



Comparison of helical blade versus lag screw in intertrochanteric fractures of the elderly treated with proximal femoral nail: A meta-analysis of randomized-controlled trials

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Currently, there are two surgical ways to treat intertrochanteric fractures among the elderly, including extramedullary or intramedullary fixation.^[1,2] Although extramedullary fixation is the conventional treatment of intertrochanteric fractures, intramedullary fixation has become a more popular method with the development and progress of intramedullary instruments.^[3] The optimal choice between the helical blade and lag screw is still controversial.^[4-6] Some pieces of literature have reported that there is no difference in the clinical efficacy, excepted for the operation time that the lag screw is longer than that of the helical blade.^[7] However, biomechanical studies have shown that the helical blade is superior to the conventional solid lag

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ABSTRACT

Objectives: In this review, we aimed to compare the radiological and functional outcomes between the helical blade and lag screw in treating intertrochanteric fractures among the elderly and to provide suggestions for clinical treatment.

Materials and methods: Between January 1st, 1990 and January 12th, 2022, the literature search in document databases identified eligible randomized-controlled trials (RCT) studies directly comparing the helical blade and lag screws for treating hip fractures. The mechanical failure rates, the excellent and good rate of fracture reduction, Harris Hip Score (HHS), and postoperative hip pain of two intramedullary devices (helical blades versus lag screws) in patients with intertrochanteric fractures were analyzed using the RevMan software and Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. The random-effects models were used for statistical analysis.

Results: A total of 11 articles containing 1,146 patients for helical blade and lag screw comparison were included. Compared to the lag screws, the mechanical failure rate (odds ratio [OR]=0.71, 95% confidence interval [CI] 0.40-1.27, p=0.25), the excellent and good rate of fracture reduction (OR=1.33, 95% CI 0.61-2.90, p=0.48), HHS (mean differences 1.83, 95% CI -0.29-1.83, p=0.09), and postoperative hip pain (OR=0.41, 95% CI 0.14-1.21, p=0.11) were similar with the helical blades. There was no significant difference between the two implants in terms of the treatment outcomes.

Conclusion: Both helical blades and lag screws are good choices for treating intertrochanteric fracture among elderly.

Keywords: Elderly, helical blade, intertrochanteric fracture, intramedullary fixation, lag screw, meta-analysis.

screw. According to the operation manual, the same length of bone tunnel as lag screw is necessary at the time of placement, resulting in more bone loss, while helical blades only need to drill through the lateral wall and tapping into femoral head directly, compassed

sequentially the surrounding bone to obtain more holding force.^[8-10] In recent years, complications are not only “cut-out”, but also a high “cut through” rate occurs in the helical blade. Superomedial migration of the helical blade has a higher “cut through” rate which migrate into the femoral head and hip joint than the conventional one.^[11,12] However, Schwarzkopf et al.^[13] found that both screws designed provided similar fixation strength for stabilization of four-part intertrochanteric fractures. A recent meta-analysis suggested that cephalomedullary implant type was not a risk factor for implant cut-out, then a tip-apex distance (TAD) of >25 mm was a reliable indicator for cut-out risk.^[14] Contemporarily, Kim et al.^[15] concluded that the helical blade had a higher rate of fixation failure than lag screws; therefore, surgeons should carefully utilize blade-type cephalomedullary nails while treating hip fractures.

At present, there is no consensus on the choice of two screws in clinical practice. Therefore, it is necessary to investigate whether helical blades lead

to better outcomes. In this review, we aimed to compare the radiological and functional outcomes between the helical blade and lag screw in treating intertrochanteric fractures among the elderly and provide suggestions for clinical treatment.

MATERIALS AND METHODS

Search strategy and selection criteria

Relevant studies published between January 1st, 1990 and January 12th, 2022 were selected by searching on PubMed, Embase, Web of Science, Medline, Cochrane Library, Science Citation Index Expanded (SCIE) 2000-present, Current Chemical Reactions (CCR), and Index Chemicus (IC). No language restrictions were applied. The following combined text and MeSH terms were used: “intertrochanteric fracture”, “lag screw”, and “helical blade”. The complete search used for PubMed as below:

((Intertrochanteric fracture)[MeSH terms]) OR ((Fractures, Hip)(Text Word)) OR ((Trochanteric

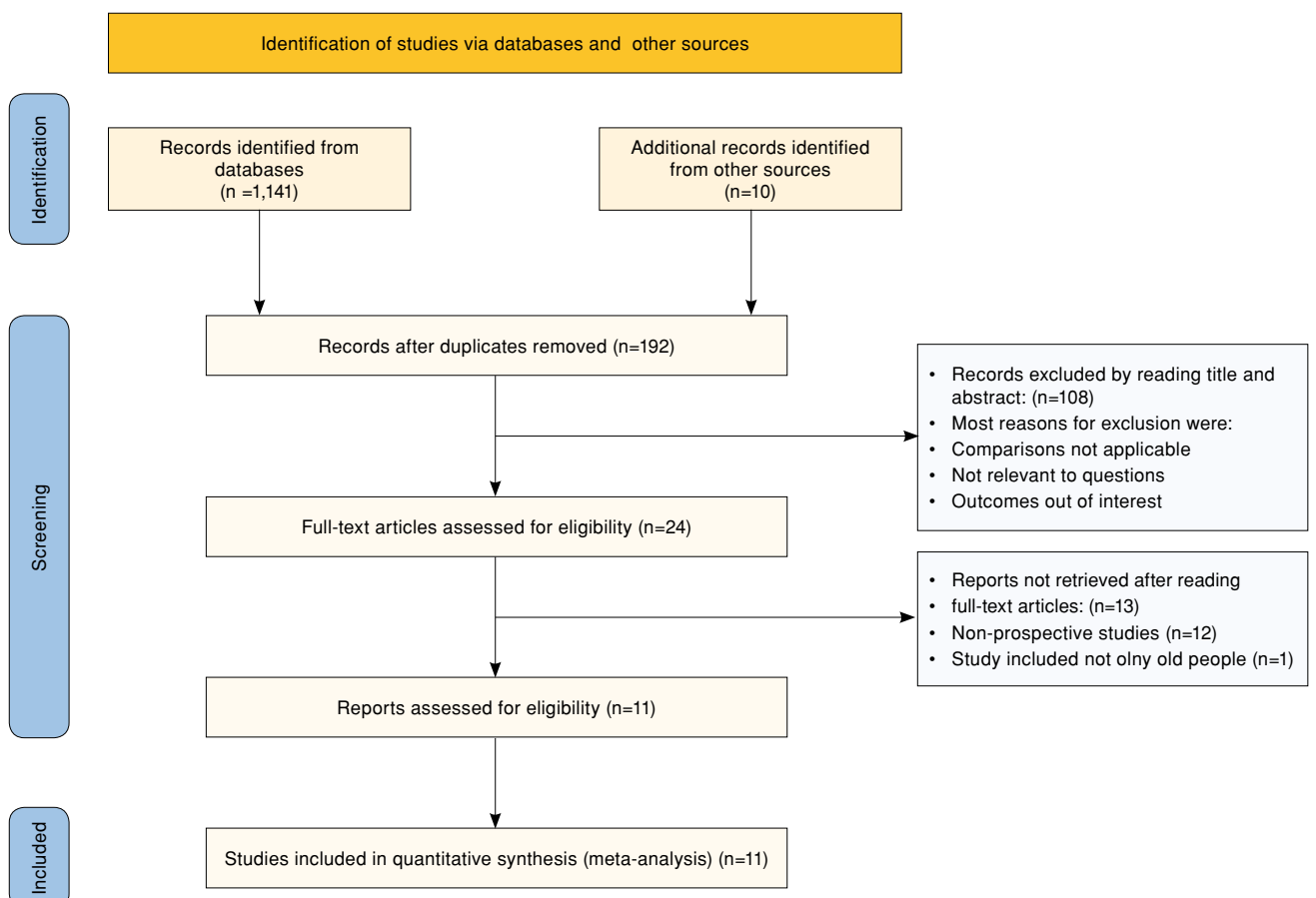


FIGURE 1. Study flowchart.

Fractures)(Text Word)) OR ((Fractures, Trochanteric)(Text Word)) OR ((Intertrochanteric Fractures)(Text Word)) OR ((Fractures, Intertrochanteric)(Text Word)) OR ((Subtrochanteric Fractures)(Text Word)) OR ((Fractures, Subtrochanteric)(Text Word)) AND (((helical blade)[MeSH terms]) OR ((Spiral blade)(Text Word)) OR((Proximal femoral nail antirotation)(Text Word)) OR ((PFNA)(Text Word))OR ((PFNA II)(Text Word))OR ((PFNA2)(Text Word)) AND ((lag screw)[MeSH terms]) OR ((TGN)(Text Word)) OR ((the third generation gamma nail)(Text Word)) OR ((PFN)(Text Word)) OR ((screw proximal femoral nails)(Text Word)) OR ((Targon PF)(Text Word)) OR ((Gamma3)(Text Word)) OR ((Zimmer natural nail)(Text Word)) OR ((ZNN)(Text Word)).

We considered all potentially eligible studies for review, irrespective of the primary outcome or language. A manual search was also carried out using the reference lists of key articles published in English. The assessment of study quality was presented in Figure 1. The Cochrane Collaboration Risk of Bias Tool applied to evaluate the quality of the randomized-controlled trials (RCTs) can be seen in Figure 2.

Study selection and data extraction

At least two review authors independently selected related studies, the assessed risk of bias, and extracted data. We performed a limited meta-analysis using the randomized-effect model. Included studies were considered eligible, if they met the Population, Intervention, Comparison, Outcomes, and Study criteria as follows:

Population: Elderly patients with intertrochanteric fractures had at least six months duration of follow-up.

Intervention: Intramedullary fixation with a helical blade.

Comparator: Intramedullary fixation with lag screw, but not Intertan screws.

Outcomes: The primary outcome was the mechanical failure rates. Mechanical failure refers to an implant cut-out, cut-in, lateral migration more than 1 cm, the implant breaks, varus displacement, or complications caused by internal fixation defects. Secondary outcomes included the excellent and good rate of fracture reduction, Harris Hip Score (HHS), and postoperative hip pain. All articles which met the inclusion criteria must include the primary outcome, followed by the inclusion or exclusion of secondary outcomes.

Study design: RCTs.

We reviewed study titles and abstracts, and studies that satisfied the inclusion criteria retrieved for full-text assessment. Trials selected for detailed analysis and data extraction were analyzed by two investigators, and disagreements were resolved by a third investigator.

Statistical analysis

The following data were extracted into the Microsoft Excel (version 2019-v19.0, Microsoft Corp., WA, USA) from each selected study, including total number of participants, age, unstable fracture rate, mean Singh indexes, follow-up duration, type of nail,

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Anirudh ShArma 2017	+	+	+	?	+	+	?
Carmelo D'Arrigo 2012	+	+	+	?	?	+	?
Felix Bonnaire 2020	+	+	+	?	?	+	+
J. Vaquero 2012	+	+	+	?	+	+	+
JUNG HO PARK 2010	+	+	+	?	+	+	?
ManjitSingh 2021	?	+	+	+	+	+	?
MICHAEL WILD 2010	+	+	+	?	+	+	?
Richard Stern 2011	+	+	+	?	+	+	?
Sharan Mallya 2019	+	+	+	+	+	+	?
XuYaozeng 2010	+	+	+	?	+	?	?
Young-Soo Shin 2017	+	+	+	?	+	+	?

FIGURE 2. The assessment of study quality.

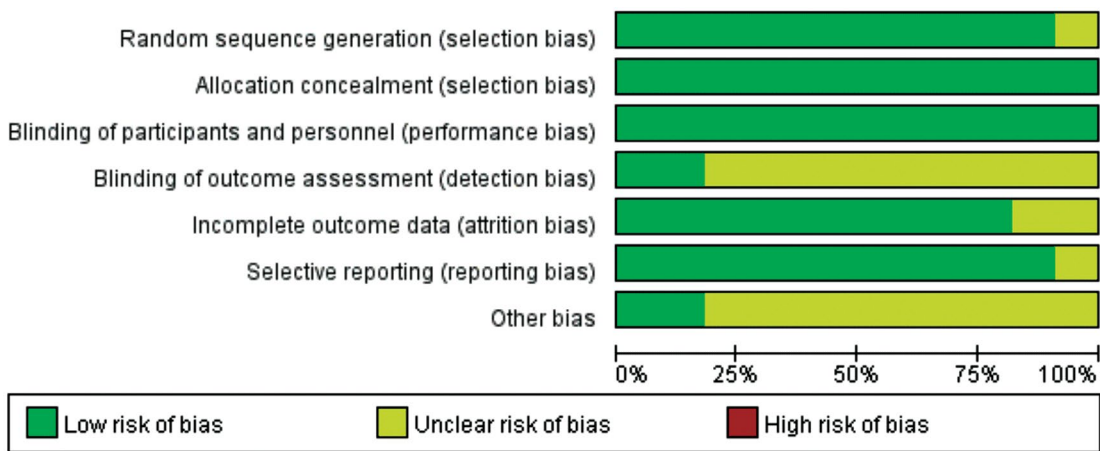


FIGURE 3. The quality of the RCTs.
RCTs: Randomized-controlled trials.

number of mechanical complications, HHS, quality of reduction, and postoperative hip pain. We assessed the effects of two types of nails on four aspects: Mechanical failure rates, HHS, excellent and good rate of fracture reduction, and postoperative hip pain. The results were analyzed using the RevMan software (Review Manager (RevMan) [computer program] version 5.4. The Cochrane Collaboration, 2020). Mechanical failure rate, the excellent and good rate of fracture reduction, and postoperative hip pain as dichotomous variables were compared using odds ratio (OR) values. A confidence interval (CI) of 95% was used. The HHS as a continuous variable

was compared using mean differences. In the meta-analyses of each outcome, we pre-planned sensitivity analyses restricted to trials comparing the helical blade and lag screw in these four aspects. This comparison is the most important clinical question about the role of the helical blade.

Grading of Recommendations Assessment Development and Evaluation (GRADE) profiler (version 3.6), which is Working Group aiming at developing and disseminating a sensible approach to grading quality of evidence and strength of recommendations, was used to evaluate the level of the evidence and strength of recommendations for

Study	Year	Type of nails	Patients	Age (mean)	Unstable fracture rate (%)	Mean Singh's Indexes	Follow-up (mean)
Yaozeng et al. ^[16]	2010	PFNA vs. TGN	55/52	76.8/76.6	0.65/0.60	N/A	17.5
Park et al. ^[17]	2010	PFNA vs. PFN	23/17	74/67	0.70/0.71	2.46/2.67	18
Wild et al. ^[18]	2010	PFNA vs. Targon PF	40/40	81.8/83.1	0.65/0.68	N/A	12
Stern et al. ^[19]	2011	PFNA vs. Gamma3	79/89	86.8/85.9	0.63/0.66	N/A	12
D'Arrigo et al. ^[20]	2012	PFNA vs. TGN	51/46	81.7/80	0.57/0.71	N/A	15.1
Vaquero et al. ^[21]	2012	PFNA vs. Gamma3	31/30	83.6/83.5	0.43/0.43	N/A	12
Shin et al. ^[22]	2017	PFNA II vs. ZNN	181/172	77.7/76.2	0.72/0.74	N/A	12.3
Sharma et al. ^[23]	2017	PFNA vs. PFN	25/23	74.1/60.8	1.00/1.00	N/A	9.0-12
Mallya et al. ^[24]	2019	PFNA2 vs. PFN	37/41	69.5/70.8	1.00/1.00	2.21/2.27	6
Bonnaire et al. ^[25]	2020	PFNA vs. Gamma3	53/53	81/83	1.00/1.00	N/A	24
Singh et al. ^[26]	2021	PFNA2 vs. PFN	15/15	64.7/59.5	N/A	N/A	6

PFNA: Proximal femoral nail antirotation; TGN and Gamma3: The third generation gamma nail; PFN: Proximal femoral nail; ZNN: Zimmer natural nail; N/A: Not Applicable.

included outcomes. The GRADE profiler (version 3.6) was used to evaluate the evidence of included outcomes. To implement this part, the data obtained by the RevMan software analysis were imported into the GRADE profiler. Statistical heterogeneity of the included research was evaluated using the chi-square test following the P and I², with values greater than 50% regarded as being indicative of high heterogeneity. We used the RevMan and GRADE software for all statistical analyses.

RESULT

Description of studies

The list of studies excluded and reasons for exclusion are shown in Figure 3, and 11 studies were included. The characteristics of included studies are shown in

Table I. The quality of the RCTs was acceptable, all the RCTs reported their methods of randomization. Some of the included RCTs reported blinding of the surgeons, participants, or assessors. All of the studies provided results for a minimum of 95% among the included patients. Eleven included studies were followed for an average of 6 to 24 months.

Effects of interventions

The meta-analysis results suggested that three subjects were concerned with exited low heterogeneity following the P and I² except for postoperative hip pain. The forest plot of four outcomes indicated the two studied devices had no statistically significant difference. Eleven studies^[7,16-25] included a total of 1,146 patients concerned with mechanical failure rates, the quality

Mechanical failure for intertrochanteric fracture

Patient or population: patients with intertrochanteric fracture

Settings:

Intervention: Mechanical failure

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Mechanical failure				
failure rate	Study population		OR 0.71 (0.4 to 1.27)	1146 (11 studies)	⊕⊕⊕⊖ moderate ¹	
Follow-up: mean 12 months	86 per 1000	63 per 1000 (36 to 107)				
	Moderate 98 per 1000	72 per 1000 (42 to 121)				

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

FIGURE 4. The quality of the evidence in mechanical failure rates.

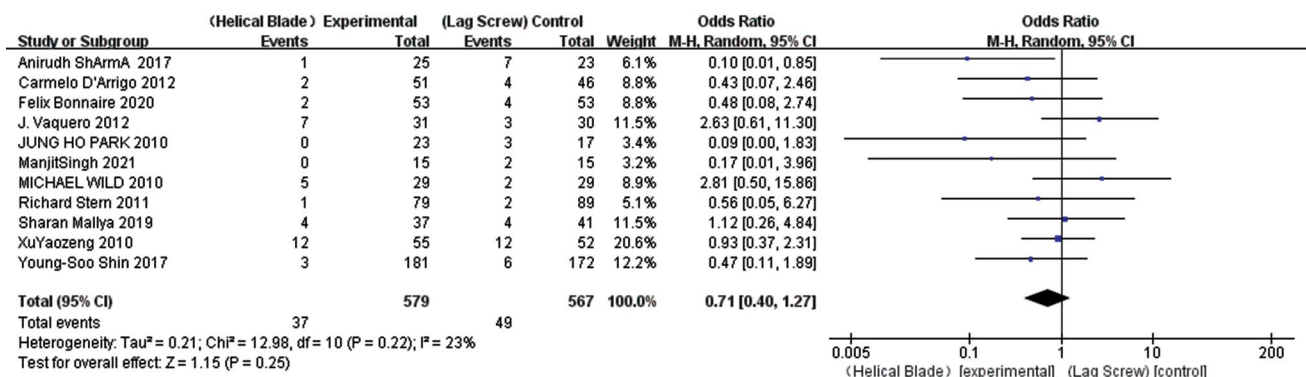


FIGURE 5. Forest plot diagram comparing mechanical failure rates between helical blade and lag screw.

Comparing helical blade and lag screw for intertrochanteric fracture among the elderly

Patient or population: patients with intertrochanteric fracture among the elderly

Settings:

Intervention: Comparing helical blade with lag screw

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Comparing helical blade with lag screw				
fracture reduction	Study population		OR 1.33	642	⊕⊕⊕⊕	
Follow-up: 6-18 months	946 per 1000	959 per 1000 (915 to 981)	(0.61 to 2.9)	(5 studies)	moderate ¹	
	Moderate					
	943 per 1000	957 per 1000 (910 to 980)				

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

FIGURE 6. The quality of the evidence in reduction quality.

of the evidence was moderate, as some articles^[7,22,25] have a small sample size and there is a risk of bias (Figure 4). No significant differences were found in helical blade versus lag screw (OR=0.71, 95% CI 0.40-1.27, p=0.22; Figure 5). The incidence of mechanical impairment was 37/579 versus 49/567, respectively. Random-effect model was used to explore heterogeneity, I²=23%, and no statistically significant heterogeneity was found between these studies. Additionally, five of the studies^[20-24] included a total of 642 patients concerned with the quality of reduction, the quality of the evidence was moderate, due to the existed inconsistency about the evaluation of reduction criteria (Figure 6). The excellent and good rate of fracture reduction was no significantly different between the helical blade and lag screw (OR=1.33, 95% CI 0.61-2.90, p=0.48; Figure 7). The excellent and good rate of fracture reduction was 313/325 versus 300/317,

respectively. I²=0%, random-effect model suggested no heterogeneity. Five of the studies^[19-21,24,25] included a total of 647 patients concerned with HHS, and the quality of the evidence was moderate, due to the existed imprecision about HHS grading (Figure 8). No significant difference was found between the helical blade versus lag screw (mean difference [MD]=1.83, 95% CI -0.29-3.95, p=0.29; Figure 9). A total of 331 and 316 patients were included in the two groups for comparison and we used the random-effect model to explore heterogeneity, and no statistically significant heterogeneity was found between the included studies (I²=20%). The number of patients with postoperative hip pain was recorded as complaints at the final follow-up. Four of the studies^[7,16,19,21] included a total of 568 patients, and the quality of the evidence was low (Figure 10). There was no statistically significant difference between the helical blade and lag screw (OR=0.41,

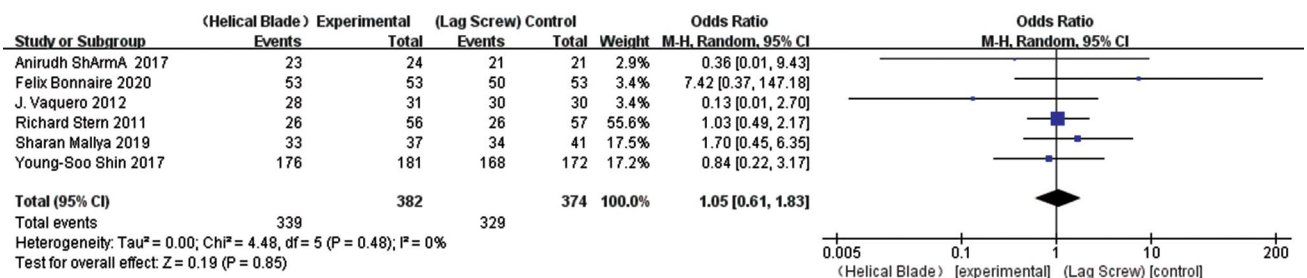


FIGURE 7. Forest plot diagram comparing reduction quality between helical blade and lag screw.

postoperation function for intertrochanteric fracture

Patient or population: patients with intertrochanteric fracture
Settings:
Intervention: postoperation function

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Postoperation function				
HHS Follow-up: mean 12 months		The mean hhs in the intervention groups was 1.83 higher (0.29 lower to 3.95 higher)		647 (5 studies)	⊕⊕⊕⊕ moderate ¹	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval;
 GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

¹ Grading is subjective

FIGURE 8. The quality of the evidence in Harris Hip Score.

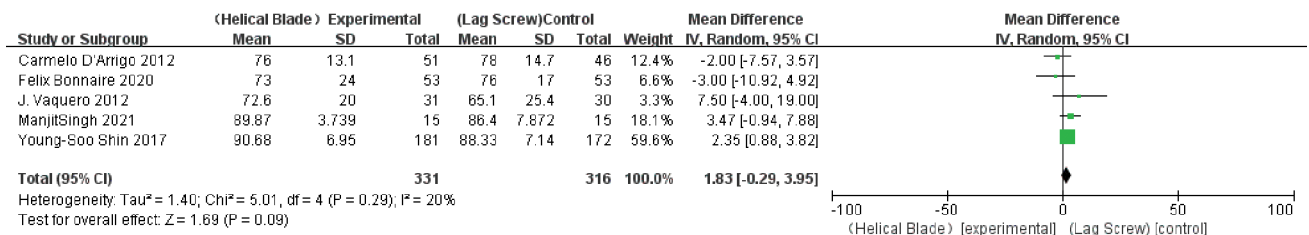


FIGURE 9. Forest plot diagram comparing Harris Hip Score between helical blade and lag screw.

Hip Pain for intertrochanteric fracture

Patient or population: patients with intertrochanteric fracture
Settings:
Intervention: Hip Pain

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Hip Pain				
Hip pain after operation Follow-up: mean 12 months	Study population 170 per 1000	76 per 1000 (30 to 181)	OR 0.4 (0.15 to 1.08)	571 (4 studies)	⊕⊕⊕⊕ high	
	Moderate 128 per 1000	55 per 1000 (22 to 137)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; OR: Odds ratio;
 GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

FIGURE 10. The quality of the evidence in postoperative hip pain.

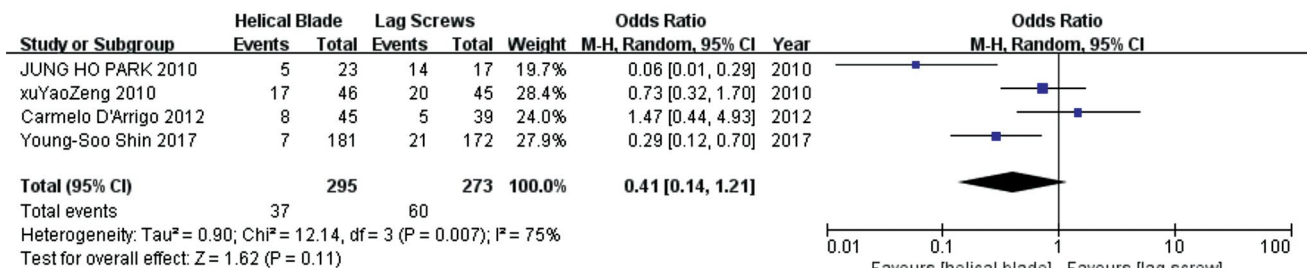


FIGURE 11. Forest plot diagram comparing postoperative hip pain between helical blade and lag screw.

95% CI 0.14-1.21, $p=0.11$; Figure 11). The incidence of postoperative hip pain was 37/295 versus 60/273, respectively. Random-effect model was used to due to high heterogeneity in postoperative hip pain.

DISCUSSION

In all 11 studies regarding mechanical failure, there was no statistically significant difference between the two screws in terms of mechanical failure. The basic principles and procedures are the same for most internal fixation devices, only the exact technique and instrumentation vary depending upon the device used.^[25] Some orthopedic surgeons believe that the key for excellent outcomes are the fracture type, general condition of the patient, and surgeon's experience, but not the implant.^[16] Bonnaire et al.^[24] suggested that there was no significant difference in perioperative complications between PFNA and Gamma3, and the cut-out was a result of the screw being poorly positioned rather than implant-related. Ibrahim et al.^[26] also agreed that there was no association between helical blade fixation and implant cut-out, and poorer fracture reduction was predictive of failure by cut-out. With the increasing frequency of intramedullary devices, particularly the PFNA, the literature on cut-in or "medial migration" has gradually increased. Some scholars believe that the anatomic reduction of the fracture, precise spiral blade placement, and the management of osteoporosis are the cornerstones to prevent screw incision. Hence, they proposed these factors resulting in the cut-in phenomenon and recognize that this is an atypical mode of failure different from cut-out.^[27] To date, this phenomenon has been reported only in screw blades, but not in lag screws.

Proximal femoral nail antirotation has a superior performance over the proximal femoral nail (PFN) in the setting of osteoporosis, which is attributed to the compaction of cancellous bone by the helical blade.^[22] However, the comparison of the resistance

to pullout strength between the two types of original screws (lag screw versus helical blade) showed that the lag screw was significantly superior to the helical blade for all bone mineral densities (BMDs), while in terms of rotational strength, the helical blade was significantly superior to the lag screw, regardless of the rotation direction and the BMD.^[28] On the contrary, some authors argued that the stability of the lag screw was correlated with the bone quality around the screw.^[29] They measured the BMD with micro-computed tomography and found that it was higher in the center region of the femoral head than in the inferior region. Therefore, lag screws are recommended to be inserted into the center of the femoral head.^[30] Although both types of implants have similar advantages, PFNA is preferred for patients with osteoporosis. Only two of the 11 included references mention the Singh indexes. Two studies were included for further classification of osteoporosis and indicated that the spiral blade group had an advantage over the lag screw group.^[7,23] Park et al.^[7] suggested that the helical blade produced better results in terms of social function scores, mobility scores, and complication rates with a statistically significant difference. Mallya et al.^[23] concluded that the helical blade group showed better results in terms of perioperative morbidity. In the current literature reports, we did not find more similar articles.

Shin et al.^[21] found that cut-out was associated with the screw or blade position within the femoral head measured with the TAD, but not in terms of the fracture reduction quality. However, TAD and the quality of fracture reduction were emphasized as the most common risk factors of fixation failure after the treatment of intertrochanteric hip fractures. Five articles on reduction quality were included in this meta-analysis. Sharma et al.^[22] reported that one patient with a poor reduction quality in the helical blade group had no complications, while four patients with a good reduction quality in the lag screw group had mechanical complications. In their

treatment, Mallya et al.^[23] found four cases of poor reduction and unsatisfactory postoperative function in the helical blade group, including two cases of mechanical failure. In the lag screw group, four patients with good reduction had implant-related complications, while four patients with poor reduction had also poor postoperative function, and three patients had favorable function. Excellent reduction quality is an important factor to achieve good postoperative function.^[31-33] Notably, no implant design can compensate for poor fracture reduction or implant placement.^[23]

The HHS indicated no significant difference between the two groups in our review. However, there were differences in the HHS among five studies included. With the increase of age, HHS showed a downward trend. Good functional results can be obtained, when good radiological parameters are restored as reported in the literature.^[23] Postoperative lateral hip pain was thought to be related to lag screw sliding distance and fracture type. More unstable fracture types and screw displacement of more than 6 mm may result in varus malreduction and iliotibial band agitation.^[21] Postoperative hip pain included in this study was obtained from patients' statements at the final follow-up; therefore, the quality of evidence is low. In our opinion, postoperative hip pain was not quantified, which could affect the synthetic result and this requires further study.

A meta-analysis on the comparison between lag screws and spiral blades concluded that fixation failure was more common with helical blades than with lag screws.^[15] However, our study concluded that there was no significant difference in the rate of fixation failure between the two groups.^[34] The reasons may be as follows: First, all the studies included were RCTs. Second, the comparison between PFNA and PFN was included in our inclusion criteria. Third, there are certain differences in the definition of mechanical fixation failure. Rather than completely rewriting the previous review, we took a pragmatic decision to reorder the categories of outcomes and highlight the primary outcomes.

Nonetheless, there were several limitations in the current analysis. First, the occurrence of mechanical failure often takes time to observe, and its occurrence is "all" or "none" relationship, the possibility of publication bias is relatively small, but we did not include the retrospective literature. Second, instead of including a single lag screw, we included the PFN, but not the Intertan screw, as the PFN was the previous generation of PFNA. The two internal

fixation devices are comparable. Third, the same results in different studies were presented in different forms; thus, we cannot make full use of these results for meta-analysis. In our opinion, further refinement of grouping and contrast according to the degree of osteoporosis would be more helpful to analyze these issues more clearly.

In conclusion, the two types of screws and their clinical efficacy have been continuously and greatly improved in the treatment of intertrochanteric fractures. Both helical blades and lag screws are good choices for fixing intertrochanteric fracture.

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Author Contributions: Designed the study, collected the data, analysed the results, generated figures, and wrote the paper: J.H.; Literature search, article revision: Q.W.

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