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Reoperation rates after proximal femur fracture fixation with single and dual screw femoral nails: a systematic review and meta-analysis

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- *Purpose:* The purpose of this study was to investigate differences in aseptic reoperation rates between single or dual lag screw femoral nails,in the treatment of intertrochanteric fractures (ITF) in elderly patients.
- *Methods:* Electronic databases were searched for RCTs and prospective cohort studies treating elderly ITF patients with a single or dual screw femoral nails. Data for aseptic reoperation rates between single screw, dual separated screw and dual integrated screw devices were pooled using a random-effects meta-analysis with 95% CIs. Pooled proportions were compared using a N-1 chi-squared test. Complications contributing to aseptic reoperation rates were extracted, and the contribution of cut-out and periprosthetic fracture as a proportion of reoperations was analysed using a negative binomial regression model.
- *Results:* Forty-two (n = 42) studies were evaluated, including 2795 patients treated with a single screw device, 1309 patients treated with a dual separated screw device and 303 patients treated with a dual integrated screw device. There was no significant difference in aseptic reoperation rates between single and dual lag screw femoral nails of both separated and integrated lag screw designs. Moreover, complications of cut-out and periprosthetic fracture as a proportion of reoperations did not differ significantly between devices.
- *Conclusion:* The current evidence showed that aseptic reoperation rates were not significantly different between single and dual screw nails of a separated lag screw design. For dual integrated screw devices, due to insufficient evidence available, further high quality RCTs are required to allow for decisive comparisons with these newer devices.

Keywords

- trochanteric fracture
- proximal femoral nail
- lag screw configuration

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Introduction

Proximal femur fractures are one of the most prevalent injuries among the elderly. There were approximately 1.66 million fractures globally in the year 2000 and a projected 2.6 million worldwide by 2025 (1, 2). Intertrochanteric fractures (ITF), accounting for approximately half of all hip fractures (3), are treated using intramedullary femoral nails with increasing frequency (4, 5, 6). While the principles of ITF stabilization via femoral nailing remain consistent, design variations exist between manufactures, a major point of difference being the configuration of the lag screw.

Currently, the lag screw configuration of a femoral nail falls predominantly into three main design types: single screw, dual screw and 'helical blade' nails (7). Dual screw devices can then be categorized as separated lag screw devices, where two lag screws function independently of one another, and integrated lag screw devices, where two lag screws are mechanically integrated to one another. Outcomes after nailing of ITF are determined by a multitude of factors (8, 9, 10); however, the effect of lag screw configuration between single and dual screw devices on fixation failure remains unclear. Given this lack of evidence and consensus in outcomes relating to a key design component of implants on the market, a

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critical question is raised. Is there a difference in aseptic reoperation rates between femoral nails comprising of a single or dual lag screw design in the management of ITFs? Moreover, is there a difference between separated dual screw and integrated dual screw devices? This systematic review and meta-analysis aim to address this question through the analysis of prospective randomized controlled trials (RCTs) and cohort studies.

Materials and methods

Protocol and registration

This systematic review and meta-analysis were registered with the International Prospective Register of Systematic Reviews and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

A search of electronic databases including Pubmed (MEDLINE), Embase, Web of Science, CINAHL and Cochrane Central Register of Controlled Trials (CENTRAL) was completed on 20 September 2020, with no restriction on publication date. The search strategy was developed using the PICO framework and included free text and subject headings (MeSH for MEDLINE (PubMed), CINAHL and CENTRAL, Emtree for Embase) relating to hip fractures and their treatment via femoral nailing. The following search strategy was used: ((('hip fractures'[MeSH Terms] OR ((hip[tiab] OR proximal femur[tiab] OR intertrochant*[tiab] OR trochant*[tiab] OR pertrochant*[tiab] OR extracapsular[tiab]) AND fracture*[tiab]))) AND ('fracture fixation, internal'[MeSH Terms] OR 'internal fixators'[MeSH Terms] OR internal fixation[tiab] OR cephalomedullary nail*[tiab] OR femoral nail*[tiab] OR trochanteric nail*[tiab] OR intramedullary nail*[tiab] OR internal fixat*[tiab] OR nail*[tiab]) AND ('reoperation'[MeSH Terms] OR 'equipment failure'[MeSH Terms] OR 'treatment outcome'[MeSH Terms] OR reoperat* OR revis* OR re operat* OR cut-out OR 'cut out')). The reference lists of articles deemed eligible were also manually searched for additional eligible articles.

Study inclusion

Eligible studies were included if they: (1) were prospective cohort studies; (2) only included adults ≥ 60 years with ITFs; (3) single or dual screw femoral nail was used to manage the fracture in at least one group; (4) included at least 30 cases in the treatment group; (5) patients were followed up for at least 3 months after surgery; (6) reoperation rates were reported and (7) articles published in English. Studies were excluded if they: (1) were retrospective; (2) included patients with other lower limb pathologies; (3) included patients with subtrochanteric or basicervical fractures only; (4) treated patients with a helical blade femoral nail solely in all groups; (5) analysed data from another study already included or; (6) did not provide data describing aseptic reoperation rates. Articles were reviewed against the eligibility criteria independently by two reviewers, in two stages, where the assessed eligibility was blinded. First, titles and abstracts from the initial search were assessed after which discrepancies were resolved through discussion. Where an agreement was still unable to be reached, a third researcher was asked to comment. Full texts were then obtained for the studies passing the initial eligibility screening and assessed for eligibility using the same approach with disagreements discussed to reach a consensus.

Quality assessment

Quality assessment of the studies was conducted using the Cochrane Risk of Bias 2 (RoB 2) tool for RCTs and the Downs and Blacks tool for non-randomized cohort studies. The Downs and Black was selected for its reliability and validity in assessing the quality of non-randomized studies (11). Previous studies have implemented a modified version of the tool where the statistical power question was given a single point when evidence of a power calculation was conducted rather than scoring based on a range of study powers (12, 13). This resulted in a total score for the tool of 28 as opposed to the original 32. From the numerical score for each study, an overall quality level of excellent (26–28), good (20–25), fair (15–19) or poor (≤14) was then assigned, as adapted from previous literature (14, 15). For this review and meta-analysis, studies of low quality were not excluded from the analysis.

Data extraction

Data were extracted by a single author from each included study using an extraction tool developed through consensus agreement with the other authors (Table 1). We extracted data relating to patient demographics, device used, fracture type, aseptic reoperation rate and reasons for reoperation. For studies with multiple groups, where a different device was used in each treatment group, only data relevant to the cohort(s) treated with a single or dual screw femoral nail were extracted. For the meta-analysis, the results were categorized into single screw devices or dual screw devices, with the dual screw data further divided into separated or integrated dual screw devices. For nails that by design, can be used as either single or dual screw devices, devices were categorized respective of whether they were used as a single or dual screw device. If there was any ambiguity, the corresponding author was contacted for the data.

Reported reasons for reoperation were extracted from each study with the authors original terminology and similar terms (e.g. periprosthetic fracture and diaphyseal

Table 1 Characteristics of the included studies.

Reference	Femoral nail lag screw type: Single	Dual (S)	Dual (I)	Cases: Total	Male	Female	Age (S.D.)	Fracture type: Stable	Unstable	Follow-up (months)	Aseptic reoperations
Aktselis *et al.* (20)	Gamma nail			36	8	28	82.9 (5.8)	0	36	12	0
Babar *et al.* (21)		Proximal femoral nail		62	23	39	74.27 (5.84)	0	62	6	5
Bonnevialle *et al.* (22)	Gamma nail			113	83	30	85.5 (NR)	0	113	6	8
Borger *et al.* (23)		Targon PFT nail		37	14	23	77.7 (NR)	0	37	12	1
Bridle *et al.* (24)	Gamma nail			49	9	40	81 (NR)	18	31	6	7
Buecking *et al.* (25)	Gamma nail			79	NR	NR	NR	32	47	12	2
Buecking *et al.* (26)	Gamma nail, Zimmer natural nail			188	58	130	82 (8)	NR	NR	12	9
Caiaffa *et al.* (27)		Endovis BA nail		266	93	173	78.1 (7.2)	85	181	12	8
Catania *et al.* (28)	Gamma nail			168	55	113	85.7 (5.48)	27	141	12	11
Chinzei *et al.* (29)	Gamma nail			59	16	43	82.7 (11.2)	26	33	6	1
Ciaffa *et al.* (30)		Endovis BA2 nail		212	138	74	76.6 (2.6)	71	141	12	11
Dong *et al.* (31)	Gamma nail			89	48	41	70.7 (2.8)	25	64	6	4
Efstathopoulos *et al.* (32)	Gamma nail			56	19	37	79.5 (NR)	12	44	8	0
		Dual (S)		56	13	43	78.1 (NR)	8	48	8	0
Foulongne *et al.* (33)	BCM nail			30	3	27	85.5 (7.9)	22	8	3	0
Giessauf *et al.* (34)	Gamma nail			65	13	49	80 (10)	27	38	12	2
Hardy *et al.* (35)	IMHS			50	8	42	81.7 (11.8)	16	34	12	3
Harrington *et al.* (36)	IMHS			50	10	40	83.8 (8.5)	0	50	12	2
Hopp *et al.* (37)	Gamma nail			39	13	26	80.73 (8.44)	0	39	6	1
			Intertan	39	7	32	82.7 (7.06)	0	39	6	2
Ito *et al.* (38)	Gamma nail			177	29	148	84 (NR)	96	81	5.2	9
Jolly *et al.* (39)		Proximal femoral nail		50	NR	NR	81.2 (7.8)	0	50	12	6
Karakus *et al.* (40)			Antirotation proximal femur nail	54	11	43	79.28 (9.54)	0	54	12	3
Kim *et al.* (41)			Intertan	100	35	65	77.8 (9.1)	12	88	12	3
Kouvidis *et al.* (42)		Endovis BA nail		86	18	72	81.95 (7.21)	26	60	12	7
Lanzetti *et al.* (43)	Supernail GT			143	24	119	85.01 (8.27	73	70	3	4
Lin *et al.* (44)		Double screw nail		144	41	103	78 (9.1)	51	93	12	6
Mavrogenis *et al.* (45)		Veronail Trochanteric nail		79	18	61	84.7 (NR)	45	34	12	1
Mavrogenis *et al.* (46)	IMHS			110	35	75	78 (NR)	31	79	14	1
Miedel *et al.* (47)	Gamma nail			93	NR	NR	NR	0	93	12	3
Papasimos *et al.* (48)	Gamma nail			40	16	24	82.8 (NR)	0	40	12	3
		Proximal femoral nail		40	17	23	79.4 (NR)	0	40	12	5
Park *et al.* (49)	Gamma nail (Asia Pacific)			30	10	20	73.7 (NR)	14	16	12	1
Schipper *et al.* (50)	Gamma nail			213	37	17	82.2 (8.4)	0	213	12	19
		Proximal femoral nail		211	38	173	82.6 (8)	0	211	12	28
Shin *et al.* (51)	Zimmer natural nail			172	63	109	76.22 (16.4)	44	128	12	6
Su *et al.* (52)	Gamma nail			50	19	31	71. 3 (8.7)	0	50	12	5
			Intertan	50	21	29	70.1 (9.2)	0	50	12	1
Vaquero *et al.* (53)	Gamma nail			30	5	25	83.5 (7.4)	0	30	12	4
Varela-Egocheaga *et al.* (54)	Gamma nail			40	6	34	82.5 (NR)	27	13	12	3
Vidyadhara *et al.* (55)	Gamma nail			37	19	18	68.6 (5.6)	0	37	24	1
		ACE nail		36	18	18	69.4 (4.6)	0	36	24	0
Wu *et al.* (56)	Gamma nail			174	43	131	72.6 (8.6)	0	174	12	5
			Intertan	87	20	67	71.4 (9.7)	0	87	12	2
Wu *et al.* (57)	Gamma nail			169	74	95	74.27 (5.84)	64	105	12	14
Xu *et al.* (58)	Gamma nail			70	27	43	75.4 (1.0)	0	70	12	1
Yang *et al.* (59)	Gamma nail			124	38	86	81.6 (NR)	21	103	12	1
Yao *et al.* (60)		Proximal femoral nail		30	14	16	77.4 (5.6)	8	22	12	0
Yaozeng *et al.* (61)	Gamma nail			52	15	37		21	31	12	0

Dual (I), dual integrated; Dual (S), dual separated; NR, not reported.

fracture) combined by a senior orthopaedic surgeon. Where data were not reported, the corresponding author was contacted for the relevant information. Complications that described similar mechanisms of failure but reported separately in papers were not combined and analysed separately (e.g. medial protrusion of lag screw and cut-out). Studies where data were unable to be obtained for the number of ITFs managed with a single or dual screw femoral nail within a single device group, and respective number of aseptic reoperations, were excluded from the meta-analysis.

Statistical analysis

A random-effects meta-analysis model was used to calculate pooled proportions and 95% CIs of reoperations within the respective device types; single screw, dual screw, dual (separated) screw, and dual (integrated) screw devices (16). Pooled proportions were then compared using a N-1 chi-squared test (17, 18). In a fixed-effect analysis, true effect size is assumed to be the same in all studies and the summary effect provides an estimate of this common effect size. In a random-effects analysis, the true effect size is assumed to vary between each study with the studies in the analysis representing a random sample of effect sizes that could be observed. The summary effect is an estimate of the mean of these effects (19).

The contribution of cut-out and periprosthetic fracture to the number of reoperations was analysed within each device type using a negative binomial regression model adjusting for offset of the natural logarithm of the number of reoperations. The statistical package used for the primary meta-analysis was Stata Statistical Software (Release 16; StataCorp LLC, College Station, TX, USA). Analysis of the reasons for reoperation was conducted in IBM SPSS Statistics for Windows (version 27; IBM Corp.).

Results

Totally 5330 articles were identified from the initial search, of which 42 studies were included in the meta-analysis (Fig. 1) (20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61).

Qualitative synthesis

From the included studies ($n = 42$), data for 4434 patients sustaining an ITF and managed with either a single or dual screw femoral nail were extracted. Studies reported a mean follow-up time of 10.8 months (range: 3–24). Studies reporting treatment of patients with a single screw device were most commonly reported in the literature, followed by dual separated screw devices. The assessment of quality and risk of bias of the included studies indicated

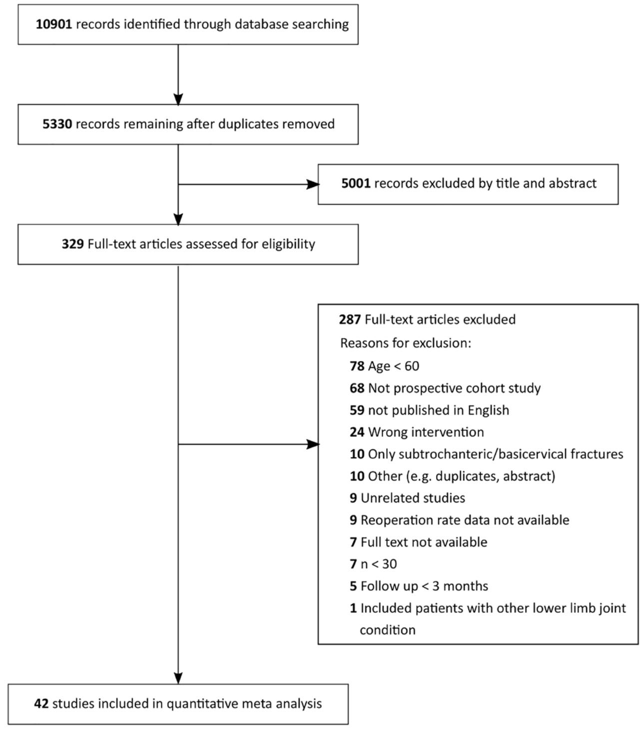

Figure 1
Flowchart summarizing study identification and selection of included studies.

moderate quality overall. For the assessment of cohort studies, the rating was good (7/18), fair (10/18) and poor (1/18). For the assessment of RCTs, the overall risk of bias was judged as low risk (4/24) and some concerns (20/24), with zero studies judged high risk (0/24). Only 5 of the 42 studies were funded by an orthopaedic implant company. Historical trends of reported device use over time are illustrated in Fig. 2 and show the introduction of each device type and the scale of use in clinical studies.

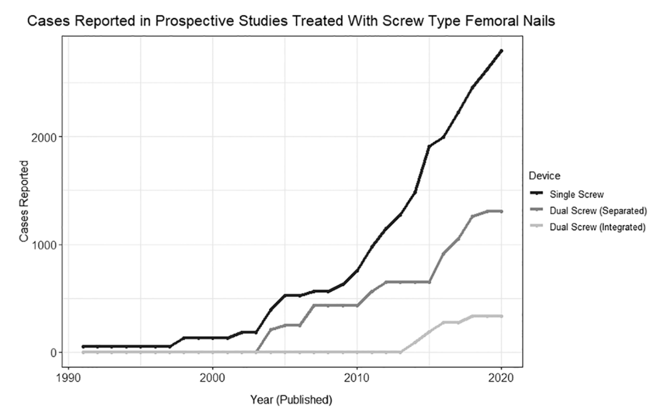

Figure 2
Historical trends of reported femoral nails use in prospective RCTs and cohort studies over time.

Quantitative synthesis

From included studies (n = 42), there were 2795 patients treated with a single screw device with a mean age of 80.1 years (range: 68.6–85.7), and 1639 patients treated a dual screw device with a mean age of 77.8 years (range: 69.4–84.7). Divided into dual separated screw and dual integrated screw devices, there were 1309 patients with a mean age of 78.4 (range:, 69.4–84.7) and 330 patients with a mean age of 76.3 (range: 70.1–77.8), respectively. Heterogeneity between studies was estimated using the I-squared statistic and Cochrane's Q P value. There was moderate heterogeneity for studies that looked at single screw devices (I^2 = 39.4%, P = 0.014), dual screw devices (I2 = 53.9%, P = 0.003) and dual separated screw devices (I^2 = 66.3%, P < 0.001). There was no indication of heterogeneity in studies that looked at dual integrated screw devices (I^2 = 0%, P = 0.909). As random-effects model was used in the analysis, the degree of heterogeneity is less relevant.

Reoperation rates

The aseptic reoperation rate for single screw devices was calculated to be 3% (95% CI: 2%, 4%) (Fig. 3). For dual separated screw nails and integrated screw nails, the aseptic reoperation rate was 4% (95% CI: 2%, 7%) and 3% (95% CI: 1%, 5%), respectively (Fig. 3). The pooled proportion of aseptic reoperations in all dual screw devices (separated and integrated devices combined) was calculated to be 4% (95% CI: 2%, 6%).

The aseptic reoperation rate was 1% higher for all dual screw devices compared to single screw designs (95% CI: 0%, 2%, P = 0.075). However, this difference was not statistically significant. Similarly, there was no significant difference in aseptic reoperation rates between dual separated screw devices and single screw devices (95% CI: 0%, 2%, P = 0.096).

Reasons contributing to aseptic reoperation

The mechanisms of failure contributing to reoperation varied between device types, with dual separated screw devices exhibiting several mechanisms of failure that were not reported to occur in single or dual integrated screw devices in the studies analysed (e.g. lag screw breakage, z-effect/reverse z-effect, medial protrusion of the lag screw and avascular necrosis of the femoral head). Moreover, for dual integrated screw devices, cut-out and periprosthetic fracture were the only reported contributing mechanisms to aseptic reoperation. For single screw and dual separated screw devices, cut-out, periprosthetic fracture and lag screw backout were the highest reported contributing mechanisms to aseptic reoperation rates. The contribution of lag screw backout to reoperations could only be compared for single and dual separated screw devices.

For single screw devices, the rates of cut-out and periprosthetic fracture requiring reoperation were 1.3% (95 CI: 1%, 2%) and 0.3% (95% CI: 0%, 1%), respectively. For all dual screw devices, the rate of cut-out was 1.4% (95 CI: 0%, 2%) and 0.3% (95% CI: 0%, 1%) for periprosthetic fracture. Further dividing dual screw devices, the incidences of cut-out and periprosthetic fracture were 1.2% (95% CI: 0%, 2%) and 0.3% (95% CI: 0%, 1%) for dual separated screw devices and 2.7% (95% CI: 0%, 5%) and 0.4% (95% CI: 0%, 2%) for dual integrated screw devices. The rate of lag screw backout requiring reoperation was 0.1% (95% CI: 0%, 1%) for single screw devices and 0.3% (95% CI: 0%, 1%) for dual separated screw devices.

As a proportion of aseptic reoperations, there was no statistically significant association between device type and cut-out (P = 0.442). There was also no association between device type and periprosthetic fracture contributing to aseptic reoperation rates (P = 0.916). Similarly, the contribution of lag screw backout to reoperations did not differ significantly between single and dual separated screw devices (P = 0.255). Reported mechanisms contributing to reoperation per 1000 cases for each device are shown in Fig. 4.

Discussion

Fixation of ITFs in elderly patients using femoral nails is a procedure which is becoming increasingly common (4, 6, 62, 63). Despite the wide use of these devices in current practice, the effect of the lag screw configuration on aseptic reoperation rates in elderly ITF patients remains unclear. Hence, it was the aim of this review and meta-analysis to identify whether differences in reoperation rates exist between single and dual screw devices. Our review identified 42 studies reporting single and dual screw devices that met inclusion criteria. The results showed that there was no significant difference in aseptic reoperation rates between single screw (3%) and dual separated screw (4%) femoral nail designs. When considering dual integrated devices, rates of reoperation were equal to those of the single screw devices (3%); although due to the limited number of cases (n = 330) managed using the dual integrated devices, there is insufficient current evidence to make decisive comparisons between these devices.

Femoral nailing is commonly associated with a number of complications relating to the mechanics of osteosynthesis and the type of nail used (64). Our meta-analysis highlighted that cut-out of the lag screw is the largest contributing mechanism to aseptic reoperation rates, followed by backout of the lag screw and periprosthetic fracture for both single and dual screw femoral nails. Our results showed that the difference in cut-out and periprosthetic fracture contributing to

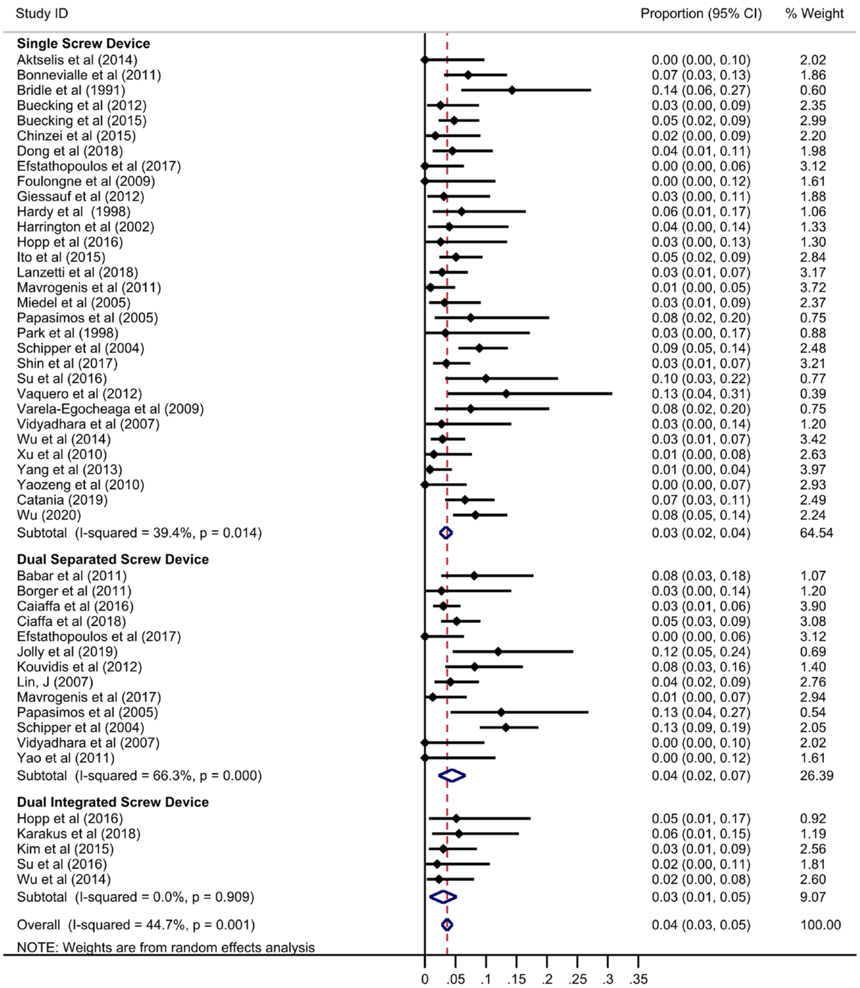

Figure 3

Aseptic reoperation rates in patients treated with a single screw, dual separated screw and dual integrated screw femoral nail calculated using a random-effects meta analysis.

aseptic reoperation rates between devices did not differ significantly. From the data available, we could not test the contribution of lag screw backout to aseptic reoperations between all three device types;however, there was no significant difference between single and dual separated screw devices. In a meta-analysis by Norris *et al*. (65) evaluating secondary fracture with uniaxial nails (single screw, pin or helical blade) and biaxial nails (two separated screws, pins or helical blades), they found there was a lower risk of periprosthetic fracture with biaxial devices compared with uniaxial screw devices. No other complications and mechanisms of failure were reported. Although the results from our study did not support this difference in periprosthetic fracture between single and dual screw devices, this may be due to the inclusion of helical blade devices into the uniaxial nail group (66, 67).

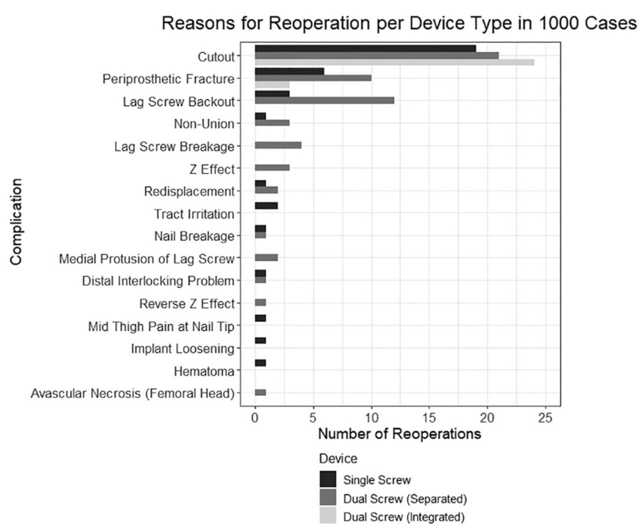

Figure 4

Reasons contributing to reoperation per device type in 1000 cases.

Limitations

Our review identified and included numerous studies assessing treatment using single ($n = 31$ studies, 2795 patients) and dual separated screw devices ($n = 13$ studies, 1309 patients); there were far fewer studies reporting patients treated with dual integrated screw devices (*n* = 5 studies, 330 patients). Due to such disparity, it is not possible based on current evidence to make any decisive conclusions relating to dual integrated screw devices. Further research is required to evaluate their performance. Secondly, this study included prospective RCTs and prospective cohort studies where at least one cohort of patients were treated with a single or dual screw femoral nail. The data from these cohorts were combined in one analysis, and we acknowledge the challenges of aggregation of data (68). The use of reoperation rates as an endpoint has some inherent flaws, as the reasons for reoperation are often affected by multiple factors which are not reported; as an outcome measure, it also fails to pick up cases where the device construct has failed but patients are not suitable for complex revision surgery. Fracture reduction is rarely reported on, despite being strongly linked to mechanical complications. A poor fracture reduction may negatively affect construct stability and is therefore likely to increase particular failure modes, in particular lag screw cut-out. Positioning of the lag screw within the femoral head has also been linked to construct stability. In particular, positioning of the tip of the lag screw in the Cleveland peripheral zones (69) and a Tip-Apex Distance (TAD) (70) of over 25 mm (71) has been correlated with increased risk of cut-out. These measures are infrequently reported alongside reoperation rates.

Femoral nails can be used in unlocked or locked modes of the proximal lag screw. Some device manufactures suggest the device be used in the dynamic mode as per the operative technique guide, while other manufacturers leave this decision to the operating surgeon. Of the included studies, no study mentioned whether the lag screw was locked or unlocked.

Finally, the papers included span a large time period from 1991 to 2020. During this time, there were numerous design changes to devices, and few intramedullary nails have remained unchanged throughout. We believe however that the majority of design changes that have occurred have been relatively minor, with the exception of the Gamma nail, which changed from gamma2 to gamma 3 in 2004, aiming to reduce nail breakage, which is a rare cause for reoperation. Our opinion is that the design changes of these devices have had minimal impact on the rates of reoperation for lag screw cut-out, lag screw backout or periprosthetic fracture.

Conclusion

This is the first comprehensive meta-analysis exploring differences in aseptic reoperation rates relating to femoral nail lag screw configuration. Analysis of the current literature has identified there to be no difference, statistical or clinical in reoperation rates when utilising either single or dual separated screw devices. Due to the inherent limitations of the available data for dual integrated screw devices, decisive comparisons for clinical advantages and benefits of antirotation nails cannot be made.

ICMJE Conflict of Interest Statement
The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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