acad Orthop Surg*. 2022;30:e1550–e1562.
- Rollo G, Rinonapoli G, Pichierri P, et al. Breakage in two points of a short and undersized “Affixus” cephalomedullary nail in a very active elderly female: a case report and review of the literature. *Case Rep Orthop*. 2018;2018:9580190.
- Iwakura T, Niikura T, Lee SY, et al. Breakage of a third generation gamma nail: a case report and review of the literature. *Case Rep Orthop*. 2013;2013:172352.
- Rappold G, Hertz H, Spitaler R. Implant breakage of the proximal femoral nail (PFN) reasons and case reports. *Eur J Trauma*. 2001;27:333–337.
- Lambers A, D’Alessandro P. Implant fracture analysis of the TFNA proximal femoral nail. *J Bone Joint Surg Am*. 2019;101:804–811.
- Goodnough LH, Chang RN, Fasig BH, et al. Risk of revision after hip fracture fixation using DePuy Synthes trochanteric fixation nail or trochanteric fixation nail advanced: a cohort study of 7,979 patients. *J Bone Joint Surg Am*. 2022;104:1090–1097.
- Chitnis AS, Holy C, Vanderkarr M, et al. Risk of nail breakage in treatment with cephalomedullary nails for proximal femoral fractures. *Value Health*. 2020;23:S580.
- Chitnis AS, Ray B, Sparks C, et al. Intramedullary nail breakage and mechanical displacement in patients with proximal femoral fractures: a commercial and medicare supplemental claims database analysis. *Med Devices (Auckl)*. 2021;14:15–25.
- Wallace A, Amis J, Cafri G, et al. Comparative safety of the TFNA-ADVANCED proximal femoral nailing system: findings from a U.S. health-care database. *J Bone Joint Surg Am*. 2021;103:1637–1645.
- Alluri RK, Leland H, Heckmann N. Surgical research using national databases. *Ann Transl Med*. 2016;4:393.
- Schneble CA, Natoli RM, Schonlau DL, et al. Reliability of International Classification of Disease-9 versus International Classification of Disease-10 Coding for proximal femur fractures at a level 1 trauma center. *J Am Acad Orthop Surg*. 2020;28:29–36.
- Tomás-Hernández J, Núñez-Camarena J, Teixidor-Serra J, et al. Salvage for intramedullary nailing breakage after operative treatment of trochanteric fractures. *Injury*. 2018;49(suppl 2):S44–S50.
- Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015;350:g7647.
- Nayar SK, Ranjit S, Adebayo O, et al. Implant fracture of the TFNA femoral nail. *J Clin Orthop Trauma*. 2021;22:101598.
- Alvarez DB, Aparicio JP, Fernández EL-A, et al. Implant breakage, a rare complication with the Gamma nail. A review of 843 fractures of the proximal femur treated with a Gamma nail. *Acta Orthop Belg*. 2004;70:435–443.
- Appelt A, Suhm N, Baier M, et al. Complications after intramedullary stabilization of proximal femur fractures: a retrospective analysis of 178 patients. *Eur J Trauma Emerg Surg*. 2007;33:262–267.
- Ballal MS, Emms N, Thomas G. Proximal femoral nail failures in extracapsular fractures of the hip. *J Orthop Surg (Hong Kong)*. 2008;16:146–149.
- Cruz-Sanchez M, Torres-Claramunt R, Alier-Fabrego A, et al. Salvage for nail breakage in femoral intramedullary nailing. *Injury*. 2015;46:729–733.
- Docquier PL, Manche E, Autrique JC, et al. Complications associated with gamma nailing. A review of 439 cases. *Acta Orthop Belg*. 2002;68:251–257.
- Erez O, Dougherty PJ. Early complications associated with cephalomedullary nail for intertrochanteric hip fractures. *J Trauma Acute Care Surg*. 2012;72:E101–E105.
- Gallagher CA, Jones CW, Kimmel L, et al. Osteoarthritis is associated with increased failure of proximal femoral fracture fixation. *Int Orthop*. 2019;43:1223–1230.
- Kasimatis GB, Lambiris E, Tyllianakis M, et al. Gamma nail breakage: a report of four cases. *J Orthop Surg (Hong Kong)*. 2007;15:368–372.

30. Liu W, Zhou D, Liu F, et al. Mechanical complications of intertrochanteric hip fractures treated with trochanteric femoral nails. *J Trauma Acute Care Surg.* 2013;75:304–310.
31. Schmitz PP, Hannink G, Reijmer J, et al. Increased failure rates after the introduction of the TFNA proximal femoral nail for trochanteric fractures: implant related or learning curve effect? *Acta Orthop.* 2022;93: 234–240.
32. Shannon SF, Yuan BJ, Cross WW, III, et al. Short versus long cephalomedullary nails for pertrochanteric hip fractures: a randomized prospective study. *J Orthop Trauma.* 2019;33:480–486.
33. Swift B, Stewart A, Grammatopoulos G, et al. Comparing the rates and modes of failure of two third generation cephalomedullary nail systems in the treatment of intertrochanteric hip fractures. *Injury.* 2022;53:2846–2852.
34. von Ruden C, Hungerer S, Augat P, et al. Breakage of cephalomedullary nailing in operative treatment of trochanteric and subtrochanteric femoral fractures. *Arch Orthop Trauma Surg.* 2015;135:179–185.
35. Yee DKH, Lau W, Tiu KL, et al. Cementation: for better or worse? Interim results of a multi-centre cohort study using a fenestrated spiral blade cephalomedullary device for pertrochanteric fractures in the elderly. *Arch Orthop Trauma Surg.* 2020;140:1957–1964.
36. Nyholm AM, Palm H, Malchau H, et al. Lacking evidence for performance of implants used for proximal femoral fractures—a systematic review. *Injury.* 2016;47:586–594.