



No difference between lag screw and helical blade for cephalomedullary nail cut-out a systematic review and meta-analysis

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Abstract

Introduction Cephalomedullary nail (CMN) cut-out is a severe complication of treatment of intertrochanteric femur fractures. This study aimed to identify modifiable risk factors predictive of implant cut-out including: CMN proximal fixation type (lag screw vs. helical blade), tip-apex distance (TAD), reduction quality, nail length, screw location, and surgeon fellowship training.

Methods A systematic review of the published literature was conducted on Pubmed/MEDLINE and Cochrane Library databases for English language papers (January 1st, 1985–May 10th, 2020), with 21 studies meeting inclusion/exclusion criteria. Studies providing quantitative data comparing factors affecting CMN nail cut-out were included, including fixation type (lag screw vs. helical blade), tip-apex distance (TAD), reduction quality, nail length, and screw location. Twelve studies were included and graded by MINOR and Newcastle–Ottawa Scale to identify potential biases. Meta-analysis and pooled analysis were conducted when possible with forest plots to summarize odds ratios (OR) and associated 95% confidence interval (CI).

Results There was no difference in implant cut-out rate between lag screws ($n=745$) versus helical blade ($n=371$) (OR: 1.03; 95% CI: 0.25–4.23). Pooled data analysis revealed TAD > 25 mm ($n=310$) was associated with higher odds of increased cut-out rate relative to TAD < 25 mm ($n=730$) (OR: 3.72; 95% CI: 2.06–6.72).

Conclusion Our review suggests that cephalomedullary implant type (lag screw vs. helical blade) is not a risk factor for implant cut-out. Consistent with the previous literature, increased tip-apex distance > 25 mm is a reliable predictor of implant cut-out risk. Suboptimal screw location and poor reduction quality are associated with increased risk of screw cut-out.

Level of evidence Level III.

Keywords Cephalomedullary nail · Intertrochanteric fracture · Lag screw · Helical blade · Implant cut-out · Tip-apex distance

Introduction

The incidence of intertrochanteric hip fractures has increased over recent years [1]. The mainstays for implant fixation of intertrochanteric fractures include the use of intramedullary nails or dynamic hip screws [2–4]. Nonetheless, the gold standard for treating unstable intertrochanteric hip fractures is internal fixation with a cephalomedullary nail (CMN) [5]. One of the most common complications of CMN fixation is cut-out, defined as implant protrusion outside the femoral head, which can lead to varus displacement [6, 7]. While the incidence is low, ranging from 1.6 to 4.3% in most studies [8–10], implant cut-out is a severe complication associated with subsequent increased patient morbidity and mortality

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[3, 11]. For patients who experience implant cut-out, subsequent operative interventions such as implant removal, re-osteosynthesis, or hip arthroplasty conversion are often warranted [3, 11, 12].

Risk factors for cut-out for intertrochanteric fractures can be broadly classified as modifiable and non-modifiable. Non-modifiable risk factors include pre-operative fracture characteristics such as a posteromedial cortex fragment, a detached basicervical component, lateral wall fracture, and an overall unstable fracture pattern [13–16]. Modifiable risk factors within surgeon control include increased tip-apex distance (TAD), proximal fixation positioning superior to the mid femoral neck, and neck-shaft angle mal-reduction [15–17]. Perhaps the most well-defined operative risk factor for screw cut-out is the TAD, first described by Baumgaertner et al. in the context of dynamic hip screws [18]. Other operative-related risk factors such as fixation type and nail length have not been as well characterized [15]. For example, the helical blade was designed and introduced to provide stronger proximal fixation relative to the lag screw by compacting cancellous bone upon insertion; however, it is unclear whether helical blades are associated with decreased implant cut-out [16, 19–22].

To this end, it is important for orthopedic surgeons to have an appropriate understanding of modifiable operative-related risk factors for cut-out when using CMN in the treatment of intertrochanteric femoral fractures. Up to now, a series of papers have been published attempting to characterize the risk factors for screw cut-out of cephalomedullary nails in intertrochanteric femur fractures, however, to our knowledge no study has attempted to systematically review this available literature [10, 13–16, 23–25]. In particular, apart from tip-apex distance which has been well characterized as a risk factor for screw cut-out [9, 18, 21, 25, 26], there has been a lack of consensus regarding whether proximal implant fixation type (lag screw versus helical blade) is associated with subsequent screw cut-out [14–16, 27–30]. Therefore, the aim of this study was to systematically review published literature to identify the association between modifiable risk factors including (1) the tip-apex distance; (2) type of proximal screw fixation (lag vs. helical blade); (3) reduction quality; (4) optimal implant location; (5) nail length (long vs. short); (6) and surgeon fellowship training.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines were used to conduct this systematic review [31]. On March 12, 2020, a search of the PubMed/MEDLINE and Cochrane Library databases was searched for all publications on cephalomedullary nail cut-out in trochanteric femur fractures using the search terms

“cephalomedullary nail,” “proximal femoral nail,” “intertrochanteric fracture,” “peritrochanteric fracture,” “cutout,” and “failure” in combination with the Boolean operators “AND” or “OR.” An orthopedic surgery resident (M.N.) and two orthopedic research fellows (N.S. and A.E.) performed a search of the aforementioned databases and determined the relevancy of articles by reviewing the title and abstract of each article. Inclusion eligibility was subsequently determined by reviewing the title and corresponding abstract for each article; those meeting initial eligibility were further screened based on a full-text review of the articles.

Study selection

Studies included in this systematic review were comparative studies on risk factors for cephalomedullary nail cut-out, which provided quantitative data comparing factors affecting cut-out rate. Studies that lacked quantitative data or that were not prospective in nature were excluded from this study. Articles were reviewed together (M.N., N.S., A.E.), and any discrepancies were discussed. The overall selection and review process are summarized in Fig. 1. If a consensus could not be reached on article inclusion, the senior author (N.P.) was included, and a final decision was made.

Data extraction

Studies meeting inclusion criteria were tabulated into Microsoft Excel (Microsoft, Redmond, WA). Title, author, year of publication, journal, type, evidence level, sample size, method of fixation (lag screw vs. helical blade; Figs. 2 and 3), TAD (length cutoff used by each individual study), reduction quality (good vs. poor, with good defined as no evidence of fracture fragment displacement > 4 mm on any radiographic views with less than 20-degree angulation on lateral X-ray, a neutral or slightly valgus neck-shaft angle (NSA, < 5° varus or > 20° valgus) [18, 32, 33], proximal screw location (optimal vs. suboptimal, with optimal defined as center-center or inferior-center) [3, 23, 29], nail length (short vs. long), and surgeon fellowship training (specifically trauma fellowship-trained or not), cut-out rate, cut-out subgroups, other complications (all major and minor), and overall conclusions.

Quality assessment

The Methodological Index for Non-Randomized Studies (MINORS) criteria was used to assess articles for quality by an orthopedic surgery resident (M.N.) and two orthopedic research fellows (N.S. and A.E.). Included studies were graded on the level of evidence using standard and pre-defined criteria [34]. Any score differences were discussed

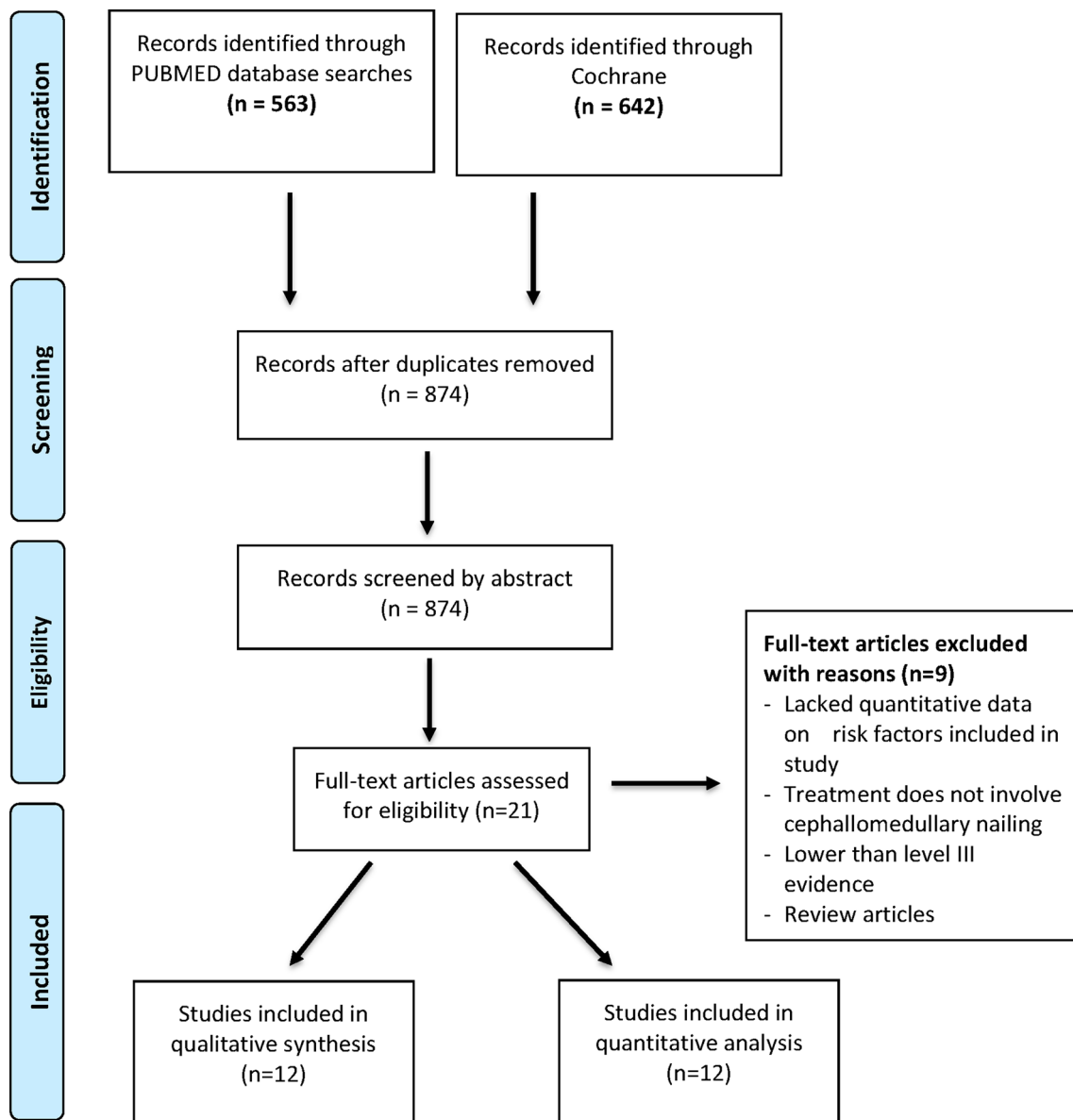


Fig. 1 Flow diagram of the literature search conducted in July 2020 by preferred reporting items for systematic reviews and meta-analyses method

among reviewers, and a consensus was reached for final scoring.

In addition, potential biases associated with the studies were addressed through the Newcastle–Ottawa Scale [35, 36], which consists of eight questions separated into three categories detailing the external validity of such studies, whether the studies were controlled for confounding variables, and any potential biases from outcome measures.

Statistical analysis

Studies included in this review were weighted based on patient size and analyzed using Review Manager (RevMan) v 5.0.

(Copenhagen: The Nordic Cochrane Center, The Cochrane Collaboration). When possible, meta-analysis and pooled analysis were conducted with forest plots constructed to summarize corresponding odds ratios (OR) and associated 95% confidence intervals (CI). Weighted means were used to compare the subgroups (TAD, implant type, reduction quality, and optimal/suboptimal location).



Fig. 2 Cephalomedullary nailing construct utilizing a lag screw with good fracture reduction and appropriate anteroposterior tip-apex distance

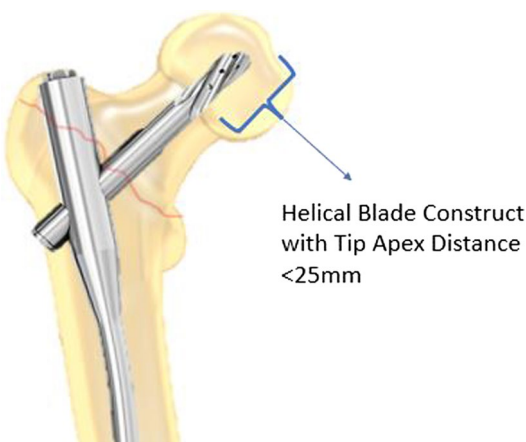


Fig. 3 Cephalomedullary nailing construct utilizing a helical blade with good fracture reduction and appropriate anteroposterior tip-apex distance

Results

General study characteristics

Our initial search yielded 21 studies meeting screening criteria, which underwent a full review. Of these, 12 studies met inclusion/exclusion criteria and were included in the analysis. All 12 studies included were retrospective case–control studies which incorporated quantitative data comparing lag screw cut-out with at least level of evidence III (Table 1). Two reviewers (M.N., N.S.) evaluated these studies using both the NOS and MINORS criteria to assess study quality. The studies had a mean NOS of 6.9 ± 0.60 (range 6–8) out of 9 with a mean MINORS of 19.2 ± 1.3 (range 18–21) out of 24.

Tip-apex distance

Overall, the 12 studies included in this study reported on a wide range of risk factors predictive of implant cut-out; this being said, the most common risk factor measured was the tip-apex distance (TAD) (Fig. 4). Altogether, TAD was used in six studies [10, 14, 16, 26–28] that included radiographic measurements of 1370 intertrochanteric hip fractures reduced by cephalomedullary nails, with the majority of studies (3/6) using 25 mm as a cutoff for predicting lag screw cut-out. These three studies by Ciuffo et al. [16], Ibrahim et al. [27], and Turgut et al. [14] included a total of 1040 hips (730 hips with TAD < 25 mm, 310 hips with TAD > 25 mm), and overall found that implants with TAD > 25 mm were associated with increased odds of cut-out relative to implants with TAD < 25 mm (Odds Ratio (OR): 3.72, 95% confidence interval (CI): 2.06–6.72) (Fig. 5). In concordance with these studies, studies that used TAD cutoffs that were close to but not 25 mm also reached similar conclusions. Shannon et al. [10] found no difference in cut-out rates between short vs. long cephalomedullary nails; however, they used a TAD cutoff of 28 mm as the only variable predictive of failure. Likewise, Li et al. [26] found that all cases of nail cut-out happened in a group with TAD > 20 mm ($p = 0.049$). Finally, John et al. [28] found that TAD was associated with cut-out even with CMNs, with a receiver operating curve using a cutoff of TAD > 23.56 mm.

Helical blade versus lag screw

The next most commonly encountered variable was proximal fixation with the use of a helical blade versus a single lag screw. A total of five studies [19, 20, 24, 25, 27] included a total of 1,116 intertrochanteric hip fractures (745 CMNs with a lag screw, 371 CMNs with a helical blade). There were a total of 59 CMN cut-outs, 37/742 lag screws (5.0%), and 22/371 helical blades (5.9%). Overall, there was no significant difference found in implant type (lag screw vs. helical blade) and risk of cut-out (OR: 1.03, 95% CI: 0.25–4.23) (Fig. 6). Of note, out of these five studies, two studies concluded that CMNs with a proximal lag screw were associated with an increased cut-out rate relative to CMNs with a helical blade [19, 20]. One was a retrospective chart review by Chapman et al. [20] including 125 patients, the smallest cohort of the group, while the other by Stern et al. [19] included 362 patients but excluded 350 patients as they did not have at least three months follow-up, although there are data supporting the majority of cut-out occurs before 12 weeks postoperatively.

Table 1 Level of evidence and population characteristics of the analyzed investigations

Author	Year	Type	LOE	N	Mean age ± SD in years (range)	Females N (%)	Fracture type (unstable [n, %])	Mean follow-up in months (range)
Ibrahim et al.	2019	Retrospective	III	314	79.4	80 (24.9%)	107 34.6%	9.3 (3–65.7)
Ciufo et al.	2017	Retrospective	III	362	83	76.8	227 (63%)	11.5 (3–88.5)
Chapman et al.	2018	Retrospective	III	125	83.65 (50–100)	104 (82.5%)	25 (19.8%)	3.6 (0.7–18.6)
Parry et al.	2018	Retrospective	III	83	81 ± 11	66%	37 (44%)	42 (6–102)
Stern et al.	2010	RCT	II	168	–	–	–	12
Turgut et al.	2016	Retrospective	III	298	74.9 ± 14.5	176 (59.1%)	178 59.7%	20.3
Pascarella et al.	2016	Retrospective	III	1022	82 (32–104)	72.62%	–	4 (3–48)
Georgiannos et al.	2014	Retrospective	III	367	80.0 (29–96)	73.0%	133 (36.2%)	12
Shannon et al.	2019	RCT	II	168	80.5 (76–84)	147 (87.5%)	8.85%	10.3 (8.8–11.7)
Stern et al.	2017	Retrospective	III	362	83	257 (76.8%)	64.4%	11.5
Li et al.	2019	Retrospective	III	87	–	–	–	–
John et al.	2019	Retrospective	III	75	69.56 (30–96)	43 (57.3%)	–	> 3 m

LOE level of evidence, RCT randomized controlled trial, SD standard deviation

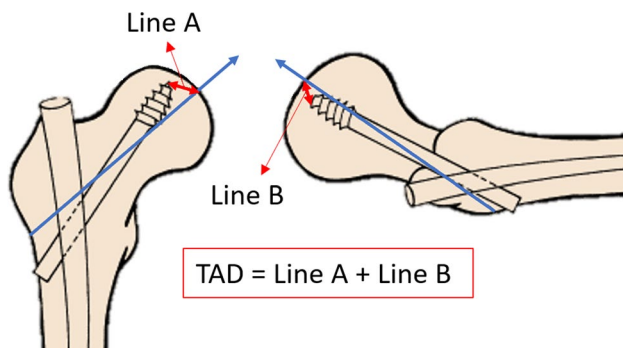


Fig. 4 Method of calculating the tip-apex distance (TAD) for cephalomedullary nails

(11.1%). Of these, 32/674 (4.7%) of CMNs with good reduction experienced implant cut-out relative to 15/84 (17.8%). Overall, meta-analysis of these three studies revealed CMNs with good reduction has statistically decreased risk of implant cut-out (OR: 0.20, 95% CI: 0.05–0.84) (Fig. 7). All three studies defined mal-reduction criteria based on those originally established by Baumgaertner et al. [18, 33], with good reductions having no evidence of fracture fragment displacement > 4 mm on any radiographic views and less than 20-degree angulation on lateral X-ray, a neutral or slightly valgus neck-shaft angle (NSA, < 5° varus or > 20° valgus) [32]. Acceptable reductions were defined as those meeting criteria for either displacement or alignment but not both, and poor reductions were meeting neither criterion.

Reduction quality

Three studies [16, 27, 37] reported reduction quality as a risk factor for implant cut-out that was incorporated for meta-analysis. A total of 758 hips were included, 674 with acceptable/good reduction (88.9%) and 84 with poor reduction

Implant optimal location

A total of three studies [14, 16, 25] compared optimal versus suboptimal implant location as a potential risk factor for implant cut-out and were included for meta-analysis. The optimal location for the head-neck fixation device portion

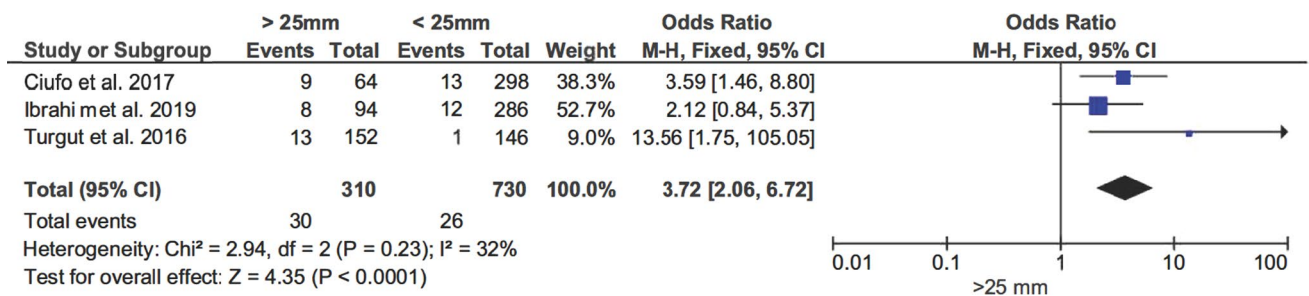


Fig. 5 Forest plot of studies comparing TAD (> 25 mm vs. < 25 mm) as risk factor for implant cut-out

of the CMN was defined by these papers as center-center or inferior-center [3, 23] and has been previously characterized as one of the most important factors to avoid subsequent mechanical failure [14, 29, 38]. Out of 735 hips, 578/735 (78.6%) were classified as having optimal location, while 157/735 (21.4%) were classified as having a suboptimal location. 23/578 (4.0%) implants with "optimized" location resulted in implant cut-out, while 18/157 (11.5%) implants with "suboptimal" location resulted in implant cut-out. Altogether, CMNs placed in an optimal location were associated with decreased implant cut-out odds relative to CMNs with suboptimal placement (OR: 0.30, 95% CI: 0.15–0.58) (Fig. 8).

Nail length

Two studies included in this study examined whether nail length was a potential risk factor for CMN implant cut-out. Parry et al. [37] included a total of 83 CMNs (74 long CMNs, nine short CMNs), all Stryker Gamma3 CMNs. 4/9 short CMNs (44.4%) were associated with implant significantly higher implant cut-out rates relative to the 5/74 (6.8%) long CMNs. Notably, their discussion agreed this was an unexpected finding as previous studies have found equivalent outcomes between short and long nails for peritrochanteric hip fractures [39, 40]. Shannon et al. [10] included a total of 168 CMNs (80 long CMNs, 88 short CMNs); of these,

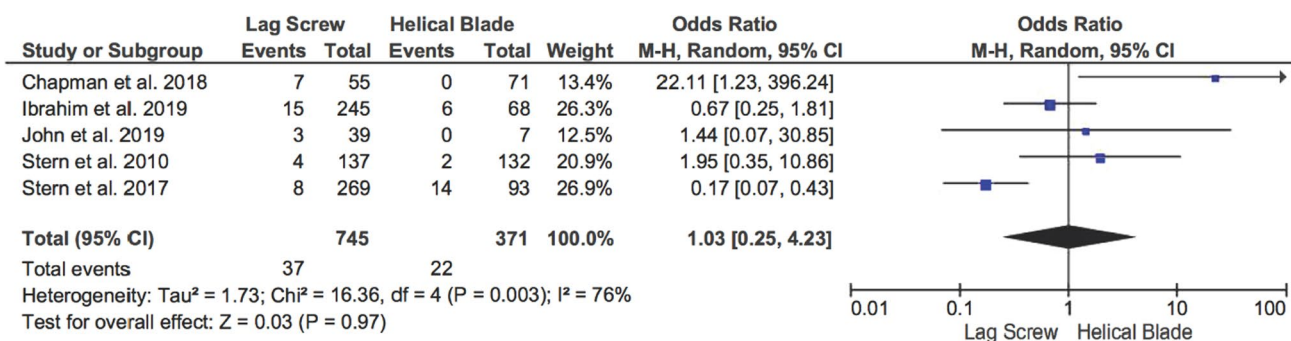


Fig. 6 Forest plot of studies comparing proximal lag screw fixation type (lag screw vs. helical blade) as risk factor for implant cut-out

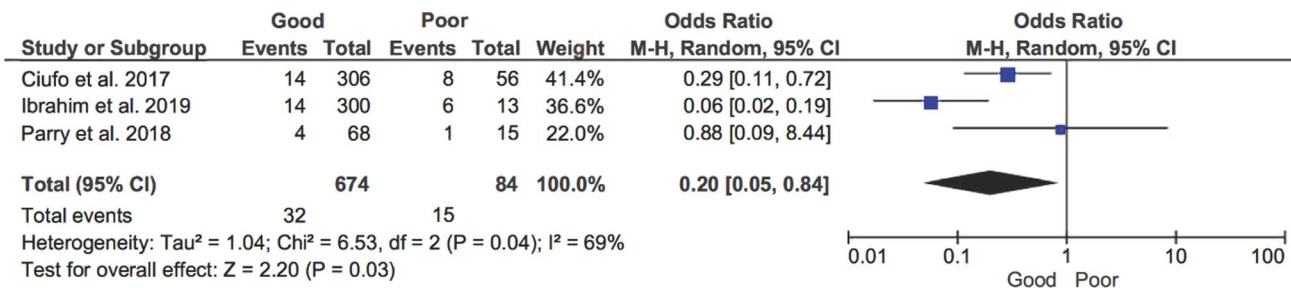


Fig. 7 Forest plot of studies comparing reduction quality (poor vs. good) as risk factor for implant cut-out

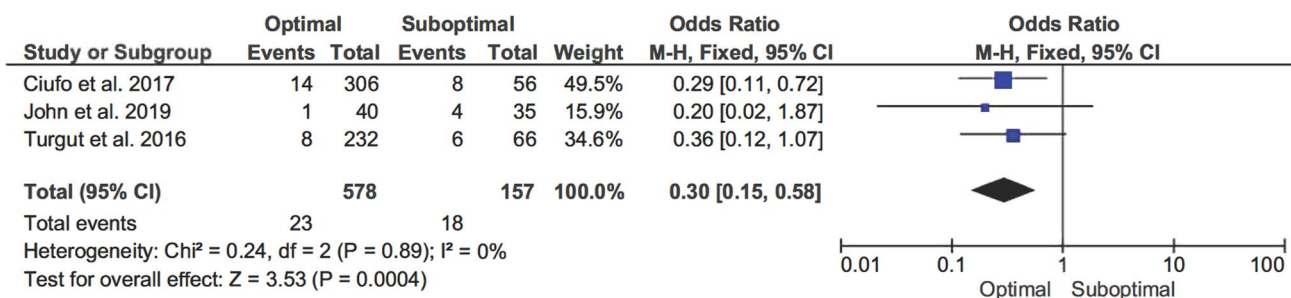


Fig. 8 Forest plot of studies comparing implant location (suboptimal vs. optimal) as risk factor for implant cut-out

3/80 long CMNs (3.75%) and 2/88 short CMNs (2.27%) experienced implant cut-out ($p=0.67$).

Surgeon fellowship training

A total of two studies examined whether lack of trauma fellowship training was a potential risk factor for CMN implant cut-out. Ibrahim et al. [27] examined 313 CMNs (268 by trauma fellowship-trained surgeons, 45 by non-trauma fellowship-trained surgeons); of these, 14/268 (5.2%) and 6/45 (13.3%) experienced implant cut-out ($p=0.051$). When multiple logistic regression was performed, they found no statistically significant association between fellowship training and risk of implant cut-out (OR: 2.713, 95% CI: 0.816–9.016, $p=0.10$). Similarly, Ciufu et al. [16] included 362 CMNs (147 by trauma fellowship-trained surgeons, 215 by non-trauma fellowship-trained surgeons); of these, 7/147 (4.7%) and 15/215 (7.0%) experienced cut-out ($p=0.21$).

Discussion

Screw cut-out is a relatively rare but significant complication when dynamic hip screws or cephalomedullary nails are used to treat intertrochanteric fractures [12–16, 27, 32]. This being said, apart from tip-apex distance, risk factors for screw cut-out have been poorly characterized [10, 14–16]. The main goal of this systematic review and meta-analysis was to identify surgical modifiable operative risk factors for cut-out failure following CMN fixation for pertrochanteric fractures. Our findings suggest that cephalomedullary proximal fixation type (lag screw vs. helical blade) is not a risk factor for implant cut-out. Consistent with the previous literature, we found increased tip-apex distance > 25 mm is a reliable predictor of screw cut-out. Suboptimal screw location and poor reduction quality were associated with increased risk of cut-out; however, nail length and lack of surgeon trauma fellowship training were not risk factors for implant cut-out.

There were several limitations to this study. First, there were a small proportion of eligible studies relative to the initial number screened, mainly due to the lack of studies providing quantitative data examining risk factors for cephalomedullary nail cut-out. Second, the majority of studies were single-center and retrospective in nature with limited inclusion of prospective, randomized trials. While the majority of orthopedic clinical research is retrospective in nature, it is important to note that the identification of risk factors often involves a retrospective review of data. In addition, among these studies, there was significant heterogeneity in the risk factors and associated outcomes reported by the studies, limiting the potential for direct data comparison. Only four risk factors (TAD, implant type, reduction quality,

and optimal/suboptimal location) were examined by three or more studies and therefore qualified for a meta-analysis. Finally, for the majority of studies, there were a small number of cut-outs per cohort, introducing the opportunity for the potential for type II errors. Overall, however, it is believed incorporation of multiple datasets for this systematic review and pooled data analysis allows for valid interpretation of raw data.

Regarding proximal fixation type, our pooled data analysis revealed no significant difference in implant cut-out when either lag screws or helical blades are used. Helical blades were originally designed with the intent to decrease implant cut-out, by providing stronger fixation through cancellous bone compaction upon insertion [24, 28, 41]. The results of studies that have examined the benefits of helical blades over traditional proximal lag screws for proximal CMN fixation have been inconclusive [19, 24, 25, 27]. As such, the choice between helical blades and lag screw for proximal CMN fixation has been left to surgeon's preference without major clinical data to clearly support one in favor of the other.

Consistent with the previous literature [18], increased tip-apex distance > 25 mm is a reliable predictor of implant cut-out risk. Although originally described in the context of an extramedullary dynamic hip screw (DHS) [18], increased TAD has been well-studied and consistently validated as a risk factor for CMN implant cut-out [5, 8, 9, 12, 14, 18, 25, 39]. The results of our meta-analysis are consistent with this, as our pooled data analysis demonstrated TAD > 25 mm is associated with increased implant cut-out. Notably, several studies that used different cutoffs close to but not precisely 25 mm also found increased implant cut-out for TAD > 20 mm [26], 23.56 mm [25], or 28 mm [10]. In this regard, our findings suggest that while there is no absolute value that increases cut-out risk, surgeons should aim to keep TAD below 25 mm.

Other modifiable and intuitive operative risk factors such as optimal screw location and good reduction quality were also associated with decreased implant cut-out. The studies included in this meta-analysis [16, 27, 37] all defined optimal position for head-neck fixation as center-center or inferior center [12, 33], based on the Cleveland zones [42], which specifies screw/blade position on anteroposterior (AP) and lateral radiographs. Proximal screw location in these zones is believed to allow for better purchase of calcar femoral, the dense posteromedial cortex aiding in force transfer from femoral neck to the shaft [43]. In addition to an optimal implant location, poor reduction quality has been consistently regarded as predictive of implant cut-out. All three studies included in this meta-analysis reached similar conclusions [14, 16, 25], basing reduction quality off criteria originally proposed by Baumgaertner et al. [18], which defines good reduction as normal/slight valgus alignment on AP radiograph with < 20° angulation and no more than

4 mm displacement. Notably, in a retrospective review of 298 patients treated with proximal femoral anti-rotation nails, varus mal-reduction was the most significant predictor of implant cut-out [14]. While optimal screw location and good reduction quality are intuitive considerations, our study has provided quantitative data pooled across multiple studies characterizing these modifiable risk factors.

Of note, potential modifiable operative risk factors such as nail length and surgeon fellowship training were not associated with implant cut-out. There is a lack of consensus regarding ideal implant length (short vs. long nail) [10, 37, 44]. Some surgeons hypothesize short nails may lack adequate diaphyseal fixation [6, 7], which can lead to increased pain [10, 14], while others claim long nails have the potential for increased iatrogenic anterior cortical perforation [44]. To date, there have been multiple studies that have demonstrated equivalent outcomes between short and nails [37, 43, 44], including the two included in our study, which revealed no significant differences in implant cut-out, functional outcomes, and peri-implant fracture [10, 37]. The two studies included in this review [16, 27] both found no statistically significant association between trauma fellowship training and decreased implant cut-out. Ibrahim et al. [27] hypothesized that trauma-fellowship-trained surgeons may be more experienced in fracture reduction than those non-fellowship trained as responsible for the borderline statistical significance observed [27].

Conclusion

This systematic review and meta-analysis have characterized surgical modifiable risk factors for CMN implant cut-out. Overall cephalomedullary proximal fixation type (lag screw vs. helical blade) and nail length (short vs. long) are not risk factors for implant cut-out. However, consistent with the previous literature, increased TAD > 25 mm, poor reduction quality, and suboptimal implant location were all associated with an increased risk of implant cut-out. A better understanding and awareness of these risk factors for cut-out will have the potential to impact patient care during the treatment of intertrochanteric femoral fracture with CMN.

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Declarations

Conflict of interest The present review of the literature did not require patient interaction, interventions, or consent. Ferghana Partners Inc: Paid consultant, ISCT: Board or committee member, Journal of Hip Surgery: Editorial or governing board, Journal of Knee Surgery: Editorial or governing board, Orthopaedic Research Society: Board or committee member, RegenLab: Research support, Zimmer: Research

support, Brooklyn Orthopaedic Society: Board or committee member, DePuy, A Johnson & Johnson Company: Paid consultant, Ahmed K. Emara, Nihar Shah, Matthew Ciminero, Kevin Zhai, and Ivan Golub have nothing to disclose.

Ethical approval The present systematic review of the literature did not require institutional review board approval.

Informed consent This was a systematic review of the published literature; therefore, no consent was required.

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