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A meta-analysis of integrated compression screw compared to single screw nails using a single lag screw or single helical blade screw for intertrochanteric hip fractures

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Abstract

Background: Surgical treatment is the optimal strategy for managing intertrochanteric fractures as it allows early rehabilitation and functional recovery. We sought to assess the clinical effectiveness of commonly used intramedullary devices for the treatment of unstable intertrochanteric hip fractures and also assess if there was a class effect of these nails.

Methods: A comprehensive systematic literature review and meta-analysis of studies was conducted comparing an Integrated Compression Screw nail (ICS) with conventional single screw nails using a single lag screw (SLS) or a single helical blade (SHB). We assessed the following outcomes, device related complications (shaft fracture, varus collapse and cut-outs), revisions, non-unions, hip and thigh pain, Harris Hip Score, health related quality of life, operating and fluoroscopy time, blood loss and other complications. We report odds ratios for dichotomous outcomes and mean difference for continuous outcomes.

Results: Twelve studies with 1,661 patients were included, 8 comparing ICS with SHB and 4 comparing ICS with SLS. Mean age was 76 years and 71% of patients were female. There were significant differences ($p<0.05$) in device performance in favour of ICS for implant related failures, fewer revisions, hip and thigh pain and better function as measured by SF-36 and HHS compared to single screw nails. Operating time and fluoroscopy time significantly favoured single screw nails. No differences were seen in non-unions, blood loss, and other complications.

Conclusion: Our meta-analysis suggests that there are significant differences between ICS and the single screw nails in favour of ICS with respect to the incidence of implant related failures, revision, functional outcomes and proportion of patients reporting hip and thigh pain. Operating time favours the single screw nails while no differences were observed regarding non-unions, blood loss and other complications. There is no evidence of class effect regarding intramedualary nails in this patient population.

Introduction

By 2050, the number of hip fractures worldwide is estimated to surpass 6.3 million. In the US alone, the number of hip fractures is estimated to increase from about 320,000 per year, of which around 150,000 are intertrochanteric fractures, to 580,000 by 2040 [1-4]. Furthermore, in the USA it is estimated that hip fractures account for approximately 14% of all fractures but result in approximately 70% of the acute care and subsequent hospital care costs associated with fracture treatment [5], with healthcare costs exceeding $10 billion per year. This is expected to continue to rise with the corresponding increase in life expectancy [1,2,6,7]. A similar trend is observed in the European Union. For instance, in 2010 there were an estimated 600,000 hip fractures costing €20 billion to the health system [8]. Studies have also suggested an association between hip fracture and mortality, with the 1-year mortality rate for hip fractures ranging from 14% to 36%, with 30% more deaths observed than with an age matched population [9-11].

Surgical intervention is the definitive treatment for these fractures as it enables patient early mobilization and subsequent return to acceptable levels of function [1,5]. Implant choice is determined by whether the fracture is "stable" or "unstable" which is predominantly dependant on the status of the posteromedial cortex [12]. According to the Orthopaedic Trauma Association (OTA/AO) fracture classification system, type A1 is universally considered stable and type A3 is generally considered unstable, while the stability of A2 fractures are less clear. For this study we considered OTA/AO fracture classification system A2-1 and above as unstable [12].

A number of studies and systematic reviews have been conducted to offer a comprehensive assessment of alternative internal fixation treatments for intertrochanteric fractures [2,11-15]. Most recently [14] reported results of an Intergrated 2-nailing system compared with one nail-system and concluded that ICS was as effective as the control group in terms of Harris Hip Score (HHS), blood loss, total complications,

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***Key words:** intramedullary nail, integrated compression screw, single lag screw, single helical blade, intertrochanteric hip fractures, intertan, PFNA, gamma3, meta-analysis*

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union time, length of hospital stay, revision rate, and fluoroscopy time. ICS showed lower rates of implant cut-out and femoral fractures when compared with control groups. This result differed from another recent systematic review by Nherera [13] which found that in addition to improved implant related failure rates, ICS also resulted in lower rates of revision and fewer reports of hip and thigh pain when compared to a single helical blade. This difference in conclusions may be due to additional studies included in Nherera [13] that were not included in the analysis by Ma [14] analysis.

We therefore sought to update the meta-analysis by Nherera [13] and the one by Ma [14] and combine all single screw nail studies (SHB and SLS) to comprehensively assess the difference in outcomes and test the hypothesis that there could be a class effect around intramedullary nails in unstable fractures. Our study thus compared ICS nail (TRIGEN◊ INTERTAN Smith & Nephew, Memphis, Tennessee) with conventional single screw nails defined as single helical blade (SHB) Proximal Femoral Nail Antirotation (PFNA™) (DePuy Synthes, Solothurn, Switzerland) and single lag screw (SLS) (Gamma3™; Stryker, Schönkirchen, Germany) in the treatment of intertrochanteric fractures.

Methods

Data sources and searches

We searched for randomised clinical trials (RCTs) and comparative observational studies comparing ICS with single screw nails (SHB, SLS) from January 2000 to May 2018. The following electronic databases were searched, PubMed, Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Health Technology Assessment (HTA) Database, ClinicalTrials.gov. The search terms used included the following "hip fracture, InterTAN, intertrochanteric fractures, integrated compression screw, cepahlomedullary nails, single screw nail, Gamma nail, Gamma 3, PFNA, PFNA-11, single helical blade, single lag screw nails". We also hand-searched references of relevant papers in and recently published systematic reviews [13,14] to ensure completeness.

Study selection and eligibility criteria

We included RCTs and prospective comparative observational studies with no language restriction if they enrolled participants diagnosed with intertrochanteric fractures; comparing ICS with SLS or SHB. The primary outcome was defined as implant related failures (i.e., cut out, varus collapse, shaft fractures). The secondary outcomes were revisions, non-union, functional measures (i.e. quality of life scores Harris Hip scores and pain), and procedural measures, (i.e. operative time, blood loss, fluoroscopy time). Mortality and length of stay were not included in this analysis because these outcomes are confounded by the patient group i.e., most patients are elderly, frail with multiple comorbidities and therefore the implants are unlikely to have an impact on mortality or length of stay. The inclusion and exclusion criteria are outlined in (Table 1).

Study procedures and data extraction

Two authors (LN and AH) independently screened all titles and abstracts based on the population, intervention, comparators and outcomes (PICO) framework [16] using a pilot-tested data extraction form. The quality of included RCTs was assessed using the Cochrane Collaboration's risk of bias tool [17] and for, observational studies we used the Good Research for Comparative Effectiveness (GRACE) checklist [18]. The following data from eligible studies were extracted; study characteristics; (year of publication, simple size, country, length of follow up); patient characteristics (gender, age); intervention/comparator and the pre-specified outcomes.

Table 1. Study inclusion exclusion criteria

Criteria	Inclusion	Exclusion
Type of study	RCTs, prospective comparative observational studies	Systematic reviews, conference abstracts, case series, case reports, narrative reviews, editorials, opinions; studies performed in animals
Population	Adults with intertrochanteric hip fractures	Stable fractures alone
Geographical location	Publications from any country	None
Interventions	Integrated compression screw nail (ICS) (InterTAN)	Other nails other than ICS, SLS and SHB.
Comparators	single lag screw (SLS) i.e, Gamma 3 and single helical blade crew (SHB) i.e, PFNA, PFNA-11	Other nails other than InterTAN and Gamma 3, PFNA.
Outcomes of interest	Post-operative implant related failures (i.e. cut out, varus collapse, shaft fractures) non-union, revisions, functional measures (i.e. quality of life scores and pain, Harris Hip Score), and procedure measures (i.e. operative time, blood loss, fluoroscopy time), other complications (deep vein thrombosis, cardiovascular disorders, pressure sores, urinary tract infection, pulmonary embolism and hematomas)	Length of stay, mortality

RCT: Randomised Controlled Trial; ICS: Integrated Compression Screw; PFNA: Proximal Femoral Nail Antirotation; SLS: Single Lag Screw; SHB: Single Helical Blade Screw.

Meta-analysis

Meta-analyses were performed in Review Manager (RevMan), Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, using either a fixed-effect or a random-effect model depending with the presence or absence of significant heterogeneity between studies. For dichotomous outcomes, odds ratio (OR) with a 95% CI was reported as the summary statistic. For continuous outcomes, such as HHS, fluoroscopy time, blood loss we used the mean difference (MD). We used the inverse variance and Mantel-Haenszel methods to combine separate statistics and if p values were less than 0.05, the results were considered statistically significant. Data were analysed separately for SBH and SLS, however, the main analysis reports the results of the combined analysis. This is depature from the analysis that was conducted by Ma [14] who did not pool the results of the individual single screw intramedullary nails.

Sensitivity analysis

The main analysis reported the pooled results of SHB and SLS. The analysis shown in the forest plots was done by considering each single screw nail individually. We also used alternative pooling methods (Peto method vs. Mantel-Haenszel method applicable to dichotomous data). Studies that reported follow-up less than 12 months and those that had mixed populations were removed from the analysis to see the impact on the overall conclusions.

Investigation of heterogeneity and assessment of reporting bias

Heterogeneity of the included studies was assessed using the I^2 statistic [19]. If the calculated I^2 statistic was less than 50%, a fixed-effect model was used (no substantial heterogeneity) and when the calculated I^2 statistic was more than 50%, a random-effects model was used. We used funnel plot to evaluate reporting biases qualitatively, however it is acknowledged that the funnel plot is incapable of identifying which type of bias is present if any [20].

Results

Literature search

The initial search found 542 articles and following the removal of duplicates and unrelated articles 25 full articles were assessed for detailed evaluation. After the evaluation of the full titles a further 13 were excluded and therefore 12 studies met the inclusion criteria and were included in the meta-analysis (Figure 1). Of those that met the inclusion criteria, 8 studies compared ICS with SHB [21-28] and 4 compared ICS with SLS [29-32]. Of the 12 studies, five were RCTs, [21,22,29,30,31] and 7 were observational studies, [23-28,32] all published between 2013 and 2018. There were 1661 patients in the 12 studies that met the inclusion criteria, of which 784 were treated with ICS while 877 were treated with single nail screws. The mean age of patients in the studies was 76 years, and 71% were females. The sample sizes ranged from 56 to 283, and the length of follow up ranged from 4.6 to 60 months. Four studies recruited both stable and unstable fractures [21,24,27,29] and none explored the effects of devices by fracture type. The majority of the RCTs were rated as having an unclear risk of bias, generally due to a lack of adequate information being reported in the methods according to the Cochrane quality checklist [17] while the observational study was deemed to be of adequate quality according to GRACE checklist [18]. The key characteristics of all included studies are summarised in (Table 2).

Clinical results

Primary outcome

Implant related failures: Eleven of the twelve studies reported implant related failure data defined as cut out, varus collapse and shaft fractures [21-23,25-32] (n=1605 patients); the only study not to report these outcomes was Wang [24]. A total of 764 patients were treated with the ICS and 841 were treated with single screw nails. The combined pooled results showed that ICS significantly reduced the risk of implant related failures by 81% compared to single screw nails OR: 0.19, 95% CI 0.12 to 0.29, I^2 = 19%, p<0.00001. The results remained significant when the single nails where considered individually (85% reduction p<0.00001 for SHB and 68% reduction p=0.007 for SLS). The results are shown in (Figure 2).

Secondary outcomes

Revisions: Nine studies reported data on revisions [21-23, 27-32] (n=1383 patients). A total of 657 patients were treated with the ICS and 726 were treated with single screw nails. The combined pooled results showed that ICS significantly reduced the risk of revisions by 65% compared to single nails OR: 0.35, 95% CI 0.20 to 0.60, I^2 = 11%, p<0.0001. The results remained statistically significant for SHB p=0.0001 when the single nails where considered individually and no difference was observed when ICS was compared with SLS alone p=0.48 as shown in (Figure 3A).

Non-unions: Four studies reported data on non-union [22,27,28,32] (n=811 patients). A total of 364 patients were treated with the ICS and 447 were treated with single screw nails. The combined pooled results showed that overall, there was no statistical difference between ICS and the single screw nails in reducing the incidence of non-unions. The pooled results did not reach statistical significance with wide confidence intervals OR: 0.54, 95% CI 0.17 to 1.66, I^2 = 0%, p=0.28 see (Figure 3B). Similar results were observed when SHB and SLS were considered individually.

Patient related functional outcomes

Harris Hip Score: All studies reported data on HHS [21-32] (n=1661 patients). A total of 784 patients were treated with the ICS and 877 were treated with single screw nails. The combined pooled results showed that ICS significantly improved the HSS compared to single screw nails MD: 1.42, 95% CI 0.23 to 2.61, I^2 = 51%, p=0.02. The results remained significant for SHB p=0.03 when the single screw nails where considered individually and no difference was observed when ICS was compared with SLS alone p=0.17 as shown in (Figure 4A).

Hip and thigh pain: Eight studies reported data on the proportion of patients who complained of hip and thigh pain [21,25-28,31,32] (n=1323 patients). A total of 620 patients were treated with the ICS and 703 were treated with single screw nails. The combined pooled results showed that ICS treated patients experienced significantly less complaints of hip and thigh pain (45% less people) compared to single screw nails OR: 0.55, 95% CI 0.38 to 0.78, I^2 = 0%, p=0.0009. The results

Table 2. Characteristics of included studies in the systematic review and meta-analysis.

Study author & year	Type of study & Sample size	Mean age in years (Range)	Percentage of males	Length of follow up, months
Seyhan [21]	RCT N=75: ICS=32; SHB=43	ICS=75.3 (61.8-88.9) SHB=75.9 (62.2-89.6)	ICS=34.4 SHB=18.6	24
Zhang [22]	RCT N=113: ICS=47; SHB=46	ICS=72.4 (64.8-80.0) SHB-II=72.4 (63.7-81.1)	ICS=40.4 SHB=33.9	12
Gavaskar [23]	Observational N=100: ICS=50; SHB=50	ICS=77 ± 7 SHB=78±8	ICS=21.9 SHB=21.9	12
Wang [24]	Observational N=56: ICS=20; SHB=36	ICS=73.5 SHB=76.8	ICS=55 SHB=47.2	4.6
Yu [25]	Observational N=168; ICS=75; SHB=72	ICS=75.2 (66.4-84.0) SHB=74.2 (65.1-83.3)	ICS=35 SHB=32	12
Zehir [26]	Observational N=195; ICS=102; SHB=93	ICS=76.9 (70.2-83.6) SHB=77.2 (70.4-84.0)	ICS=38.2 SHB=38.5	16
Zhang [27]	Observational N=174; ICS=86; SHB= 88	ICS=72.7 (7.6) SHB=74.6 (6.3)	ICS=34.8 SHB=38.6	40
Zhang [28]	Observational N=283; ICS=144; SHB=139	ICS=76.1 SHB=76.1	ICS=56 SHB=62	38.8
Berger-Groch [29]	RCT N=104; ICS=55; SLS=49	ICS=81.6 (72.2-91.0) SLS=82.0 (72.8-91.2)	ICS=21.8 SLS=24.5	60
Hopp [30]	RCT N=78; ICS=39; SLS=39	ICS=82.7 SLS=80.7 years	ICS=18 SLS=33.3	12
Su [31]	RCT N=100; ICS=50; SLS=50	ICS=70.1 SLS=71.3	ICS=42.0 SLS=38.0	12
Wu [32]	Observational N=261; ICS=87; SLS=174	ICS=71.4 (61.7-81.1) SLS=72.6 (64.0-81.2)	ICS=23.0 SLS=24.7	12

ICS: Integrated Compression Screw; SHB: Single Helical Blade Screw; N: Total number enrolled in the study; RCT: Randomised Controlled Trial; SLS: Single Lag Screw.

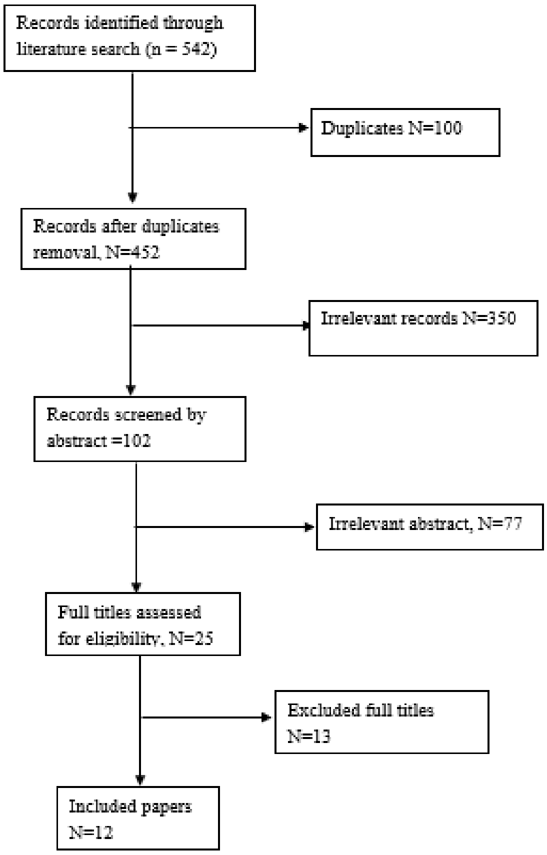

Figure 1. PRISMA flow diagram

Study or Subgroup	Integrated Compression Screw Events	Integrated Compression Screw Total	Single screw nails Events	Single screw nails Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1.1.1 Single helical blade screw (Implant failures)						
Gavaskar 2018	2	50	9	50	7.1%	0.19 [0.04, 0.93]
Seyhan 2015	0	32	2	43	1.7%	0.26 [0.01, 5.51]
Yu 2016	6	75	24	72	18.5%	0.17 [0.07, 0.46]
Zehir 2015	0	102	13	96	11.4%	0.03 [0.00, 0.52]
Zhang 2013	0	47	7	46	6.2%	0.06 [0.00, 1.00]
Zhang 2017 a	2	86	12	88	9.5%	0.15 [0.03, 0.70]
Zhang 2017 b	7	144	31	139	24.6%	0.18 [0.08, 0.42]
Subtotal (95% CI)		**536**		**534**	**79.0%**	**0.15 [0.09, 0.25]**
Total events	17		98			
Heterogeneity: Chi² = 2.19, df = 6 (P = 0.90); I² = 0%						
Test for overall effect: Z = 7.24 (P < 0.00001)						
1.1.2 Single lag screw (Implant failures)						
Berger-Groch 2016	1	55	1	49	0.9%	0.89 [0.05, 14.60]
Hopp 2016	5	39	3	39	2.1%	1.76 [0.39, 7.96]
Su 2016	1	47	5	45	4.1%	0.17 [0.02, 1.55]
Wu 2014	2	87	26	174	13.9%	0.13 [0.03, 0.58]
Subtotal (95% CI)		**228**		**307**	**21.0%**	**0.34 [0.16, 0.74]**
Total events	9		35			
Heterogeneity: Chi² = 6.97, df = 3 (P = 0.07); I² = 57%						
Test for overall effect: Z = 2.71 (P = 0.007)						
Total (95% CI)		**764**		**841**	**100.0%**	**0.19 [0.12, 0.29]**
Total events	26		133			
Heterogeneity: Chi² = 12.36, df = 10 (P = 0.26); I² = 19%						
Test for overall effect: Z = 7.64 (P < 0.00001)						
Test for subgroup differences: Chi² = 3.10, df = 1 (P = 0.08), I² = 67.7%						

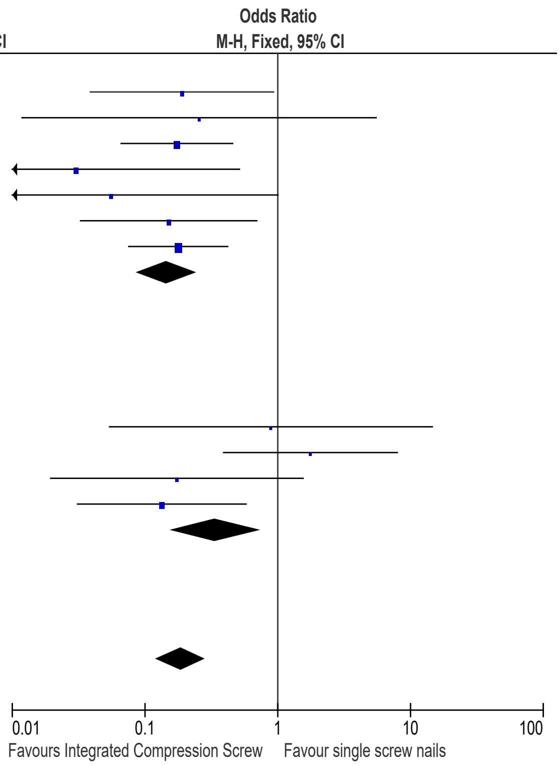

Figure 2. Impact of Integrated compression screw nail compared with single lag screws (a single lag screw or a single helical blade) on implant related failures defined as cut out, shaft fractures, varus collapse

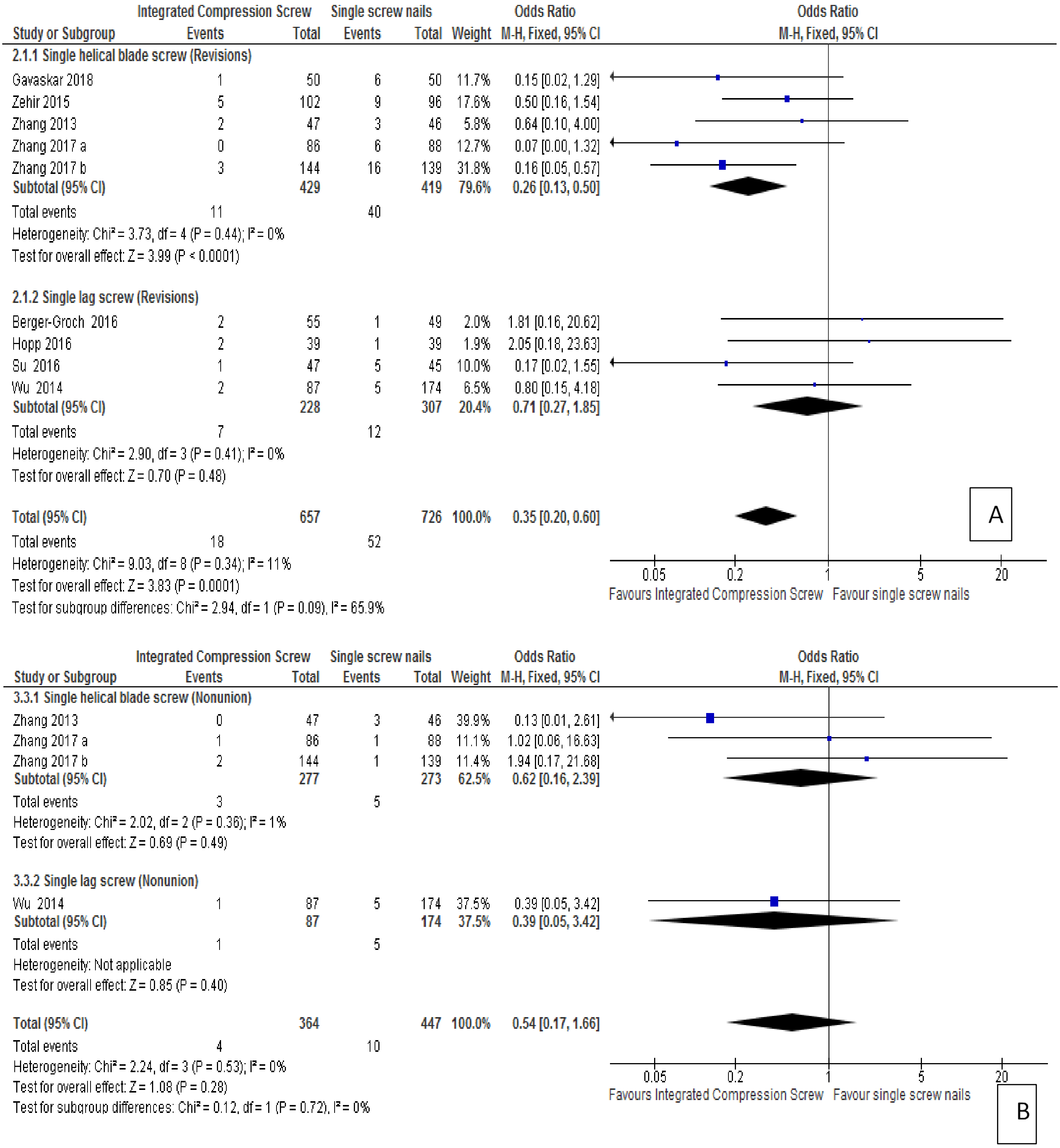

Figure 3. Impact of Integrated compression screw nail compared with single lag screws (a single lag screw or a single helical blade) on (A) Revisions and (B) Non-unions.

remained significant for SHB p=0.0005 when the single screw nails where considered individually and no difference was observed when ICS was compared with SLS alone p=0.9 as shown in (Figure 4B).

Health related quality of life (Short form 36 physical function)

Only one study reported health related quality of life outcomes [29] and had 104 patients in total. Overall, there was a statistically significant difference between ICS and SLS for this outcome in favour of ICS, the mean difference MD: 7.40, 95% CI 2.73 to 12.07, p=0.002 see (Figure 4C).

Intra operative outcomes

Operating time: Ten studies reported data on surgery time [21,22,24-27,29-32] (n=1387 patients). A total of 648 patients were

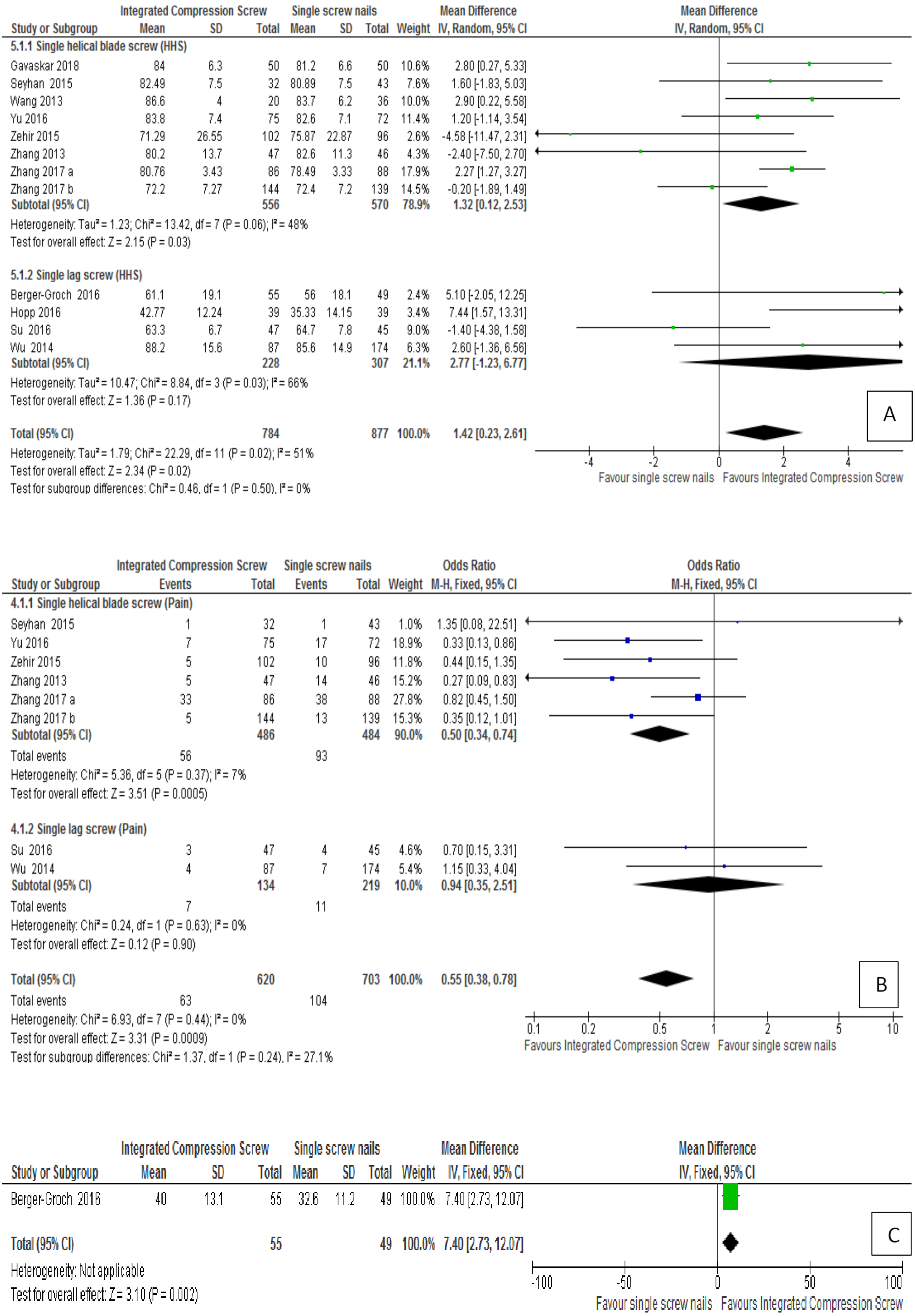

Figure 4. Impact of Integrated compression screw nail compared with single lag screws (a single lag screw or a single helical blade) on (A) Harris Hip Score, (B) Hip and thigh pain and (C) Physical component of the SF-36.

treated with ICS and 739 were treated with single screw nails. The pooled results showed that ICS was associated with a marginally longer surgery time (+7.32 minutes) compared to single screw nails MD: 7.32, 95% CI 1.00 to 13.64, I^2 = 98%, p=0.02. There were no differences seen when single screw nails were considered individually for SHB p=0.09 and SLS alone p=0.07 as shown in (Figure 5A).

Fluoroscopy time: Five studies reported data on fluoroscopy time [22,25,26,30,32] (n=777 patients). A total of 350 patients were treated with ICS and 427 were treated with single screw nails. The combined pooled results showed that ICS was associated with extended fluoroscopy time (+1 minute) compared to single screw nails. MD: 1.00, 95% CI 0.31 to 1.68, I^2 = 0%, p=0.004. The results remained significant for SHB p=0.02 and SLS p<0.00001 when the single screw nails where considered individually as shown in (Figure 5B).

Blood loss

Eight studies reported data on the the amount of blood loss during surgery [22,24-26,28,30-32] (n=1216 patients). A total of 564 patients were treated with ICS and 652 were treated with single screw nails. The combined pooled results showed that there was no significant difference in the amount of blood loss between patients treated with ICS and single screw nails, MD: 6.40, 95% CI -7.07 to 19.88, I^2 = 98%, p=0.35. The results were different when ICS was compared with SHB p=0.03, in favour of SHB, while no differences were observed when ICS was compared with SLS alone p=0.35 although less blood loss was observed for ICS as shown in (Figure 5C).

Other complications

Six studies reported data on other complications. [21,22,28,30-32] (n=903 patients). A total of 399 patients were treated with ICS and 504 were treated with single screw nails. Other complications considered in this study were deep vein thrombosis, cardiovascular disorders, pressure sores, urinary tract infection, pulmonary embolism and hematomas. The combined pooled results showed that there was no difference in the incidence of other complications between ICS compared to single screw nails OR: 0.99, 95% CI 0.65 to 1.49, I^2 = 0%, p=0.94. This result was maintained when the single screw nails where considered individually SHB p=0.85 and SLS p=0.95 as shown in (Figure 5D).

Publication bias

A funnel plot demonstrated no visual evidence of publication bias (Figure 6) for the primary outcome. Similar results were obtained for other outcomes. The outer dashed lines indicate the triangular region within which 95% of studies are expected to lie in the absence of both biases and heterogeneity.

Sensitivity analysis

The sensitivity analyses using alternative analysis methods (Peto method vs. Mantel-Haenszel method), and considerations of heterogeneity (random-effects vs. fixed-effect) did not show important changes in the pooled effects for these outcomes. One study had a follow up of less than 12 months [23] and contributed data on revisions and HHS outcomes. When this study was removed from the analysis, the overall conclusions remained the same.

We also assessed the impact of removing studies which had mixed populations. Four studies included patients with stable fractures OA/OTA AI [21,24,28,29]. The proportion of patients with A1 was 8% i.e, 140 patients of the 1,661 total patients in the meta-analysis. When these studies were removed from the analysis to assess the effect of the implants on unstable patient only, the treatment effect slightly improved in favour of ICS for the primary outcome, i.e, reduction in implant related failures increased from 81% to 82% p<0.00001.

Discussion

Our study was conducted to explore whether integrated compression screw intramedullary nail provided better clinical outcomes compared to the single screw nailing system in unstable intertrochanteric fractures. Our pooled data showed that ICS provides more reliable fixation than single screw nail devices in this patient population. In particular the implant related fixation failure rate was reduced by 81% while revision rates were reduced by 65% the ICS group compared with the single screw nail fixation. We cannot be certain if all of the varus collapse reported in the studies were clinically relevant leading to revisions or they were simply varus progression of the neck or screw migration seen on the X-ray. Therefore, the reduction seen for implant failure needs to be interpreted with caution. Patients in the ICS group reported improvement in quality of life as measured by the physical component of the SF-36 and fewer people complained of hip and thigh pain. Significantly the HHS was improved overall in patients treated with ICS. These findings suggest that there is unlikely to be a class effect of intramedullary nails for the treatment of unstable intertrochanteric fractures.

Statistically significant differences in favour of single screw devices regarding surgery time (-7 minutes faster) and fluoroscopy time (-1 minute) were identified, although the absolute change in time, within the context of the surgical procedure, was considered marginal. Our study did not find any difference in non-union rates, blood loss or other complications such as deep vein thrombosis, cardiovascular disorders, pressure sores, urinary tract infection, pulmonary embolism and hematomas.

Previous studies have noted that quality of life and functional status following surgery are of particular importance. HHS is used to evaluate the results of hip surgery and the score can comprehensively assess the function of the patient after hip surgery. Our meta-analysis showed that ICS significantly improved postoperative functional recovery as well as reducing hip and thigh pain. Yu [25], observed that long-term pain arises due to implant failures and in line with the proposed association between implant failure and long term pain our study demonstrated that, the use of ICS resulted in a significant reduction in implant related failures and reduced hip and thigh pain. We appreciate that a direct causal relationship cannot be established from our analysis, however we believe it adds further weight to the conclusion by Yu [25]. There was a relative paucity of data on quality of life in the studies, with only one study reporting relevant data [29]. Whilst there is a plausible hypothesis that improvements in pain, revisions and implant failures is likely to result in improved QoL, further data on this outcome would be desirable.

Surgery and fluoroscopy time favoured single screw nails. This finding is in line with other previous analyses which found that ICS requires more time [13-15]. The causes of the difference in operating time are not clearly understood although it is speculated that the shape of ICS device may contribute to this. As in previous studies [13], the differences in operating time (7 minutes) are considered marginal when considered in the context of the entire procedure. Similarly, although no difference was observed regarding blood loss, there was a marginal increase in blood loss for ICS treated patients (6mL). The difference in blood loss is most likely attributable to the longer surgical

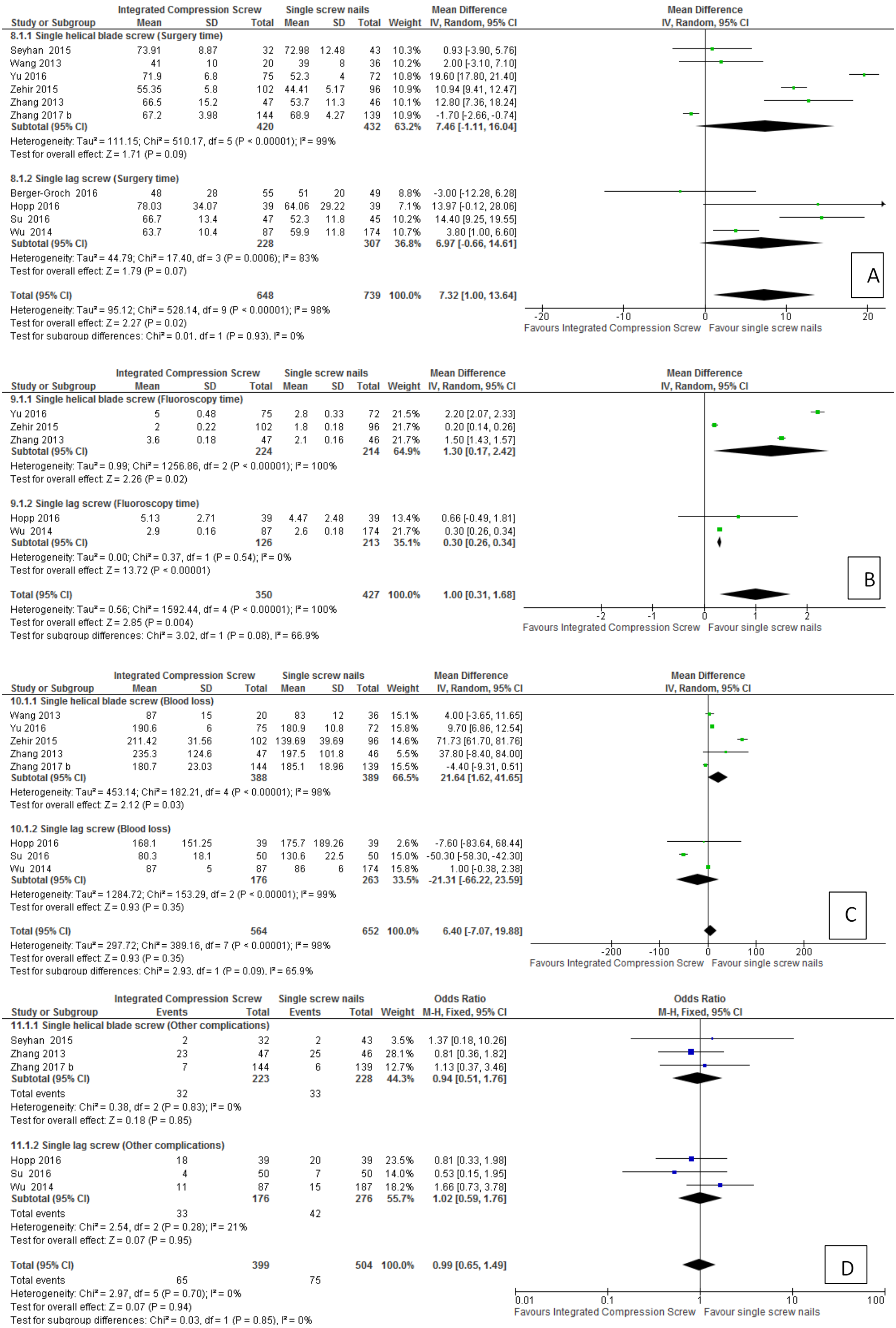

Figure 5. Impact of Integrated compression screw nail compared with single lag screws (a single lag screw or a single helical blade) on (A) operating time, (B) fluoroscopy time, (C) blood loss and (D) Other complications.

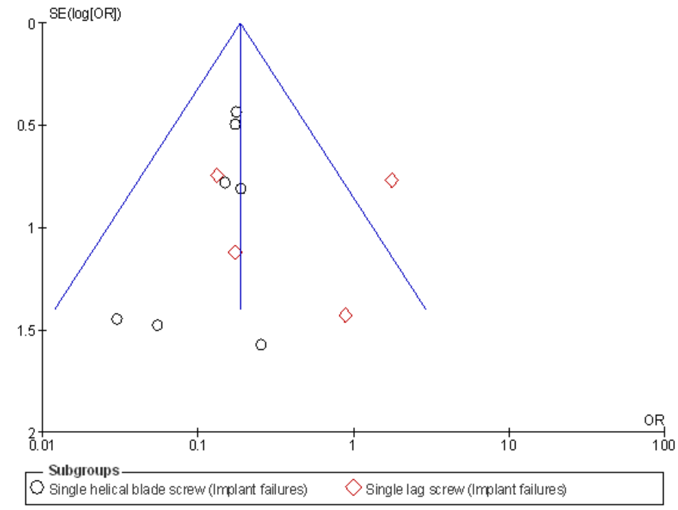

Figure 6. Funnel plot for the meta-analysis of the Integrated compression screw nail compared to single screws nails (a single lag screw or a single helical blade). (The forest plots show the odds ratio (OR) calculated by the random effects model or the mean difference (MD) calculated by the fixed effects model. Squares represent individual study effects and diamonds represent the summary effect from the meta-analysis. Horizontal bars represent 95% CIs and the vertical line in plot is at 1 for OR and 0 for MD, corresponding to the null hypothesis of no effect. I^2 = test of heterogeneity, CI, confidence interval; df, degree of freedom; M-H, Mantel–Haenszel).

time associated with ICS nails as was reported by Su (2016) [31]. The procedure results differed according to the type of single screw nail used, for instance there was more operating time in ICS nails when compared to SHB and less time when compared to SLS. We suspect that the presence of the varying procedural outcomes between studies may also result from different levels of expertise/experience among the surgeons participating in those studies.

We conducted a comprehensive systematic review and meta-analysis using rigorous methods using all available published comparative evidence i.e. both RCT and observational evidence. A total of 12 studies were included in the analysis with 1661 patients treated with either ICS nails (784) or single screw nails (877). This gives a sample size which is large enough to draw meaningful conclusions about the performance of the nails under consideration. Also, by considering all published comparative evidence, we were able to utilise the advantages of each type of study design i.e., RCTs providing internal validity and efficacy information while observational studies provide external validity and effectiveness information of the intervention [13]. Although our analysis reported the combined results of both single screw nails, we were also able to consider the single screw nails individually. We noted that all the single screw nails were in agreement with regards to the primary outcome of implant related failures and that there was further agreement with regards to HHS. There was divergence for instance with regards to revision and pain where there was significant reduction when ICS nails was compared to SHB and no difference when compared with SLS. These outcomes may be attributable in part to differences in the volume of data considered in the analysis, i.e. there were 8 studies included for SHB and 4 studies for SLS.

There are some limitations in our systematic review and meta-analysis. Firstly, 5 of the 12 studies included in the analysis were RCTs and the rest (7) were observational studies. The sample sizes of the RCTs ranged from 75 to 113 while observational studies ranged from 56 to 283. The results may have been driven by the less well-controlled observational studies which contributed more patients in the analysis. However, we assessed the possibility of publication bias using the funnel plots. The funnel plot did not suggest asymmetry because the estimated effects are scattered within the superimposed limits. Assessment of publication bias is often difficult if the number of studies is not large (<10) [20], however since we had more than 10 studies in our meta-analysis we are confident with the no bias finding of our analysis. Secondly, the follow-up of patients is different between the included articles. One study conducted by Wang [24] reported the mean time of follow up is 4.6 months while the majority of studies reported 12 months or over. This study only reported on two outcomes (HHS and surgery time). Removing the study from the analysis did not change the overall findings. Thirdly, we noted there was variation in procedure outcomes, mainly surgery and fluoroscopy time. For instance the difference between the shortest, 41 minutes in the study by Wang [24], and longest surgery time, 78 minutes in the study by Hopp [30], was 37 minutes. Such heterogeneity may be indicative of different levels of surgical experience and may may affect the results of meta-analysis. However, we accept that such differences between studies are inevitable and are experience dependant. Finally, we would have preferred to have results reported by fracture type for those studies that included mixed populations of stable and unstable fractures, but this was not always reported. We are still nonetheless confident that the results are representative of unstable fractures as 95% of the patients included in the analysis had unstable fractures and furthermore removing the studies with mixed populations had little impact on the overall conclusions of the meta-analysis.

Conclusion

The current body of evidence suggests that ICS nails may offer improved outcomes in terms of implant related complications, revision rates and better functional outcomes, including reduced pain, when compared to single screw nails. Procedure related outcomes, such as surgery time, tend to favour the single screw nails compared to ICS nails. We noted there was no difference between ICS compared to single screw nails with regards to blood loss, non-unions and other complications. There is a need for further studies especially between ICS nails and SLS and further evidence on quality of life would also be beneficial. Given the superiority of ICS for the major outcomes in patients with intertrochanteric fractures, clinicians and policy makers should be encouraged to implement protocols that incorporate appropriate use of ICS nails in order to maximise health benefits to the patients and bring value to the payers. This evidence has led to the rejection of the notion that there could be a class effect of intramedullary nails for unstable fractures.

Authorship

LN Conducted the meta-analysis and interpretation of results including the writing of the manuscript, PT, AH, AJJ, JTW contributed to the interpretation of results and commenting on the manuscript.

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Competing interest

LN, PT & AH are employees of Smith & Nephew the manufacturer of InterTAN. AJJ & JTW have no competing interests.

Ethical approval

Not applicable as this article does not contain any studies with human participants or animals that were performed by any of the authors.

Informed consent

Not applicable, as the study is a secondary analysis of data.

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