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[Intervention Review]

# Condylocephalic nails versus extramedullary implants for extracapsular hip fractures

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## ABSTRACT

### Background

Two types of implants used for the surgical fixation of extracapsular hip fractures are condylocephalic nails (intramedullary nails that are inserted up through the femoral canal from above the knee and across the fracture) and extramedullary implants.

### Objectives

To compare condylocephalic nails (e.g. Ender and Harris nails) with extramedullary implants (e.g. fixed nail plates and sliding hip screws) for the treatment of extracapsular (trochanteric and subtrochanteric) hip fracture in adults.

### Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (September 2004), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* Issue 3, 2004), MEDLINE (1966 to September week 1 2004), EMBASE, the UK National Research Register, orthopaedic journals, conference proceedings and reference lists of articles.

### Selection criteria

Randomised or quasi-randomised trials comparing condylocephalic nails with extramedullary implants.

### Data collection and analysis

We independently assessed trial quality and extracted data. Ender nails and Harris nail data were presented separately. Results from fixed nail plates and sliding hip screws were subgrouped.

### Main results

Eleven trials involving 1667 people with predominantly trochanteric fractures were included. Ten compared Ender nails with either a fixed nail plate or a sliding hip screw. One compared the Harris condylocephalic nail with a sliding hip screw.

The only advantages of condylocephalic nails were a reduced deep wound sepsis rate (0.9% versus 4.2%; relative risk 0.28, 95% confidence interval 0.11 to 0.62), length of surgery and operative blood loss. However, there was an increased risk of reoperation (20.9% versus 5.5%; relative risk 3.72, 95% confidence interval 2.54 to 5.44) and later fracture of the femur when compared with extramedullary implants. There was an increased risk of cut-out of the implant from the femoral head for Ender nails compared with the sliding hip screw, but not for fixed nail plates. Backing out of the nail was a frequent complication (30%) of Ender nails and often resulted in revision surgery.

Ender nails had an increased risk of shortening of the leg and external rotation deformity and potentially a poorer return to previous walking ability. An increase in residual pain, predominantly knee pain, was also evident in patients undergoing condylocephalic nailing. There was no apparent difference in mortality between the condylocephalic nail and extramedullary implant groups.

**Authors' conclusions**

Any advantages in intra-operative outcomes of condylocephalic nails are outweighed by the increase in fracture healing complications, reoperation rate, residual pain and limb deformity when compared with an extramedullary implant, particularly a sliding hip screw. The use of condylocephalic nails (in particular Ender nails), for trochanteric fracture is no longer appropriate.

**PLAIN LANGUAGE SUMMARY****Condylocephalic nails versus extramedullary implants for extracapsular hip fractures**

A hip fracture is a break near the top of the thigh bone (femur). Those located further away from the hip joint are termed extracapsular. Such fractures may be surgically fixed using metal implants. Two types of implant are compared here. Condylocephalic nails, such as Ender nails, are inserted near the knee, and pushed up through the bone marrow of the femur and across the fracture site. Extramedullary implants consist of a screw or rod, inserted in the upper part of the femur to bridge the fracture, connected to a plate secured to the femur. This review found that, despite quicker surgery, Ender nails were associated with an increased risk of complications and reoperation when compared with extramedullary implants in common use.

## BACKGROUND

Approximately half of all hip fractures (which are fractures of the proximal femur: the upper part of the thigh bone) are extracapsular (outside the hip joint capsule). A more exact definition of an extracapsular hip fracture is a fracture that traverses the femur within the area of bone bounded by the intertrochanteric line proximally to a distance of five centimetres below the distal part of the lesser trochanter. Numerous subdivisions and classification methods exist for these fractures and other terms used to describe these fractures include trochanteric, subtrochanteric, pertrochanteric, intertrochanteric, basal and lateral femoral fractures (Parker 2002). In general, there is a distinction made between trochanteric and subtrochanteric fractures. One definition of subtrochanteric fractures are "those fractures in which the fracture line traversing the femur is predominantly within the 5 cm length of femur immediately distal to the lesser trochanter" (Parker 2002).

Operative treatment was introduced in the 1950s using a variety of different implants. Implants may be either intramedullary or extramedullary in nature. Intramedullary implants are nails which are passed across the fracture within the intramedullary canal. These can either be inserted from distal to proximal (condylocephalic nails) or from proximal to distal (cephalocondylic nails). Extramedullary fixation refers to an implant with a lag screw or nail, which is passed up the femoral neck to the femoral head. The screw or nail is then attached to a plate on the side of the femur and the device secured.

Condylocephalic nails are inserted at the level of the femoral condyle above the knee and passed across the fracture and up into the femoral head. Two types of condylocephalic nails have been described. Ender nails (Ender 1970) are pre-bent flexible rods. Three to five of these of appropriate length are inserted into the femoral canal. The femoral canal is thus 'stacked' with nails, whilst their tips should radiate out to produce a secure fixation within the femoral head. The Harris nail (Harris 1980) is a larger nail used as a single nail. These nails are considered in this review.

Cephalocondylic nails are inserted through the greater trochanter of the femur and secured by a cross pin or screw, which is passed up the femoral neck into the femoral head. Examples include the Gamma nail, Intramedullary hip screw and Kuntscher-Y nail. Cochrane reviews have compared the Gamma nail and other cephalocondylic nails with the sliding hip screw (an extramedullary device) (Parker 2004a), and different intramedullary (cephalocondylic or condylocephalic) nails for the treatment of extracapsular proximal femoral fractures (Parker 2005).

Extramedullary implants may be either 'dynamic' or 'static'. The sliding hip screw (SHS) which is synonymous with the term compression hip screw and equivalent models such as the Dynamic, Richards or Ambi hip screws, is the most commonly used dynamic implant. These are considered 'dynamic' implants as they have the capacity for sliding at the plate/screw junction to allow for collapse at the fracture site. Similar implants which have a nail instead of a lag screw are the Pugh and Massie nails. The Jewett, Thornton and McLaughlin nail plates are also extramedullary fixation implants but have no capacity for sliding and hence are termed 'static' or 'fixed' implants. Comparisons between

the different types of extramedullary implants are considered in another Cochrane review (Parker 2004b).

## OBJECTIVES

The original aim of our review was to compare condylocephalic nailing with alternative fixation implants for the treatment of extracapsular proximal femoral fractures (Parker 2004c). Upon publication of a Cochrane review comparing different designs of intramedullary nails (Parker 2005), the scope of this review has been limited to the comparison of condylocephalic nailing with extramedullary fixation implants. The absence of randomised comparisons of intramedullary nailing involving condylocephalic nails means that this has not resulted in any substantive change to the review findings.

Our revised null hypothesis was:

There is no difference in outcome between condylocephalic nails and extramedullary fixation implants for the treatment of extracapsular proximal femoral fractures.

In our analyses, we subgrouped 'dynamic' and 'static' extramedullary fixation implants, which reflected the different characteristics of these two implant types (Parker 2004b).

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All randomised controlled trials which compared condylocephalic nails with alternative implants. Quasi-randomised trials (for example, allocation by alternation) and trials in which the treatment allocation was inadequately concealed were also included.

#### Types of participants

Skeletally mature patients with an extracapsular proximal femoral (hip) fracture.

#### Types of interventions

Surgical fixation of the fracture with condylocephalic nails (Ender or Harris nails) compared with 'static' (e.g. Jewett, Thornton and McLaughlin nail plates) or 'dynamic' (sliding hip screws, e.g. Dynamic, Richards or Ambi hip screws) extramedullary fixation implants.

#### Types of outcome measures

The following outcomes, which include both those clinically relevant to the patient, and some which are predominantly of technical importance to the surgeon, were sought:

##### (1) Operative details

- length of surgery (in minutes)
- operative blood loss (in millilitres)
- radiographic screening time (in seconds)

##### (2) Fracture fixation complications

- 'cut-out' of the implant proximally (penetration of the implant from the proximal femur either into the hip joint or external to the femur).
- 'backing out' of the implant (either at the site of insertion at the knee for condylocephalic nails or at the site of implant insertion for an extramedullary fixation implant).
- non-union of the fracture within the follow-up period (the definition of non-union was that used within each individual study).
- fracture of the femur (around or below the implant, including those at the site of nail insertion in the distal femur).
- reoperation (within the follow-up period of the study).
- superficial wound infection (infection of the wound in which there is no evidence that the infection extends to the site of the implant)
- deep wound infection (infection around the implant)

### (3) Post-operative complications

- pneumonia
- pressure sores
- deep vein thrombosis
- pulmonary embolism
- any medical complication (as detailed in each individual study, but excluding wound or fracture healing complications)
- length of hospital stay (in days)

### (4) Anatomical restoration

The data given in the brackets following the outcome measures are threshold values indicating potentially clinically important deformity.

- external rotation deformity (> 20 degrees)
- leg shortening (> 2 cm)
- varus angulation (> 10 degrees)

### (5) Final outcome measures

- early mortality (under 2 months)
- long term mortality (6 months and above)
- pain at the hip or knee (persistent pain of moderate to severe intensity at the final follow-up assessment)
- failure to return to living at home
- inability to regain mobility, use of walking aids

## Search methods for identification of studies

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (September 2004), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* Issue 3, 2004), MEDLINE (1966 to September week 1 2004), EMBASE (1988 to 2004 Week 26), the National Research Register Issue 2, 2004 (<http://www.update-software.com/National/nrr-frame.html>), our own reference databases and reference lists of articles. We undertook a general perusal of locally accessible conference proceedings: for example, British Orthopaedic Association Congress 2000, 2001, 2002 and 2003. We also scrutinised weekly downloads of "Fracture" articles in new issues of 17 journals (*Acta Orthop Scand*; *Am J Orthop*; *Arch Orthop Trauma Surg*; *Clin J Sport Med*; *Clin Orthop*; *Emerg Med Clin North Am*; *Foot*

*Ankle Int*; *Injury*; *J Accid Emerg Med*; *J Am Acad Orthop Surg*; *J Arthroplasty*; *J Bone Joint Surg Am*; *J Bone Joint Surg Br*; *J Foot Ankle Surg*; *J Orthop Trauma*; *J Trauma*; *Orthopedics*) from AMEDEO (<http://www.amedeo.com>). No language restriction was applied and translations were obtained when necessary.

The generic search for hip fracture was run for MEDLINE (2002 to September week 1 2004) (see [Appendix 1](#)). This was combined with all three stages of the optimal trial search strategy ([Alderson 2004](#)).

The general EMBASE search strategy for hip fracture trials is shown in [Appendix 2](#).

Prior to 1999, additional review specific searches in MEDLINE were carried out using the search terms:

(a) MEDLINE SilverPlatter (1983 to April 1997)

Ender\* near (rod\* or pin\* or nail\*)

(b) MEDLINE Ovid online (1966 to 1982)

Ender\$ adj12 (pin\$ or nail\$ or rod\$)

(c) Medline Ovid online (1980 to 1998)

Harris adj5 nail\$

## Data collection and analysis

All four authors of the first version of the review independently performed methodological quality assessment, without masking, and data extraction of the included trials. Any disagreement was resolved by discussion.

The main assessment of methodological quality was by the method of randomisation, which was also separately graded A, B or C according to the scheme within the Cochrane Handbook. In total, 10 aspects of methodology were rated giving a maximum score for each study of 12.

1. Trials with clear concealment of allocation (e.g. sequentially numbered sealed opaque envelopes) were coded as A and scored 3. Those which stated their method of randomisation, but gave insufficient details of safeguards to prevent disclosure of assignment (e.g. sealed envelopes) were coded B and scored 2. Those in which it is unclear were coded as C and scored 1. Those in which allocation concealment was clearly not obscured such as those using quasi-randomisation (e.g. even or odd date of birth) were coded as C and scored 0.

2. Were the inclusion and exclusion criteria clearly defined? Score 1 if text states type of fracture and which patients included and those excluded. Otherwise score 0.

3. Were the outcomes of patients who withdrew or were excluded after allocation described and included in an intention to treat analysis? Score 1 if yes or text states that no withdrawals occurred or data are presented clearly showing 'participant flow' that allows this to be inferred. Otherwise score 0.

4. Were the treatment and control groups adequately described at entry and if so were the groups well matched or appropriate co-variate adjustment made? Score 1 if at least four admission details given (e.g. age, sex, mobility, function score, mental test score, fracture type) with no significant difference between groups or appropriate adjustment made. Otherwise score 0.



5. Did the surgeons have prior experience of the operations they performed in the trial, prior to its commencement? Score 1 if text states there was an introductory period or that surgeons were experienced. Otherwise score 0.
6. Were the care programmes other than trial options identical? Score 1 if text states they were or if this can be inferred. Otherwise score 0.
7. Were the outcome measures clearly defined in the text with a definition of any ambiguous terms encountered? Score 1 if yes. Otherwise score 0.
8. Were the outcome assessors blind to assignment status? Score 1 if assessors of pain and function at follow up were blinded to treatment outcome. Otherwise score 0.
9. Was the timing of outcome measures appropriate? A minimum of six months follow up for all surviving patients. Score 1 if yes. Otherwise score 0.
10. Was loss to follow up reported and if so were less than 5% of patients lost to follow up? Score 1 if yes. Otherwise score 0.

There was no return to trialists for additional information, aside from clarification of study type sought from three studies (Hayward 1983; Merenyi 1995; Tonino 1982).

For each study, relative risks and 95% confidence intervals were calculated for dichotomous outcomes, and mean differences and 95% confidence intervals for continuous outcomes. Where appropriate, results of comparable groups of trials were pooled using both fixed-effect and random-effects models with 95% confidence intervals. Random-effects model results were only reported in instances of substantial heterogeneity where they differed importantly from the fixed-effect results.

Heterogeneity between comparable trials was tested using a standard chi squared test and, latterly, the I squared test (Higgins 2003). Some exploratory sensitivity analyses were performed to test potential bias. Fixed nail plates were grouped separately from sliding hip screws in order to explore and present possible differences of these two types of implant when compared with Ender nails. Any tests of interaction that were calculated to determine if the results for subgroups were significantly different are based on odds ratio results.

## RESULTS

### Description of studies

Thirty-one studies were identified, of which 11 randomised or quasi-randomised controlled trials were included and 20 were excluded for reasons described in the 'Characteristics of excluded studies' table.

Individual trial details of the 11 included studies, which involved a total of 1667 patients, are given in the 'Characteristics of included studies' table. Three studies (Dalen 1988; Hayward 1983; Hogh 1981) compared Ender nails with the McLaughlin nail plate (MNP), a fixed nail plate device. Seven studies compared Ender nails with a sliding hip screw (SHS). One study (Trafton 1984) compared the Harris nail with a sliding hip screw.

Of the 11 included studies, eight made no mention of including any other fractures than trochanteric fractures, whilst Hayward 1983 and Hogh 1981 included subtrochanteric fractures (8% and 24% of total respectively), and Chapman 1981 included both subtrochanteric and basal neck fractures (14% and 5% respectively). The proportion of male patients reported by eight studies ranged from 23% to 59%. The mean age of patients reported by 10 studies ranged from 68 to 81 years.

### Risk of bias in included studies

Nine of the included studies were full publications within the orthopaedic journals, one (Liem 1993) was published as a book chapter and one (Trafton 1984) was only available as a conference abstract. In no study was the allocation concealment clearly concealed, however it was likely in two studies which used closed or sealed envelopes (Nungu 1991; Sernbo 1988). Allocation concealment was also unclear in Hogh 1981 which used random numbers, and Juhn 1988, Liem 1993 and Trafton 1984 where the method of randomisation was not reported. The remaining studies were quasi randomised in which the treatment allocation was inadequately concealed using either even or odd dates of birth (Dalen 1988; Dalsgard 1987), even or odd medical record numbers (Chapman 1981) or day of hospital admission (Brostrom 1992; Hayward 1983).

The results of the methodological assessment for individual trials are given below. No study included a blinded assessment of outcome and only one (Sernbo 1988) reported prior experience of surgeons for both operations.

### Table: Assessment of methodology

	1	2	3	4	5	6	7	8	9	10	total
Ender nails	0	1	0	0	0	1	0	1	0	3	Brostrom 1992
	0	1	1	0	1	1	0	1	1	7	Chapman 1981
	0	1	0	0	1	0	0	1	4	Dalen 1988	
	0	1	0	0	0	0	0	1	3	Dalsgard 1987	
	0	0	0	0	0	0	0	1	2	Hayward 1983	
	1	1	1	0	1	1	0	1	8	Hogh 1981	
	1	0	0	1	0	0	0	1	3	Juhn 1988	
	1	0	1	1	0	1	0	1	6	Liem 1993	
	2	1	0	1	0	1	1	8	Nungu 1991		
	2	1	0	1	1	0	0	1	7	Sernbo 1988	
Harris nail	1	0	0	0	0	0	0	1	3	Trafton 1984	

### Effects of interventions

All 11 included studies except Hayward 1983 reported that patient characteristics at enrolment were similar for each of the two randomised groups.

The outcomes reported by each trial are listed in the 'Characteristics of included studies' table and presented graphically where sufficient data are available. In the graphs, the 10 studies of Ender nails are grouped separately from the Harris nail study (Trafton 1984). For Ender nails, the three studies (Dalen 1988; Hayward 1983; Hogh 1981) that compared Ender nails with the McLaughlin nail plate, a fixed nail plate device, are grouped



separately from the other seven studies that compared Ender nails with a sliding hip screw.

### (1) Operative details

In all Ender nail studies, the time to complete surgery or time in the operating room was less in the Ender nails group. Four studies reported a statistically significant reduction in the operative time for Ender nails (Brostrom 1992; Dalen 1988; Dalsgard 1987; Sernbo 1988 (unstable fractures)), whereas three (Chapman 1981; Hayward 1983; Juhn 1988) concluded that there was a difference without qualification and three (Hogh 1981; Liem 1993; Nungu 1991) reported that the reduction was not significant. Data for pooling were only available from two studies (Brostrom 1992; Sernbo 1988) (see Graph 01.01: weighted mean difference (WMD) -22.77 minutes, 95% CI -27.71 to -17.84 minutes). Trafton 1984 reported that "procedure time" was 48 minutes less for the Harris nail group than in the sliding hip screw group.

All the Ender nail studies except one (Hogh 1981) reported operative blood loss but only two studies (Brostrom 1992; Sernbo 1988) provided data that could be pooled. Six studies (Brostrom 1992; Chapman 1981; Dalen 1988; Dalsgard 1987; Hayward 1983; Sernbo 1988 (unstable fractures)) indicated that blood loss during the operation was significantly reduced for the Ender nails group. Juhn 1988 however noted that both groups received the same amount of blood during the entire hospital stay. Two studies (Liem 1993; Nungu 1991) concluded that the observed reduction in blood loss for the Ender nails group was not statistically significant. Pooled data from two studies (Brostrom 1992; Sernbo 1988) support a significantly lower operative blood loss in participants treated by Ender nails (see Graph 01.02: WMD -207.88 ml, 95% CI -261.99 to -154.08 ml). Trafton 1984 reported that there was no significant difference in the blood replacement requirements for the Harris nail and SHS groups.

Only one study (Sernbo 1988) reported on radiographic screening time and found a significant increase for Ender nails (see Graph 01.03: WMD 65.00 seconds, 95% CI 20.10 to 109.90 seconds).

### (2) Fracture fixation complications

The complications of 'cut-out', and 'backing out' were quite common and frequently resulted in a reoperation. The incidence of cut-out of Ender nails was significantly increased in comparison with the sliding hip screw (see Graph 01.04: 6.1% versus 1.7%; relative risk (RR) 3.52, 95% confidence interval (CI) 1.77 to 7.01) but not with the McLaughlin fixed nail plate (11.1% versus 12.3%; RR 0.90, 95% CI 0.37 to 2.21). In the latter group, the description of the outcome data given in Dalen 1988 was ambiguous but did not appear to contradict the results in Hogh 1981. The significant difference of treatment effect between fixed nail plates and the sliding hip screw is not surprising, due to the different mechanical properties of the two implants (test of interaction  $Z = 2.23$ ;  $P = 0.026$ , calculation based on Peto odds ratios from Graph 01.05). The sliding hip screw allows for collapse at the fracture site and therefore should reduce the risk of cut-out.

Backing out of the implant, usually from the insertion point above the knee, is only relevant to condylocephalic nails and frequently resulted in pain at the knee necessitating removal of the nails or re-fixation (see Graph 01.06). The overall incidence of backing out for Ender nails was 30% and ranged from 15% (Juhn 1988) to 57% (Sernbo 1988).

Fracture non-union was clearly reported in six Ender nail studies (Brostrom 1992; Chapman 1981; Hayward 1983; Hogh 1981; Nungu 1991; Sernbo 1988) and was uncommon with no significant difference between treatment methods (see Graph 01.07: 1.1% versus 1.5%; RR 0.81, 95% CI 0.27 to 2.37). A similarly non-statistically significant finding (see Graph 02.01: 8.1% versus 0.0%; RR 7.55, 95% CI 0.40 to 141.46) was also found in Trafton 1984.

There was a higher incidence of later fracture of the femur after condylocephalic nailing (see Graph 01.08: 2.4% versus 0.4%, RR 3.24, 95% CI 1.18 to 8.90). The site of the fracture was in the supracondylar region of the femur in four studies (Chapman 1981; Hayward 1983; Juhn 1988; Sernbo 1988) and was undefined in the four other studies with data, these being described as re-fracture in two studies (Liem 1993; Nungu 1991), fall related re-fracture in Dalsgard 1987 and fracture of femur within the context of technical problems in Hogh 1981. There were an additional five fractures involving the medial cortex of the distal femur at the site of Ender nail insertion in Juhn 1988.

The excess of complications of the Ender nails group resulted in a significant increase in the reoperation rate, compared with extramedullary fixation (see Graph 01.09: 20.9% versus 5.5%; RR 3.72, 95% CI 2.54 to 5.44). We selected this important and well represented outcome to explore the potential effect of allocation concealment and overall methodological quality score (analyses shown in Graphs 01.10 and 01.11). Although the score thresholds are arbitrary, these analyses and the general homogeneity in the results of other important outcomes confirmed our impression that further sensitivity analysis would not aid interpretation of results. The significant excess of fixation fractures (see Graph 02.02: 28.6% versus 0%; RR 25.00, 95% CI 1.53 to 409.03) in the Harris nail group in Trafton 1984 was the reason stated for trial closure. This was reflected in an increase in the reoperation rate in the Harris nail group. The difference, however, between the two groups was not statistically significant (see Graph 02.03: 16.7% versus 4.8%; RR 3.50, 95% CI 0.77 to 15.88).

The criteria used for superficial and deep wound infections were generally not defined. The infections reported in Brostrom 1992 and Hayward 1983, were placed in the superficial category for this review since they appeared to be without serious consequence. Many of the deep infections resulted in reoperation (Nungu 1991). Three studies (Dalen 1988; Juhn 1988; Liem 1993) gave prophylactic antibiotics to both groups whereas one (Sernbo 1988) seems to have given this only to the sliding hip screw group. This latter approach, although not useful for comparative purposes, reflects the commonly held view that Ender nails would have a lower infection rate. The graphs confirm that there was no significant difference between implants for superficial sepsis (see Graph 01.12: 2.9% versus 4.1%; RR 0.74, 95% CI 0.39 to 1.39) but a significantly reduced risk of deep wound infection (see Graph 01.13: 0.9% versus 4.2%; RR 0.26, 95% CI 0.11 to 0.62) for Ender nails. Trafton 1984 reported no significant difference in infection rate between the two treatment groups.

### (3) Post-operative complications

Four studies reported on pneumonia and pressure sores. Three of these (Brostrom 1992; Hogh 1981; Liem 1993) provided data split by treatment whilst the other (Chapman 1981) reported seven cases of pneumonia and three of pressure sores. Pooled results showed no statistically significant differences in either pneumonia (see Graph

01.14: 8.0% versus 5.5%; RR 1.53, 95% CI 0.74 to 3.18) or pressure sores (see Graph 01.15: 3.2% versus 6.5%; RR 0.46, 95% CI 0.18 to 1.18).

It was clearly stated that anticoagulant prophylaxis was not given in two studies (Dalsgard 1987; Juhn 1988) and was given (either dextran or heparin) in one (Nungu 1991). Four studies (Brostrom 1992; Chapman 1981; Dalsgard 1987; Hogh 1981) gave separate data for deep vein thrombosis (DVT) and pulmonary embolism (PE). The only thrombosis reported in Liem 1993 was unspecified and for this review was included in the DVT analysis. It was not clear in Chapman 1981 to which group the sole DVT belonged. Hayward 1983 reported an incidence of thromboembolism of "approximately 10%" in both groups. Pooling of results found no statistically significant differences in the incidence of DVT (see Graph 01.16: 4.1% versus 3.9%; RR 1.18, 95% CI 0.51 to 2.72) or pulmonary embolism (see Graph 01.17: 2.7% versus 1.2%; RR 1.84, 95% CI 0.54 to 6.31) following fixation by Ender nails versus extramedullary devices.

There were data available for a summation of reported medical complications except those relating to the wound or fracture union in five studies (Brostrom 1992; Chapman 1981; Dalsgard 1987; Hogh 1981; Liem 1993): see Graph 01.18 (23.8% versus 25.6%; RR 0.90, 95% CI 0.68 to 1.19). The complications presented varied between studies and were generally incompletely reported: the substantial heterogeneity ( $I^2 = 59.8\%$ ) of the pooled results may reflect this. Trafton 1984 reported an increase in frequency and severity in both local and medical complications in the Harris nail group.

All eight Ender nail studies reporting length of hospital stay (Brostrom 1992; Chapman 1981; Dalen 1988; Hayward 1983; Hogh 1981; Juhn 1988; Liem 1993; Sernbo 1988) described no or little difference between the groups. Trafton 1984 reported that the Harris nail group patients were hospitalised for longer than those in the SHS group. Although means and standard deviations were provided for three studies (Brostrom 1992; Sernbo 1988; Trafton 1984), doubts over the numbers involved and awareness that distributions of lengths of stay can be very skewed, precluded pooling.

#### (4) Anatomical restoration

Results pooled from five studies reporting external rotation deformities of over 20 degrees (Hogh 1981; Juhn 1988; Nungu 1991), or over 10 degrees (Brostrom 1992), or with "exorotation" (Liem 1993) showed a significant increase after Ender nails (see Graph 01.19: 24.9% versus 7.0%; RR 3.73, 95% CI 2.47 to 5.64). The results presented as mean external malrotation values from Sernbo 1988 support this. Hayward 1983 only presented results for 'varus deformity' which was less frequent after Ender nailing (6.9% versus 19.7%). Trafton 1984 noted that 42% of patients treated with the Harris nail had obvious external rotation deformities, but did not provide comparative data.

Graph 01.20 shows a significant tendency for shortening of the affected leg after Ender nails when compared with sliding hip screws (11.0% versus 4.3%; RR 2.71, 95% CI 1.60 to 4.59). Four studies (Brostrom 1992; Dalsgard 1987; Nungu 1991; Sernbo 1988) gave data for shortening of over two centimetres whilst two gave no threshold value (Juhn 1988; Liem 1993). Dalen 1988 reported that there was no significant difference between the two groups.

#### (5) Final outcome measures

Data on mortality were available from all studies. For the Ender nail trials, mortality data are presented in two separate analyses which show short (under two months) and long term (six months and over) mortality. There were no statistically significant differences for the Ender nail trials between the treatment groups in short term mortality (see Graph 01.21: 8.8% versus 7.2%; RR 1.12, 95% CI 0.73 to 1.71) or long term mortality (see Graph 01.22: 23.5% versus 23.3%; RR 1.02, 95% CI 0.82 to 1.27). Likewise, there was no statistically significant difference in mortality in the Harris nail trial (see Graph 02.04: 11.9% versus 4.8%; RR 2.50, 95% CI 0.51 to 12.17).

All but two papers (Hayward 1983; Juhn 1988) made some reference to pain, but data for this outcome were characterised by the use of non-validated scales, poor description of outcome measurement, and varying length of follow up. The use of condylocephalic nails prompted an additional focus on knee pain in most studies. Pain was reported in a variety of ways, according to both site, activity and times. Dalsgard 1987 referred to knee pain as a reason for reoperation in the Ender nail group; Hogh 1981 recorded severe, moderate (and slight) hip pain at one year and reported that 15 Ender nail patients had knee pain after six months (no data for SHS); Sernbo 1988 recorded pain in the hip at rest at six months and pain on palpation of hip and knee or both at six months; Liem 1993 only noted knee pain as a complication in the Ender nail group; Chapman 1981 incorporated hip pain data within a functional score (no separate data available) and presented data on knee pain/stiffness at six months; Dalen 1988 reported no significant ( $P > 0.05$ ) difference in hip pain assessed between three and six months but that one third of Ender group participants had knee pain; Brostrom 1992 presented pain data (moderate and severe) at six weeks and also at six months for participants of their gait-analysis/walking study; Nungu 1991 gave separate data on knee and hip pain on weight bearing at one year. Trafton 1984 reported that hip pain was similar in both treatment groups; however knee pain was reported in 34% of patients treated with the Harris nail.

The overall pain analysis for Ender nail studies is an attempt at portraying long term persistent pain and thus omits data from both Dalsgard 1987 and Liem 1993. Knee and hip pain data could be summed from Nungu 1991 but only hip pain data were available from Hogh 1981 and knee pain data from Chapman 1981. This may explain the substantial heterogeneity ( $I^2 = 83.4\%$ ) in these results (see Graph 01.23: 34.6% versus 17.2%; RR 2.10, 95% CI 1.54 to 2.85). This result was not significant when using the random-effects model (RR 1.88, 95% CI 0.83 to 4.28). A second graph (Graph 01.24: 9.6% versus 13.6%; RR 0.69, 95% CI 0.41 to 1.18) that just presents hip pain data is inconclusive but shows a non-significant decrease in hip pain in the Ender nails group for two trials. Overall, despite the incompleteness of the data, there is a clear indication of a significant increase in long term pain in the condylocephalic nails group, which is a consequence of the excess of pain at the knee.

Where reported, the outcome measures of walking ability, return of activities of daily living and residential status were presented in a variety of ways which often related to pre-fracture status, and only for a select subgroup of patients. The available data for long term (six months and above) return to pre-fracture residence presented in Graph 01.25 consist of non-return to own home (now in nursing home) of previous home-living survivors at one year for Hogh 1981, failure to return to original residence of survivors at six months (Sernbo 1988) and a deterioration in dependence (implied by a move from home to institution) of survivors at one year

(Nungu 1991). The lack of significant difference in non-return to pre-fracture residence shown in Graph 01.25 (20.1% versus 18.6%; RR 1.05, 95% CI 0.70 to 1.57) is supported without data in Dalen 1988 and for the overall group with reference to social status in Hogh 1981. Destination on discharge from hospital was reported by Chapman 1981 and Brostrom 1992.

Mobility outcomes were also inconsistently reported, as immediate weight bearing in hospital (Liem 1993), days to mobilisation (Hayward 1983), post-operative walking with full weight bearing (Juhn 1988) and longer term outcomes such as use of walking aids after hospital discharge. Of all the studies, Brostrom 1992 gave the greatest emphasis on walking ability and included a gait analysis study between three and six months. It was possible to identify and pool data on deterioration in walking function from three Ender nail studies (Dalsgard 1987; Nungu 1991; Sernbo 1988); the analysis based on the fixed-effect model shows better ambulatory function in the sliding hip screw group (see Graph 01.26: 57.1% versus 44.4%; RR 1.27, 95% CI 1.05 to 1.54). However, these trial results were substantially heterogeneous ( $I^2 = 72.2\%$ ) and the finding was not significant using the random-effects model (RR 1.41, 95% CI 0.89 to 2.23). The finding was contradicted by Brostrom 1992 where 14% of Ender nail patients and 33% of SHS patients had not recovered their ambulatory function between three to six months (uncertainty over denominators precluded pooling of this data). Both Dalen 1988 and Hogh 1981 noted that there was no difference in walking capacity between the fixed nail plate and Ender nails group but did not present data. More, but not statistically significantly, people failed to recover their former mobility in the Harris nail group of Trafton 1984 (see Graph 02.05: 48.6% versus 30.0%; RR 1.62, 95% CI 0.91 to 2.89).

## DISCUSSION

Previous case series reports of condylocephalic, mainly Ender, nails indicate that they suffer from complications of cut-out of the implant, fracture around the nail insertion site, backing out of the nail and a high reoperation rate. The results from these randomised trials confirm that condylocephalic nails have a markedly increased incidence of fracture fixation complications in comparison with extramedullary fixation. This is reflected by the four fold increase in the reoperation rate for Ender nails.

Though all trials are methodologically flawed, their results are consistent. Indeed the general homogeneity in the results of important outcomes with data available from several studies, as well as the lack of data from other studies limited the potential usefulness of sensitivity analysis. An exploratory analysis of the effects of allocation concealment and overall trial quality for reoperation confirmed our impression that further sensitivity analysis would not aid interpretation of results. Thus though the trials are flawed, we suspect that their results are valid in the direction of effect.

Longer term functional outcomes were reported in various ways that precluded overall quantitative analysis. However the increased risk of shortening and external rotation deformity for the condylocephalic nails patient group is consistent with the potentially poorer return to previous ambulatory function in this

group when compared with the sliding hip screw. The excess of residual pain sited at the knee in condylocephalic nails group may also impair patient mobility. Mortality appeared the same for both treatment types and it was not possible to demonstrate any significant difference in dependency as shown by return to previous residence. Condylocephalic nails do however have the advantage of being less traumatic to insert. This is associated with a reduced deep wound sepsis, length of surgery and operative blood loss. Total blood loss however may not be any different between condylocephalic nails and extramedullary fixation, as most of the blood loss from an extracapsular fracture is into the tissues rather than that lost at surgery. Both studies addressing total blood loss (Juhn 1988; Trafton 1984) found no difference in transfusion requirements.

Ender nails continue to be used in a number of countries, perhaps because the cost of the implant is lower than that of a SHS. There has been no cost benefit analysis performed for the two implants. Nevertheless the marginal financial saving on the cost of Ender nails will be insignificant in relation to the costs incurred by the increased fracture healing complications and reoperations involved for Ender nails. A lower implant cost should therefore not be used to justify the continued use of Ender nails.

## AUTHORS' CONCLUSIONS

### Implications for practice

Ender nails are the only type of condylocephalic nail that have been adequately compared with extramedullary devices by randomised trials. Any advantages for Ender nails in operative outcomes of deep wound sepsis, operative time and blood loss are outweighed by the increased risk of fracture-healing complications, reoperation, residual pain and deformity when compared with extramedullary implants, primarily a sliding hip screw. Thus the use of Ender nails for trochanteric fracture is no longer appropriate.

### Implications for research

Modifications to Ender nails to increase the stability of the fixation at the site of insertion have been developed. It is unlikely that these advances will negate the other major complications associated with Ender nails.

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\* Indicates the major publication for the study

**CHARACTERISTICS OF STUDIES**
**Characteristics of included studies** [ordered by study ID]

**Brostrom 1992**

Methods	Randomised by day of hospital admission. Methodological quality score: 3
Participants	Orthopaedic hospital, Stockholm, Sweden 149 people with trochanteric fracture. Age: mean 77 years Male: 31% Unstable fractures: 57% (69/120) Number lost to follow up: not clearly stated, varies (> 13%)
Interventions	Ender nails versus sliding screw plate
Outcomes	Length of follow up: 6 months

**Condylcephalic nails versus extramedullary implants for extracapsular hip fractures (Review)**

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**Brostrom 1992** (Continued)

Cut-out of implant  
 Backing out of the nail  
 Non-union  
 Reoperation  
 Wound infection (assumed superficial)  
 Length of surgery  
 Operative blood loss  
 Deep vein thrombosis  
 Pulmonary embolism  
 Pneumonia  
 Pressure sores  
 Medical complications - all  
 Length of hospital stay  
 Mortality (6 weeks, 6 months)  
 Pain at follow-up  
 Residential status  
 Ambulatory function  
 Leg shortening (> 2 cm)  
 External rotation deformity (> 10 degrees)

Notes Multiple publications of same study with different numbers randomised and analysed.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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Allocation concealment?	High risk	C - Inadequate
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**Chapman 1981**

Methods Randomised by even or odd medical record number.  
 Methodological quality score: 7

Participants Orthopaedic hospital, San Francisco, USA  
 100 people with intertrochanteric or subtrochanteric fracture  
 Age: mean 68 years (range 21-97)  
 Male: 59%  
 Unstable fractures: 63%  
 Number lost to follow up: 4 (4%)

Interventions Ender nails versus compression hip screw

Outcomes Length of follow up: 6 months minimum (range 6-25 months)

Cut-out of implant  
 Backing out of the nail  
 Non-union  
 Later fracture of the femur  
 Reoperation  
 Deep wound infection  
 Wound complications  
 Length of surgery  
 Operative blood loss  
 Deep vein thrombosis  
 Pulmonary embolism  
 Medical complications - all  
 Length of hospital stay



**Chapman 1981** (Continued)

Mortality (6 weeks, 6 months)  
Pain at follow-up  
Functional results - scale included ambulatory function

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

**Dalen 1988**

Methods	Quasi randomised by even or odd date of birth. Methodological quality score: 4
Participants	Orthopaedic hospital, Skovde, Sweden 143 people with pertrochanteric fracture Age: 79 mean Male: 38% Unstable fractures: 64% (83/120) Number lost to follow up: 13 (excluded) (9%)
Interventions	Ender nails versus McLaughlin nail plate
Outcomes	Length of follow up: 3-6 months (6 years)  Cut-out of implant (?) Backing out of the nail Reoperation Deep wound infection Length of surgery Operative blood loss Length of hospital stay Mortality (2 weeks, 6 years) Pain at follow-up Residential status Ambulatory function

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

**Dalsgard 1987**

Methods	Quasi randomised by even or odd dates of birth. Methodological quality score: 3
Participants	Orthopaedic hospital, Aalborg, Denmark

**Condylocephalic nails versus extramedullary implants for extracapsular hip fractures (Review)**

**Dalsgard 1987** (Continued)

101 people with trochanteric fracture  
Mean age 79 years (range 47-90).  
Male: 25%  
Unstable fractures: 62%  
Number lost to follow up: 3%

Interventions	Ender nails versus sliding hip screw
Outcomes	Length of follow up: 6 months minimum  Later fracture of the femur Cut-out of the implant Reoperation Backing out of the nail Superficial wound infection Deep wound infection Pneumonia Deep vein thrombosis Pulmonary embolism Any medical complications Deterioration in walking Shortening Mortality

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

**Hayward 1983**

Methods	Quasi randomised by day of admission and the policy of the on-call firm for that day. Methodological quality score: 2
Participants	Orthopaedic hospital Harrow, UK 182 people with trochanteric or subtrochanteric (15) fracture Age mean 77 (range not given). Male: % not given Unstable fractures: 38% Number lost to follow up: not given
Interventions	Ender nails versus McLaughlin nail plate
Outcomes	Length of follow up: 6 months minimum  Length of surgery Operative blood loss Non-union Fracture of the femur Distal nail migration Wound infection Length of hospital stay Varus deformity Mortality

**Condylocephalic nails versus extramedullary implants for extracapsular hip fractures (Review)**

**Hayward 1983** (Continued)

Notes Trialist gave details of randomisation method used. Included pathological fractures. Separated out 15 subtrochanteric fractures from main analysis. Concluded that comparison was compromised by use of outdated nail plate system.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

**Hogh 1981**

Methods	Randomised by random numbers. Methodological quality score: 8
Participants	Orthopaedic hospital, Aarhus, Denmark 145 people with trochanteric or subtrochanteric (24) fracture Age: mean 76 years (range 19-88) Male: 23% Unstable fractures: 43% (52/121) Number lost to follow up (at 1 year): 4 (3%)
Interventions	Ender nails versus McLaughlin nail plate
Outcomes	Length of follow up: 12 months  Cut-out of implant Backing out of the nail Non-union Later fracture of the femur Reoperation Deep wound infection Superficial wound infection Length of surgery Deep vein thrombosis Pulmonary embolism Pneumonia Pressure sores Medical complications - all Length of hospital stay Mortality (1, 6, 12 months) Pain at follow-up Residential status Ambulatory function Leg shortening External rotation deformity (> 20 degrees)
Notes	Figures taken from the main report Hogh et al 1981 and follow-up report Lund et al 1981. Small discrepancies noted in: 1. Abstract, Hogh et al 1980: 146 participants; 6 deaths at 1 month in Ender nail group. 2. Subsequent comparison including data from trial, Hogh et al 1982: postoperative complications of cardiac complications, haematoma, and superficial infections.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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**Condylocephalic nails versus extramedullary implants for extracapsular hip fractures (Review)**

**Hogh 1981** (Continued)

Allocation concealment?	Unclear risk	B - Unclear
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**Juhn 1988**

Methods	Randomised: method not stated. Methodological quality score: 3
Participants	Orthopaedic hospital, Haifa, Israel 201 people with pertrochanteric fracture Age: mean 76 years (range 23-104) Male: 35% Unstable fractures: 48% Number lost to follow up: not stated
Interventions	Ender nails versus compression hip screw (Richards)
Outcomes	Length of follow up: 7 months average  Cut-out of implant Backing out of the nail Later fracture of the femur Deep wound infection Superficial wound infection Length of surgery Operative blood loss Length of hospital stay Mortality (1 month) Pain at follow-up Ambulatory function (weight bearing post-op.) Leg shortening External rotation deformity (> 20 degrees)

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

**Liem 1993**

Methods	Randomised: method not stated. Methodological quality score: 6
Participants	Orthopaedic Hospital, Rotterdam, The Netherlands 136 people with pertrochanteric fracture Age: range of mean ages: 81 - 82 years Male: 23% Unstable fractures: 45% Number lost to follow up: not stated
Interventions	Ender nails versus dynamic hip screw

**Condylocephalic nails versus extramedullary implants for extracapsular hip fractures (Review)**

**Liem 1993** (Continued)

Outcomes	Length of follow up: 6 months  Cut-out of implant Backing out of the nail Later fracture of the femur Reoperation Superficial wound infection Length of surgery Operative blood loss Deep vein thrombosis (assumed) Pneumonia Pressure sores Medical complications - all Length of hospital stay Mortality (14 days, 6 months) Ambulatory function (weight-bear in hospital) Leg shortening External rotation deformity ('exorotation')
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Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

**Nungu 1991**

Methods	Randomised by sealed envelopes. Methodological quality score: 8
Participants	Orthopaedic hospital, Uppsala, Sweden 220 people with an intertrochanteric fracture Age: mean 81 years Male: 26% Unstable fractures: 50% Number lost to follow up: 5 (2%)
Interventions	Ender nail versus sliding hip screw
Outcomes	Length of follow up: 12 months  Cut-out of implant Backing out of the nail Non-union Later fracture of the femur Reoperation Deep wound infection Length of surgery Operative blood loss Mortality (1 year) Pain at follow-up Residential status Ambulatory function Leg shortening (> 2 cm) External rotation deformity (> 20 degrees)

**Nungu 1991** (Continued)

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

**Sernbo 1988**

Methods	Randomised using sealed envelopes. Methodological quality score: 7
Participants	Orthopaedic hospital, Malmo, Sweden 206 people with an unstable intertrochanteric fracture Age: range of mean ages: 70-83 years Male: 23% Unstable fractures: 100% Number lost to follow up: none
Interventions	Ender nail versus compression hip screw (Richards)
Outcomes	Length of follow up: 12 months  Cut-out of implant Backing out of the nail Non-union Later fracture of the femur Reoperation Deep wound infection Superficial wound infection Length of surgery Operative blood loss Radiographic screening time Length of hospital stay Mortality (12 months) Pain at follow-up Residential status Ambulatory function Leg shortening (>2.5 cm) External rotation deformity (malrotation)

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

**Trafton 1984**

Methods	Randomised: method not stated.
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**Trafton 1984** (Continued)

Methodological quality score: 3

Participants	Orthopaedic hospital San Francisco, USA 84 people with intertrochanteric femoral fractures Mean age, proportion male and unstable fractures - not stated Loss to follow up: not given
Interventions	Harris nail versus sliding hip screw
Outcomes	Length of follow up: 6 months  Non-union Fixation failure Reoperation Mortality Failure to regain mobility Length of hospital stay

Notes

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Cut-out: refers to when a screw or nail cuts out of the bone (e.g. femoral head) into which it was originally placed

Backing out: refers to when a screw or nail backs out or away from its original position

**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
<a href="#">Amici 1980</a>	Not randomised. Retrospective comparison. Ender nail series and comparative study with McLaughlin nail plate.
<a href="#">Andersson 1984</a>	Not randomised. Multicentre comparison. Fixation according to standard practice in individual hospitals.
<a href="#">Aparisi 1990</a>	This study is only described in a conference abstract, which reported a randomised trial comparing Ender nails with an AO plate osteosynthesis for 412 patients. No quantitative data were presented; although the incidence of complications and re-operations was stated to be higher in the Ender group. The study was excluded because of inadequate reporting of results.
<a href="#">Claes 1985</a>	Not randomised. Retrospective comparison: non-concurrent groups.
<a href="#">Cobelli 1985</a>	Not randomised. This was a matched pair case series for 87 patients with extracapsular hip fractures treated with either Ender nails or a sliding hip screw. (Results showed more technical problems in the Ender nail group.)
<a href="#">Demartin 1984</a>	Not randomised. Comparative study. Sliding hip screw were preferred for those under 70 years, and Ender nails for those over 80 years. In Italian.
<a href="#">Geissler 1992</a>	Not randomised. Retrospective comparison: Ender nail used for older and frailer patients, DHS the converse. In German.



Study	Reason for exclusion
<a href="#">Gratz 1978</a>	Not randomised. May be retrospective. Older patients preferentially treated with Ender or Kuntscher nails; younger with AO angle plates. In German.
<a href="#">Hontzsch 1990</a>	Not randomised. Retrospective comparison. In German with English abstract.
<a href="#">Indemini 1982</a>	Not randomised. Retrospective comparison.
<a href="#">Jensen 1980</a>	Not randomised. Not trial. Comparative study of several implants.
<a href="#">Jones 1977</a>	Not randomised. Non-concurrent comparison.
<a href="#">Lanfranchi 1982</a>	Not randomised. No mention of study design. Comparison of Ender nails and AO nail plates. Italian paper with English abstract.
<a href="#">Ludtke-Handjery 1991</a>	This study compared the results of 82 extracapsular fractures treated with Ender nails, with 85 treated with the dynamic hip screw (DHS). These results were compiled from the results of three periods: in the first period, only Ender nails were used; in the second period Ender nails and DHS were used in a random study; in the final period, only DHS was used. Separate results for the randomised study were not available.
<a href="#">Merenyi 1995</a>	This conference abstract suggested a randomised trial comparing 40 Ender nails with 40 angle plates, 40 Gamma nails, 40 intramedullary hip screws and 40 long intramedullary hip screws. Correspondence with the authors suggested that there was no randomisation of patients only a 'random' selection of comparison patients which had been previously treated with one of the different implants.
<a href="#">Muller 1994</a>	Not randomised. Prospective comparison with Ender nails given to older more fragile patients. In German.
<a href="#">Schottle 1975</a>	Not randomised. Some indication that AO plate given to younger patients and Ender nails to older patients. In German.
<a href="#">Sherk 1985</a>	Not randomised. A comparative series of 35 patients treated with a single condylocephalic rod compared with 35 patients subsequently treated with a sliding hip screw. Not concurrent.
<a href="#">Tonino 1982</a>	This study which compared the results of 100 trochanteric fractures treated with Ender nails, with 100 treated with the McLaughlin nail plate, was reported only as a conference abstract. On inquiry about methodology, the author revealed that it was not a randomised or quasi-randomised trial.
<a href="#">Zukor 1985</a>	Not randomised. Retrospective comparison. Non-concurrent groups.

## DATA AND ANALYSES

### Comparison 1. Ender nails versus extramedullary fixation implants

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<a href="#">1 Length of surgery (minutes)</a>	2	326	Mean Difference (IV, Fixed, 95% CI)	-22.77 [-27.71, -17.84]

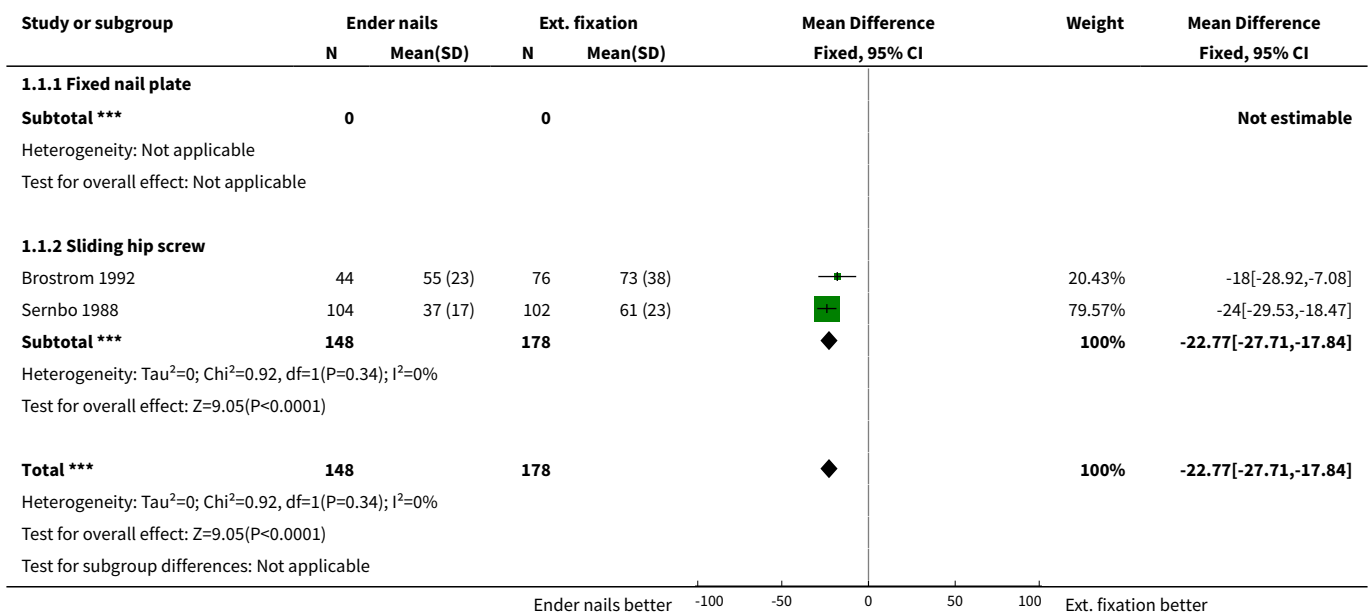
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Fixed nail plate	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Sliding hip screw	2	326	Mean Difference (IV, Fixed, 95% CI)	-22.77 [-27.71, -17.84]
<b>2 Operative blood loss (ml)</b>	2	326	Mean Difference (IV, Fixed, 95% CI)	-207.88 [-261.69, -154.08]
2.1 Fixed nail plate	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Sliding hip screw	2	326	Mean Difference (IV, Fixed, 95% CI)	-207.88 [-261.69, -154.08]
<b>3 Radiographic screening time (seconds)</b>	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Fixed nail plate	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Sliding hip screw	1	206	Mean Difference (IV, Fixed, 95% CI)	65.0 [20.10, 109.90]
<b>4 Cut-out of implant</b>	8	1258	Risk Ratio (M-H, Fixed, 95% CI)	2.28 [1.35, 3.85]
4.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.37, 2.21]
4.2 Sliding hip screw	7	1113	Risk Ratio (M-H, Fixed, 95% CI)	3.52 [1.77, 7.01]
<b>5 Cut-out of implant (odds ratio results)</b>	8	1258	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.38 [1.41, 4.03]
5.1 Fixed nail plate	1	145	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.89 [0.32, 2.44]
5.2 Sliding hip screw	7	1113	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.44 [1.86, 6.35]
<b>6 Backing out of the nail</b>	10	1495	Risk Ratio (M-H, Fixed, 95% CI)	45.21 [18.64, 109.65]
6.1 Fixed nail plate	3	418	Risk Ratio (M-H, Fixed, 95% CI)	41.06 [8.28, 203.62]
6.2 Sliding hip screw	7	1077	Risk Ratio (M-H, Fixed, 95% CI)	47.10 [16.25, 136.54]
<b>7 Non-union</b>	6	906	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.27, 2.37]
7.1 Fixed nail plate	2	288	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.26, 3.79]
7.2 Sliding hip screw	4	618	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.09, 3.63]
<b>8 Fracture of the femur</b>	7	1109	Risk Ratio (M-H, Fixed, 95% CI)	3.24 [1.18, 8.90]
8.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	15.21 [0.88, 261.40]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.2 Sliding hip screw	6	964	Risk Ratio (M-H, Fixed, 95% CI)	1.90 [0.60, 6.02]
<b>9 Reoperation</b>	8	1130	Risk Ratio (M-H, Fixed, 95% CI)	3.72 [2.54, 5.44]
9.1 Fixed nail plate	2	275	Risk Ratio (M-H, Fixed, 95% CI)	3.37 [1.63, 6.94]
9.2 Sliding hip screw	6	855	Risk Ratio (M-H, Fixed, 95% CI)	3.86 [2.47, 6.03]
<b>10 Reoperation: by allocation concealment (quality score)</b>	8	1130	Risk Ratio (M-H, Fixed, 95% CI)	3.72 [2.54, 5.44]
10.1 Fixed nail plate: quasi randomised (0)	1	130	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [1.24, 6.59]
10.2 Fixed nail plate: concealment unclear (1 or 2)	1	145	Risk Ratio (M-H, Fixed, 95% CI)	5.07 [1.15, 22.33]
10.3 Sliding hip screw: quasi randomised (0)	3	293	Risk Ratio (M-H, Fixed, 95% CI)	2.54 [1.18, 5.47]
10.4 Sliding hip screw: concealment unclear (1 or 2)	3	562	Risk Ratio (M-H, Fixed, 95% CI)	4.62 [2.65, 8.03]
<b>11 Reoperation: by overall trial quality (total score)</b>	8	1130	Risk Ratio (M-H, Fixed, 95% CI)	3.72 [2.54, 5.44]
11.1 Fixed nail plate: rated low (6 or less)	1	130	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [1.24, 6.59]
11.2 Fixed nail plate: rated high (7 or more)	1	145	Risk Ratio (M-H, Fixed, 95% CI)	5.07 [1.15, 22.33]
11.3 Sliding hip screw: rated low (6 or less)	3	329	Risk Ratio (M-H, Fixed, 95% CI)	5.01 [2.00, 12.54]
11.4 Sliding hip screw: rated high (7 or more)	3	526	Risk Ratio (M-H, Fixed, 95% CI)	3.51 [2.10, 5.85]
<b>12 Superficial wound infection</b>	7	1052	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.39, 1.39]
12.1 Fixed nail plate	2	288	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.10, 1.36]
12.2 Sliding hip screw	5	764	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.45, 1.99]
<b>13 Deep wound infection</b>	7	1103	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.11, 0.62]
13.1 Fixed nail plate	2	275	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.03, 1.20]
13.2 Sliding hip screw	5	828	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.11, 0.76]
<b>14 Pneumonia</b>	3	382	Risk Ratio (M-H, Fixed, 95% CI)	1.53 [0.74, 3.18]
14.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	1.35 [0.61, 3.01]
14.2 Sliding hip screw	2	237	Risk Ratio (M-H, Fixed, 95% CI)	2.50 [0.41, 15.33]

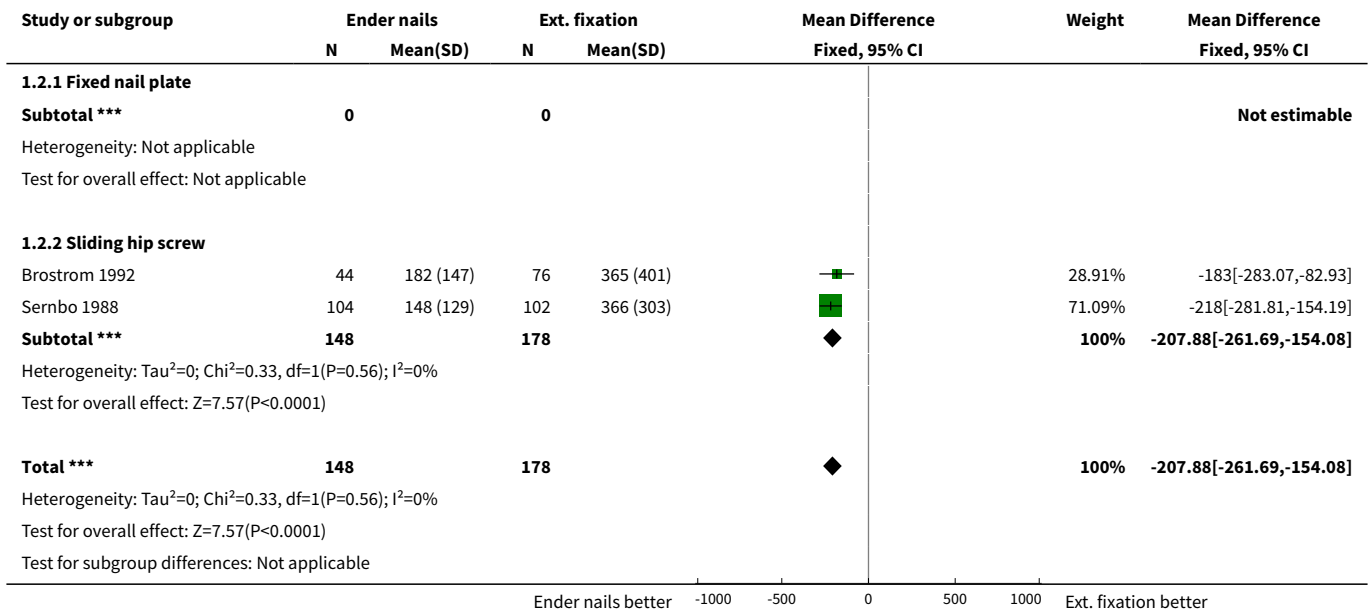
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<a href="#">15 Pressure sores</a>	3	401	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.18, 1.18]
15.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.06, 1.35]
15.2 Sliding hip screw	2	256	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.19, 2.20]
<a href="#">16 DVT (deep vein thrombosis)</a>	4	502	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.51, 2.72]
16.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	1.52 [0.26, 8.83]
16.2 Sliding hip screw	3	357	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.42, 2.82]
<a href="#">17 Pulmonary embolism</a>	4	466	Risk Ratio (M-H, Fixed, 95% CI)	1.84 [0.54, 6.31]
17.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	3.04 [0.32, 28.56]
17.2 Sliding hip screw	3	321	Risk Ratio (M-H, Fixed, 95% CI)	1.38 [0.31, 6.22]
<a href="#">18 Any medical complications</a>	5	602	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.68, 1.19]
18.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.74, 1.75]
18.2 Sliding hip screw	4	457	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.55, 1.13]
<a href="#">19 External rotation deformity</a>	5	741	Risk Ratio (M-H, Fixed, 95% CI)	3.73 [2.47, 5.64]
19.1 Fixed nail plate	1	145	Risk Ratio (M-H, Fixed, 95% CI)	55.75 [3.47, 897.02]
19.2 Sliding hip screw	4	596	Risk Ratio (M-H, Fixed, 95% CI)	2.66 [1.74, 4.07]
<a href="#">20 Shortening of leg</a>	6	843	Risk Ratio (M-H, Fixed, 95% CI)	2.71 [1.60, 4.59]
20.1 Fixed nail plate	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.2 Sliding hip screw	6	843	Risk Ratio (M-H, Fixed, 95% CI)	2.71 [1.60, 4.59]
<a href="#">21 Mortality: short term (&lt;2 months)</a>	7	962	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.73, 1.71]
21.1 Fixed nail plate	2	275	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [0.67, 2.43]
21.2 Sliding hip screw	5	687	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.57, 1.79]
<a href="#">22 Mortality: long term follow up</a>	7	1090	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.82, 1.27]
22.1 Fixed nail plate	2	327	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.72, 1.89]
22.2 Sliding hip screw	5	763	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.77, 1.25]
<a href="#">23 Pain at follow up: any (knee, hip)</a>	5	599	Risk Ratio (M-H, Fixed, 95% CI)	2.10 [1.54, 2.85]
23.1 Fixed nail plate	1	110	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.44, 2.04]
23.2 Sliding hip screw	4	489	Risk Ratio (M-H, Fixed, 95% CI)	2.43 [1.73, 3.41]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
24 Pain at follow up: hip pain	3	429	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.41, 1.18]
24.1 Fixed nail plate	1	110	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.44, 2.04]
24.2 Sliding hip screw	2	319	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.26, 1.14]
25 Failure to return previous residence	3	393	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.70, 1.57]
25.1 Fixed nail plate	1	74	Risk Ratio (M-H, Fixed, 95% CI)	1.97 [0.76, 5.12]
25.2 Sliding hip screw	2	319	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.57, 1.40]
26 Deterioration in walking function	3	385	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [1.05, 1.54]
26.1 Fixed nail plate	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
26.2 Sliding hip screw	3	385	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [1.05, 1.54]

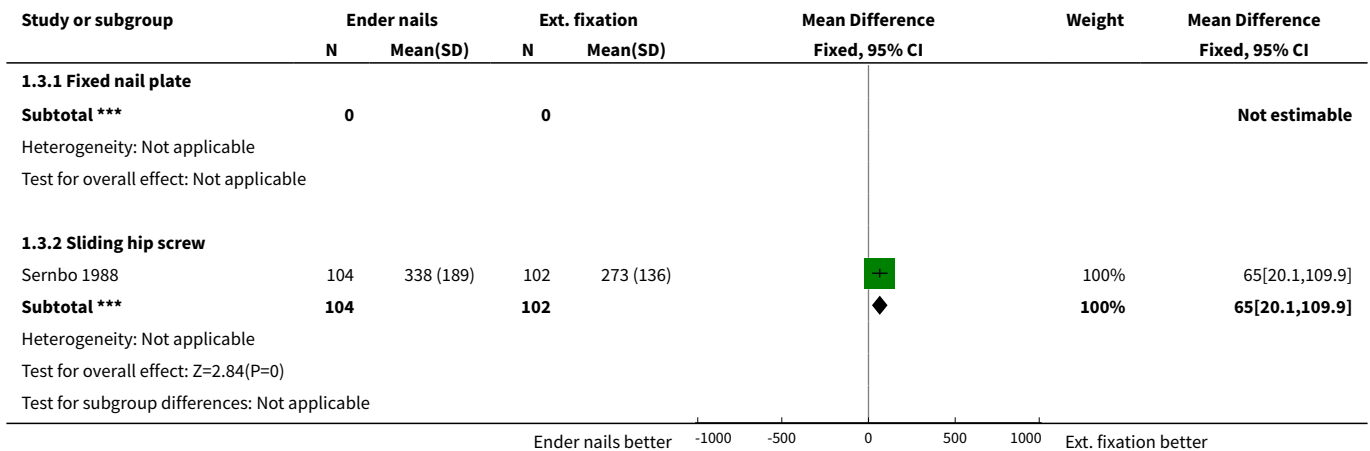
**Analysis 1.1. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 1 Length of surgery (minutes).**



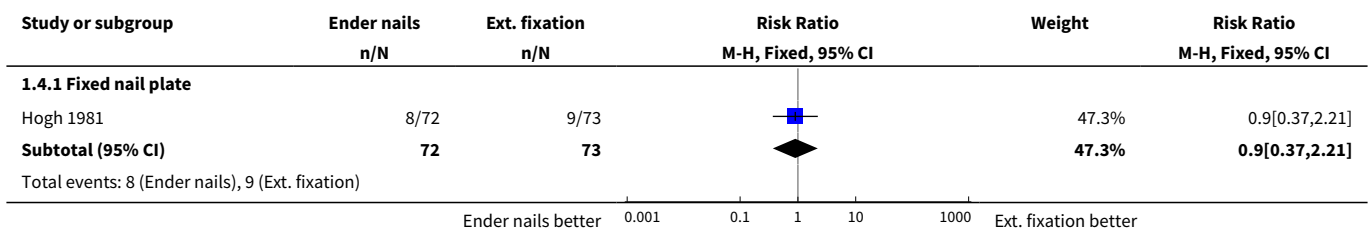
**Analysis 1.2. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 2 Operative blood loss (ml).**

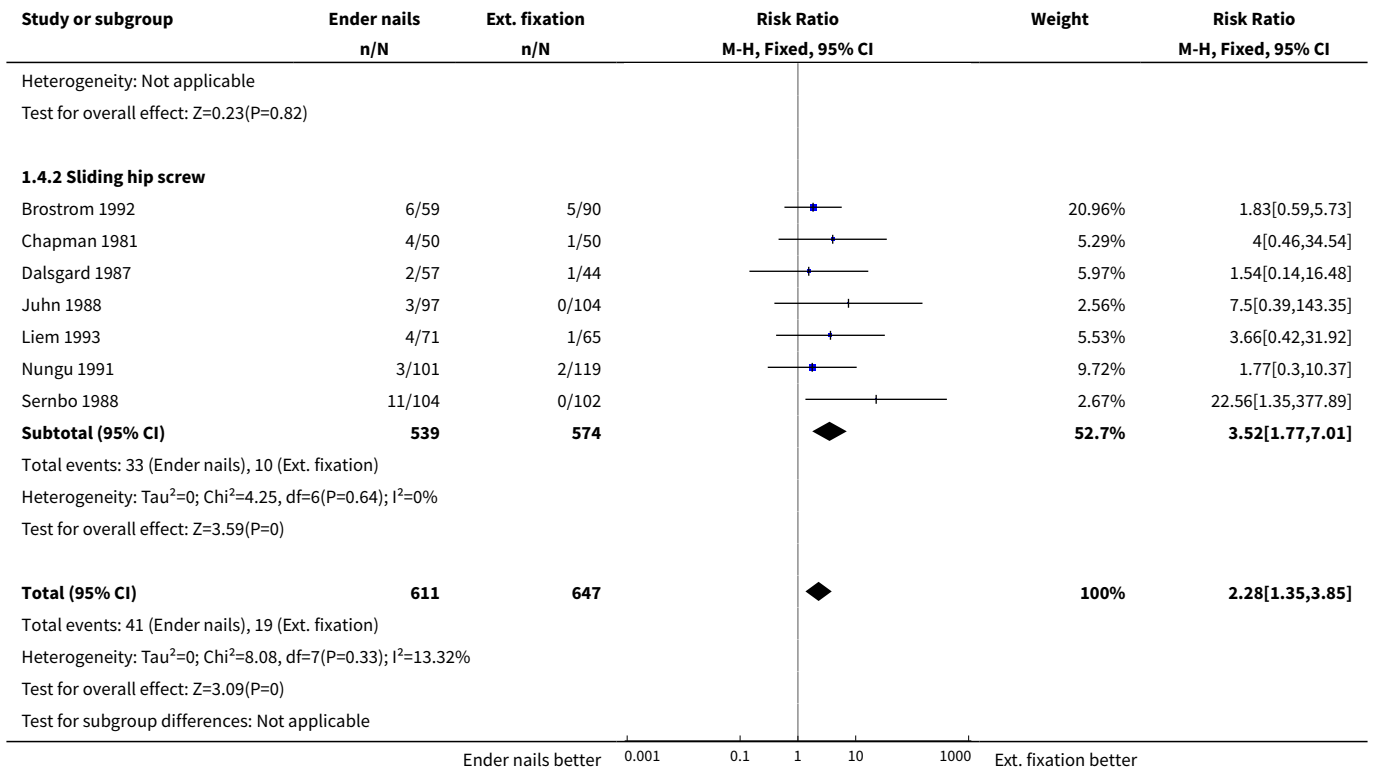


**Analysis 1.3. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 3 Radiographic screening time (seconds).**

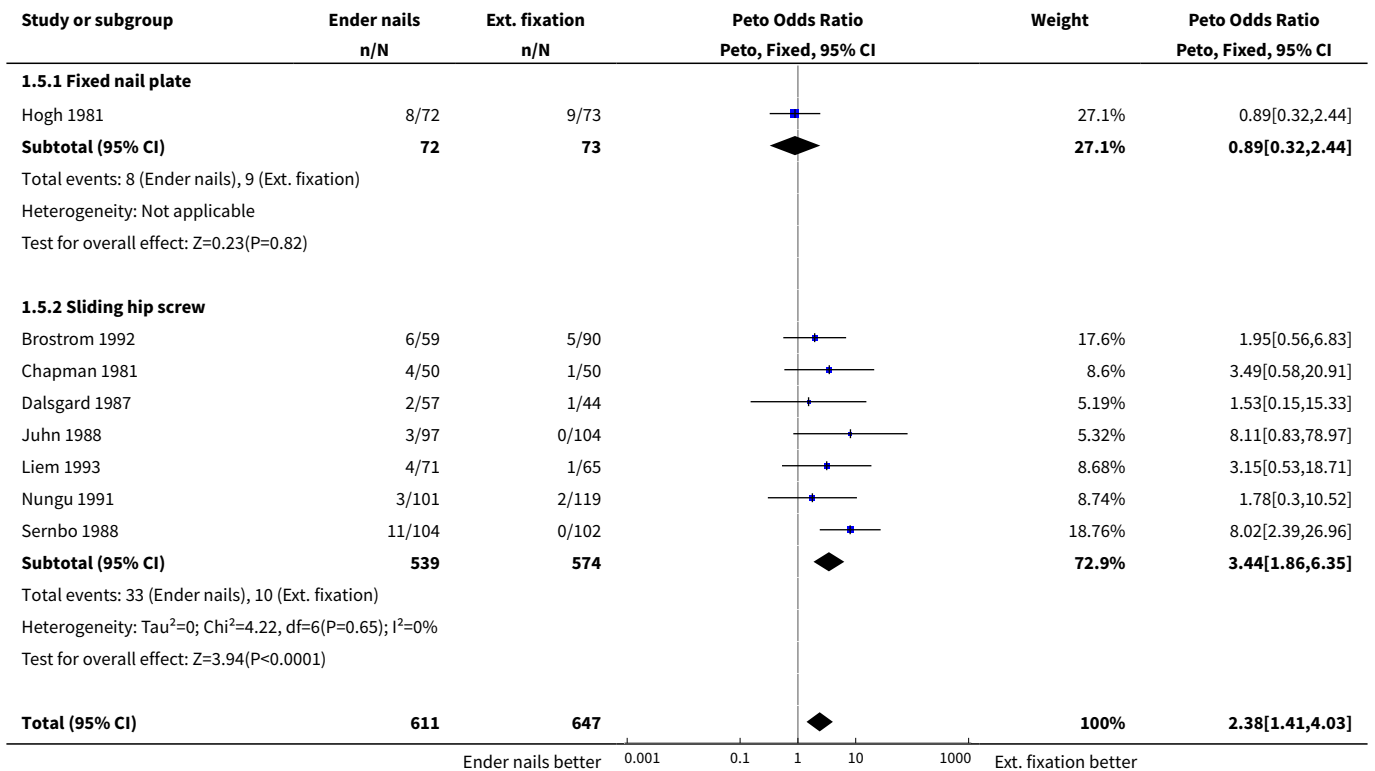


**Analysis 1.4. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 4 Cut-out of implant.**

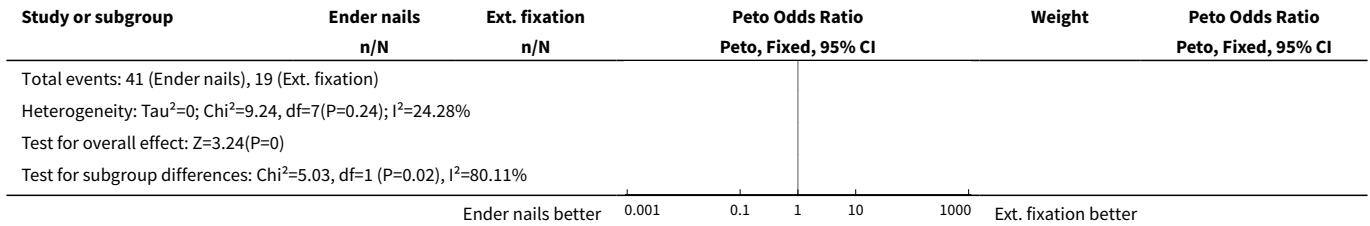




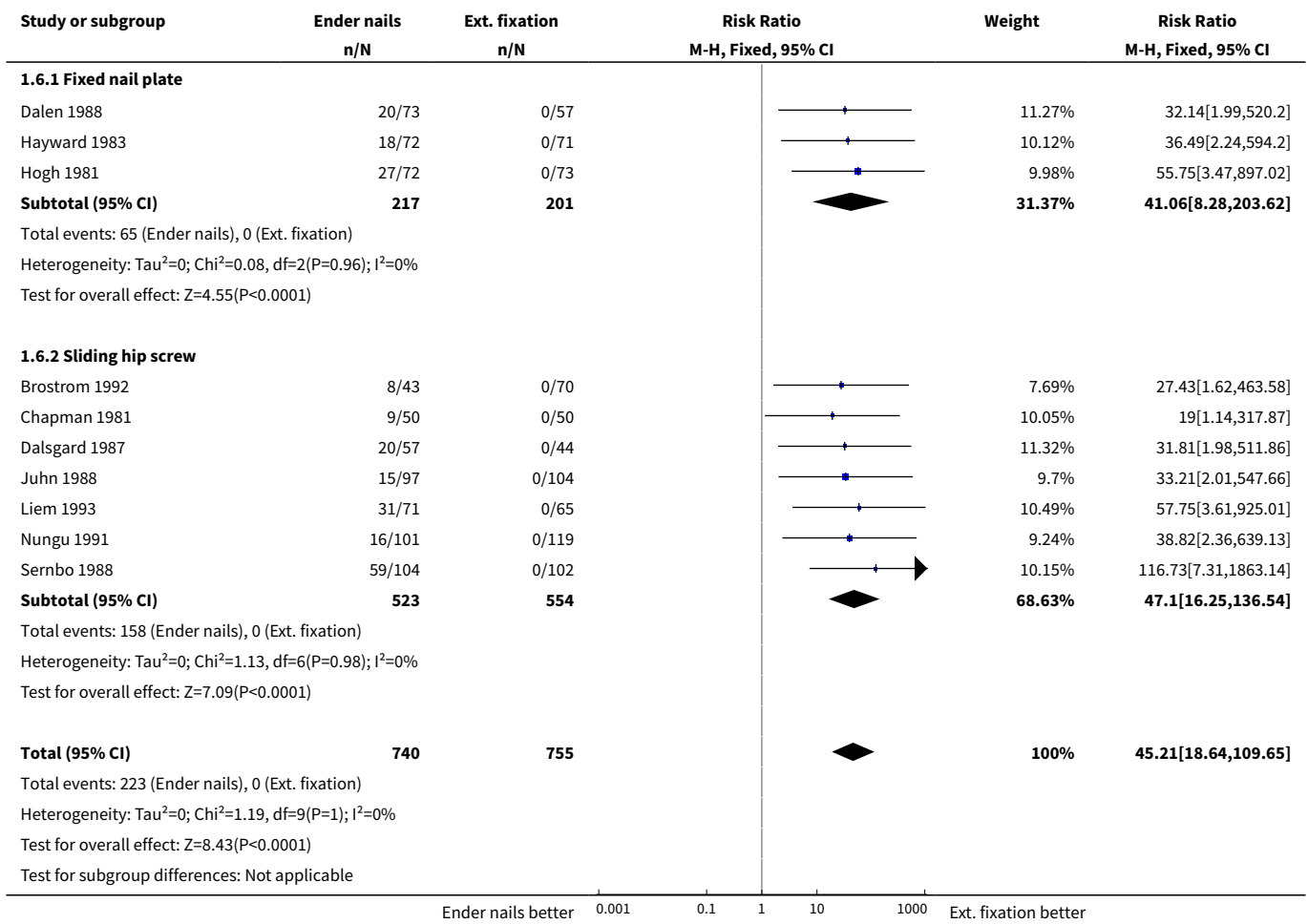
**Analysis 1.5. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 5 Cut-out of implant (odds ratio results).**



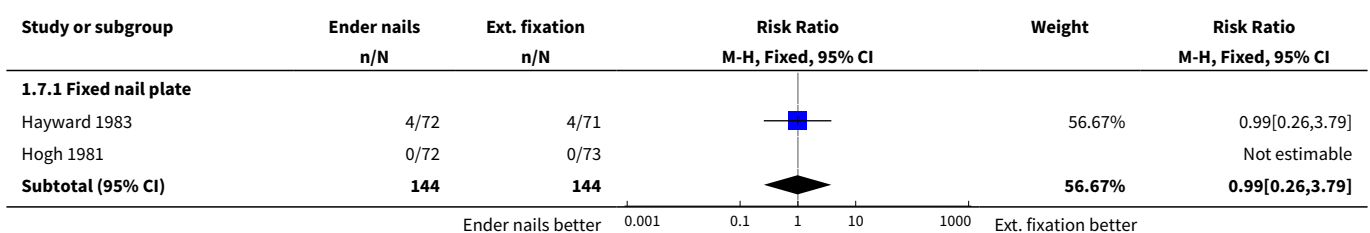


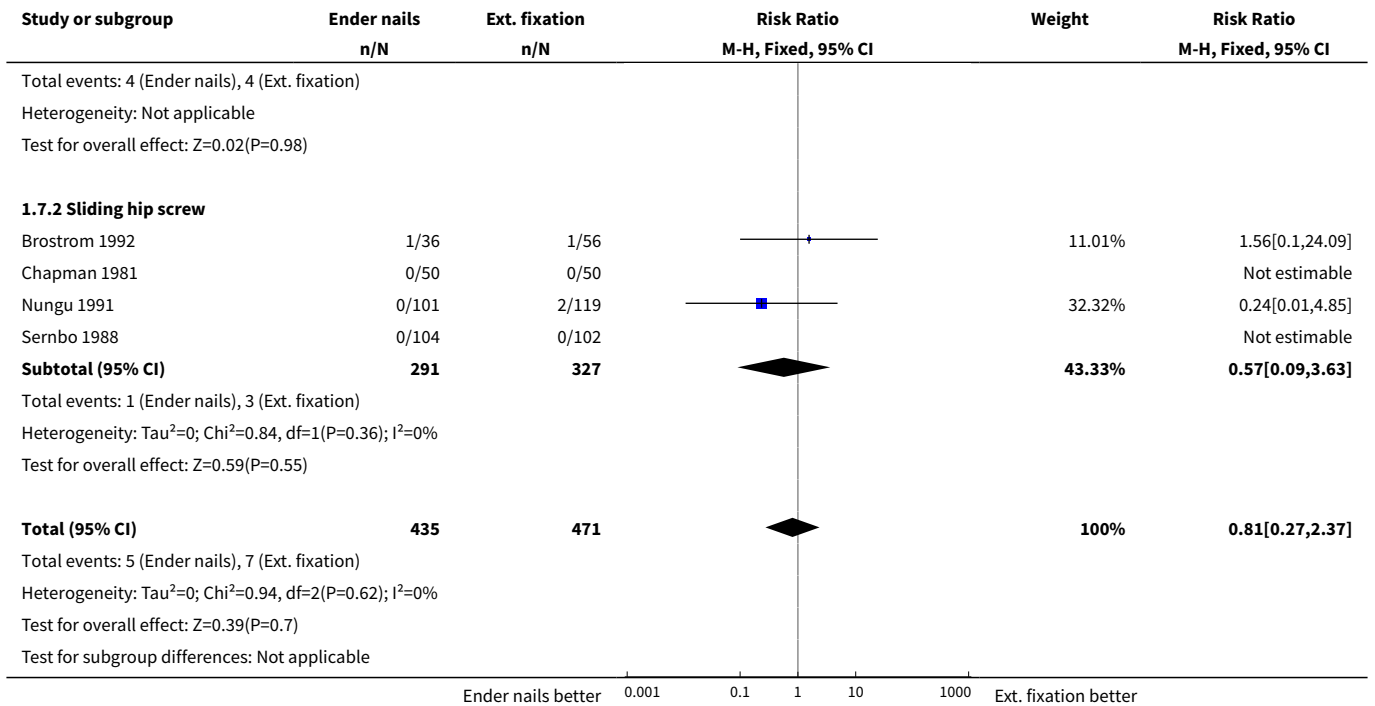


**Analysis 1.6. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 6 Backing out of the nail.**

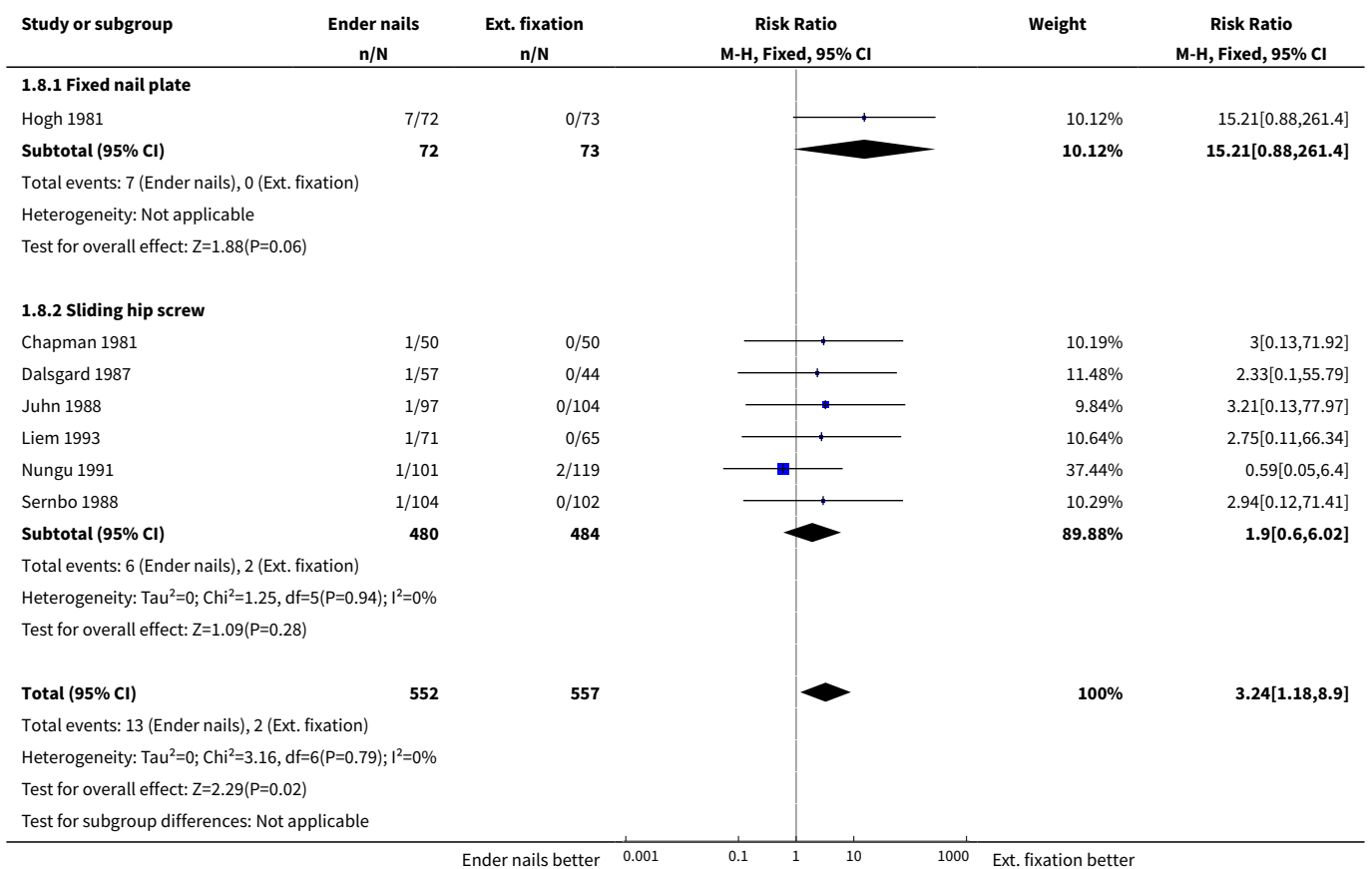


**Analysis 1.7. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 7 Non-union.**

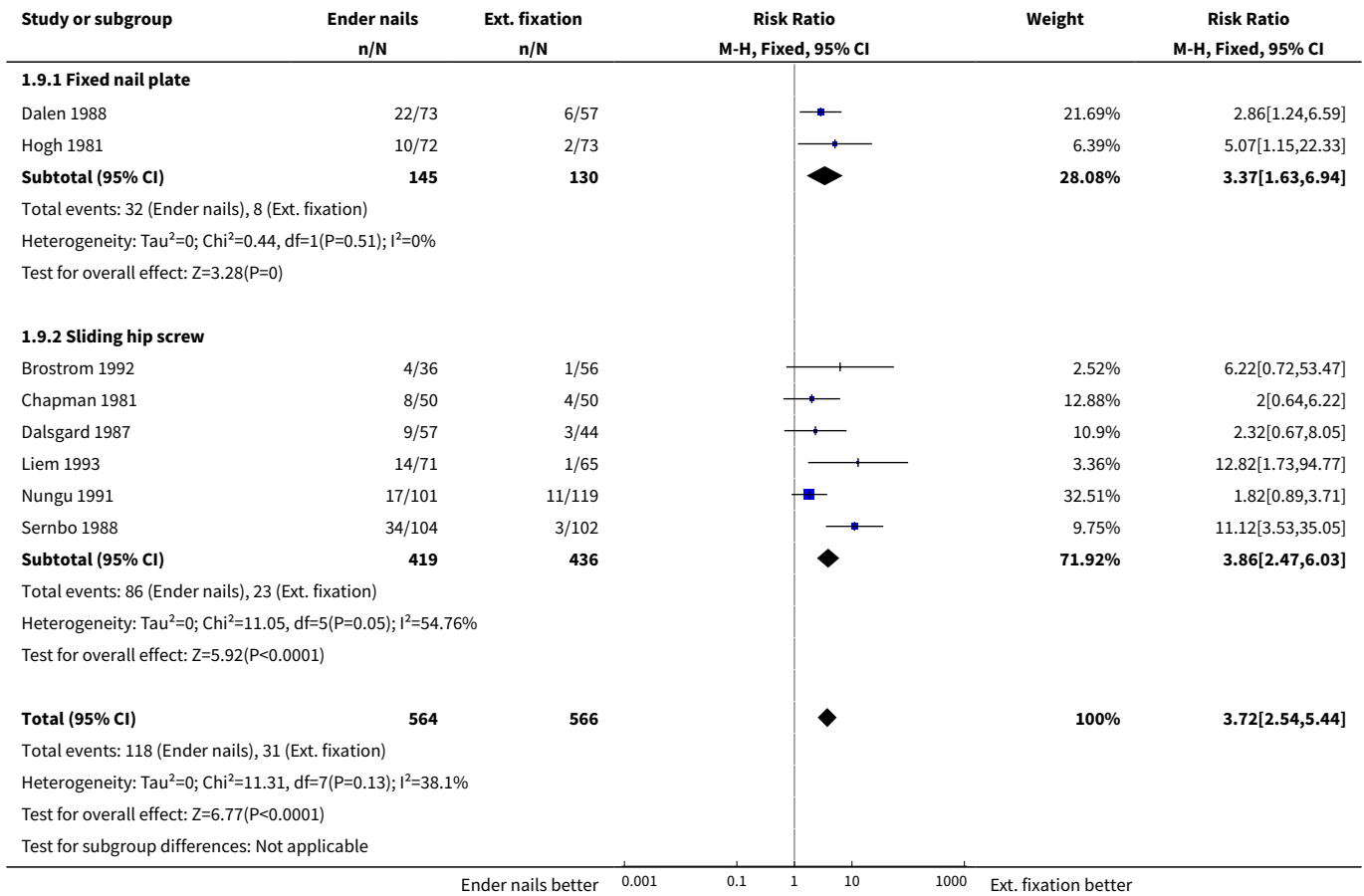




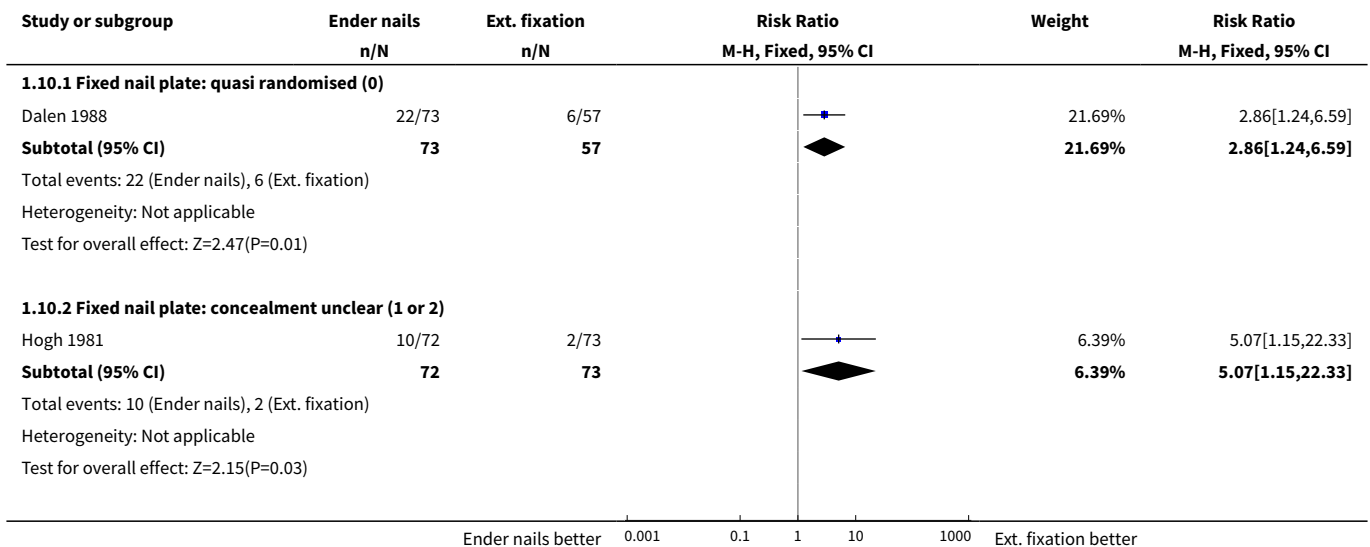
**Analysis 1.8. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 8 Fracture of the femur.**

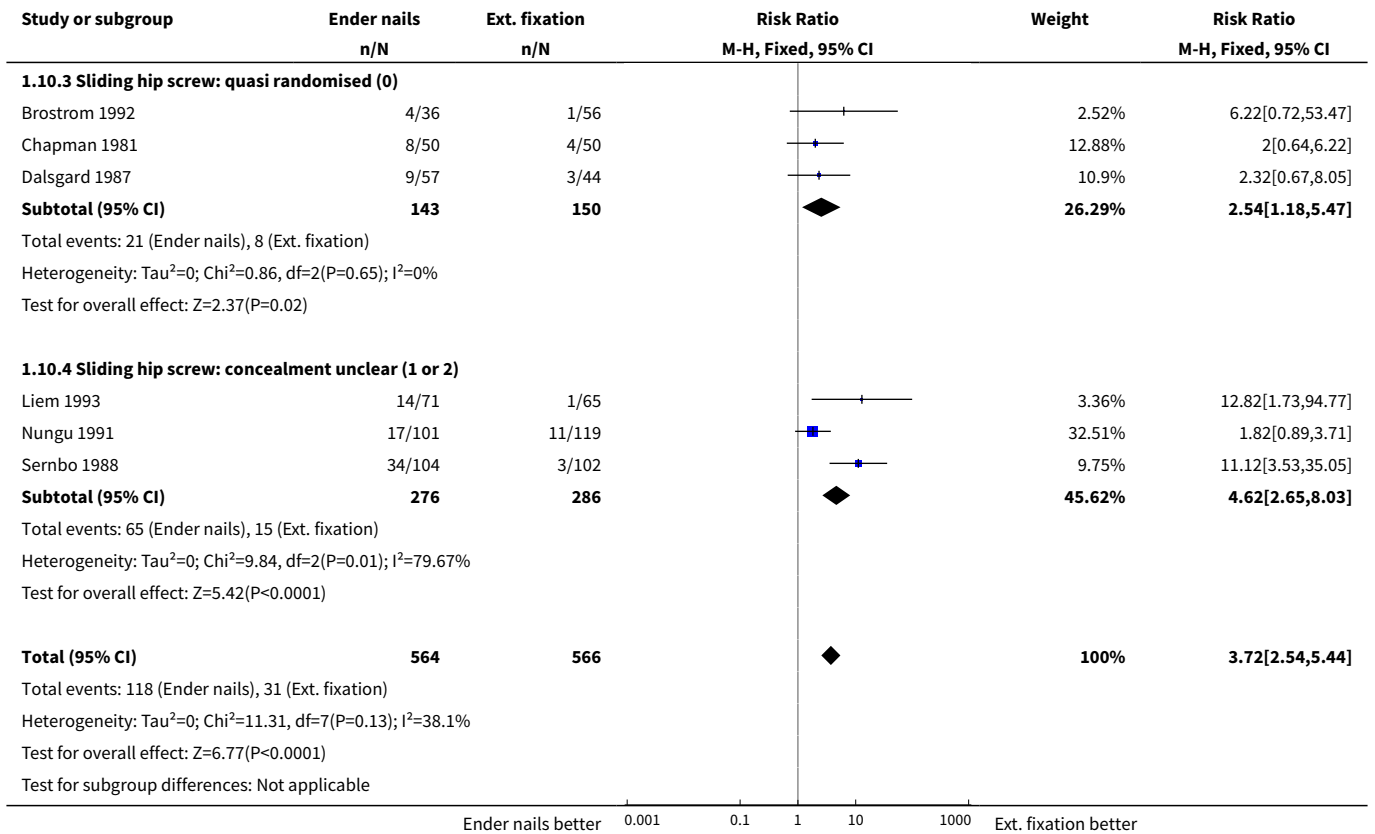


**Analysis 1.9. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 9 Reoperation.**

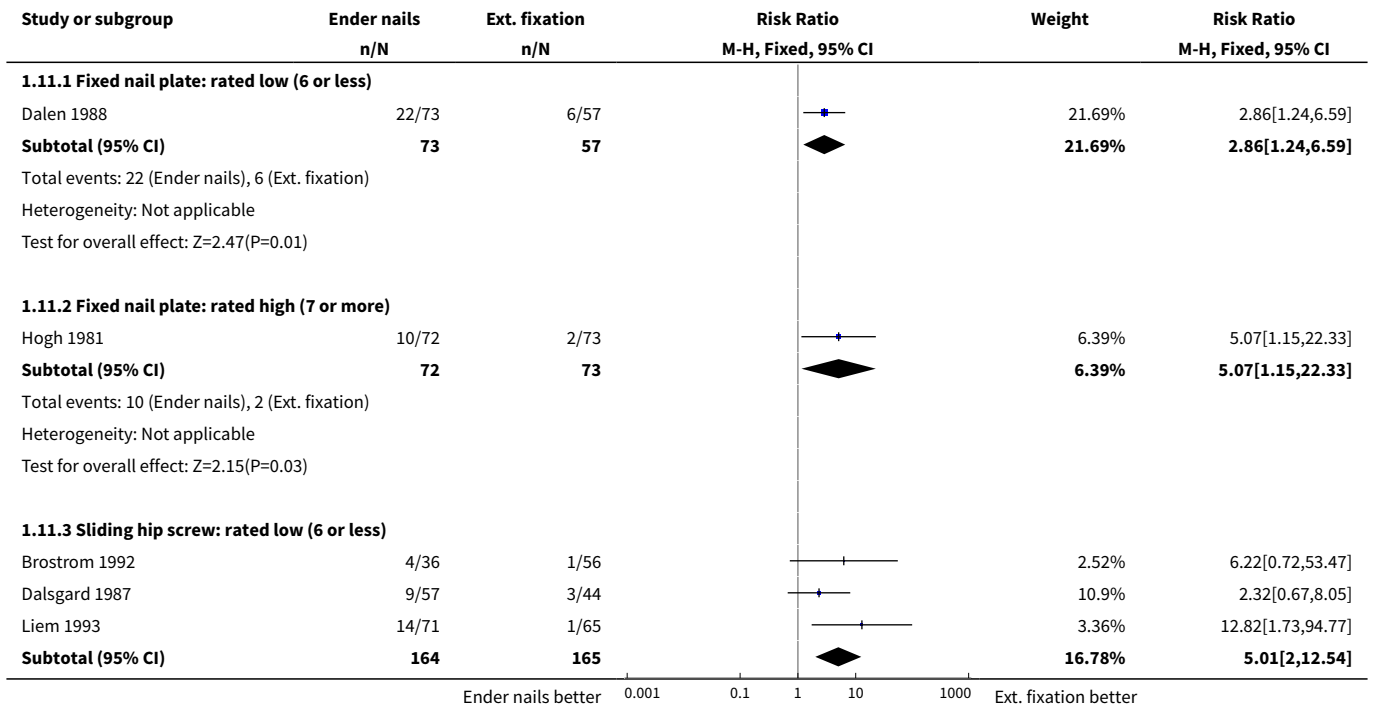


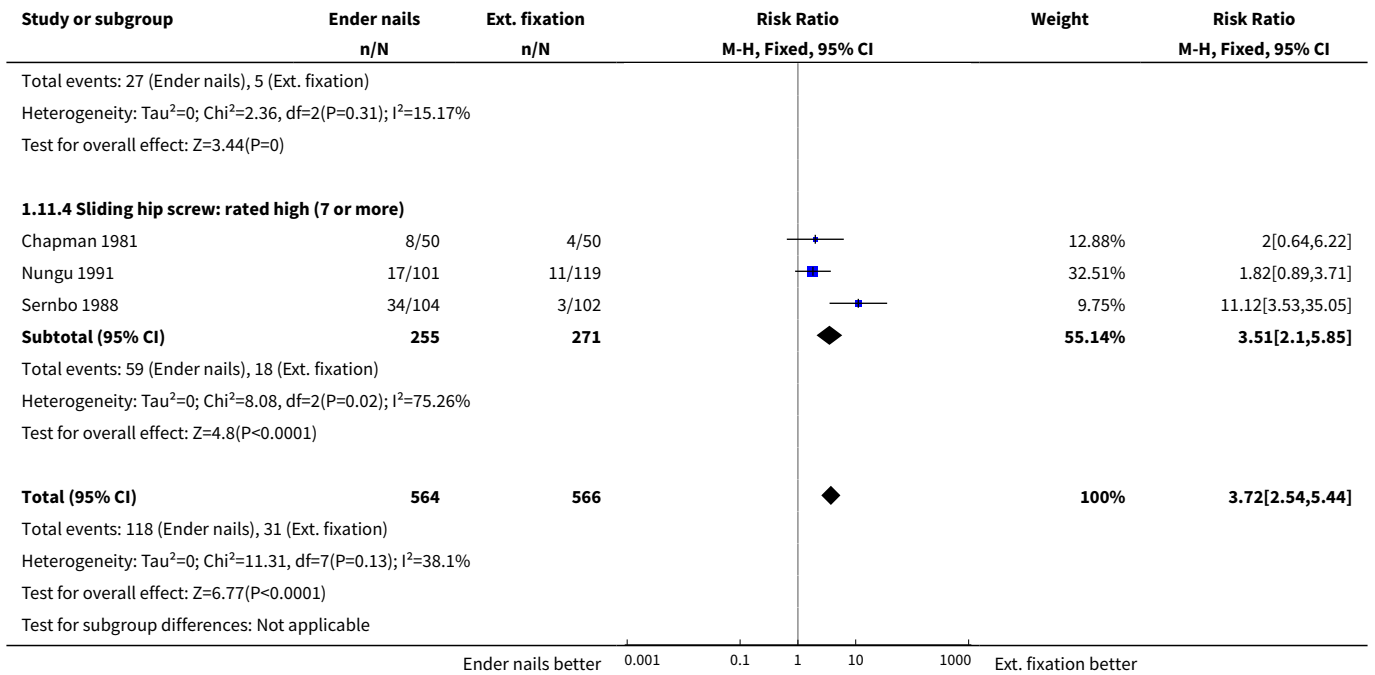
**Analysis 1.10. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 10 Reoperation: by allocation concealment (quality score).**



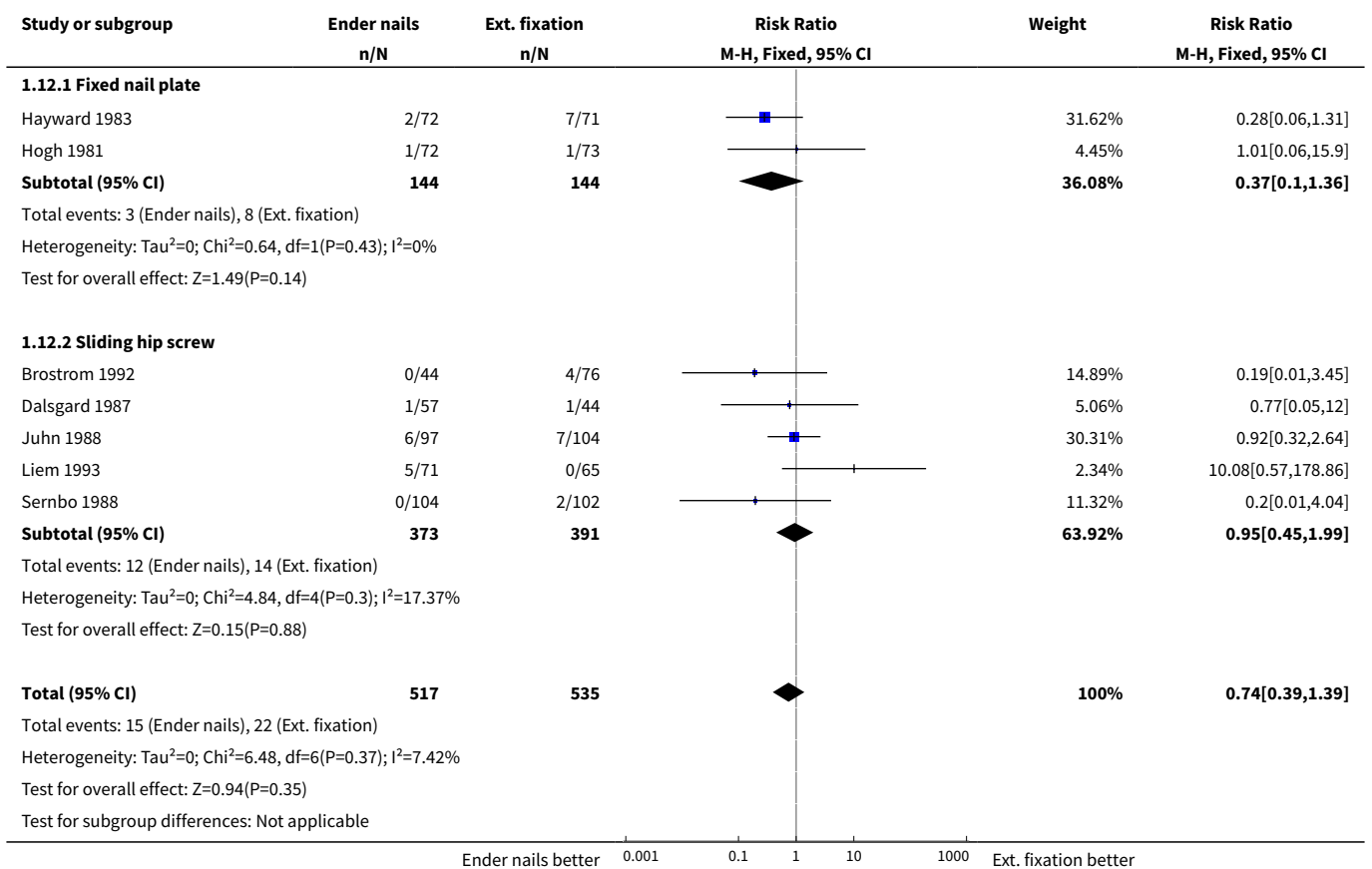


**Analysis 1.11. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 11 Reoperation: by overall trial quality (total score).**

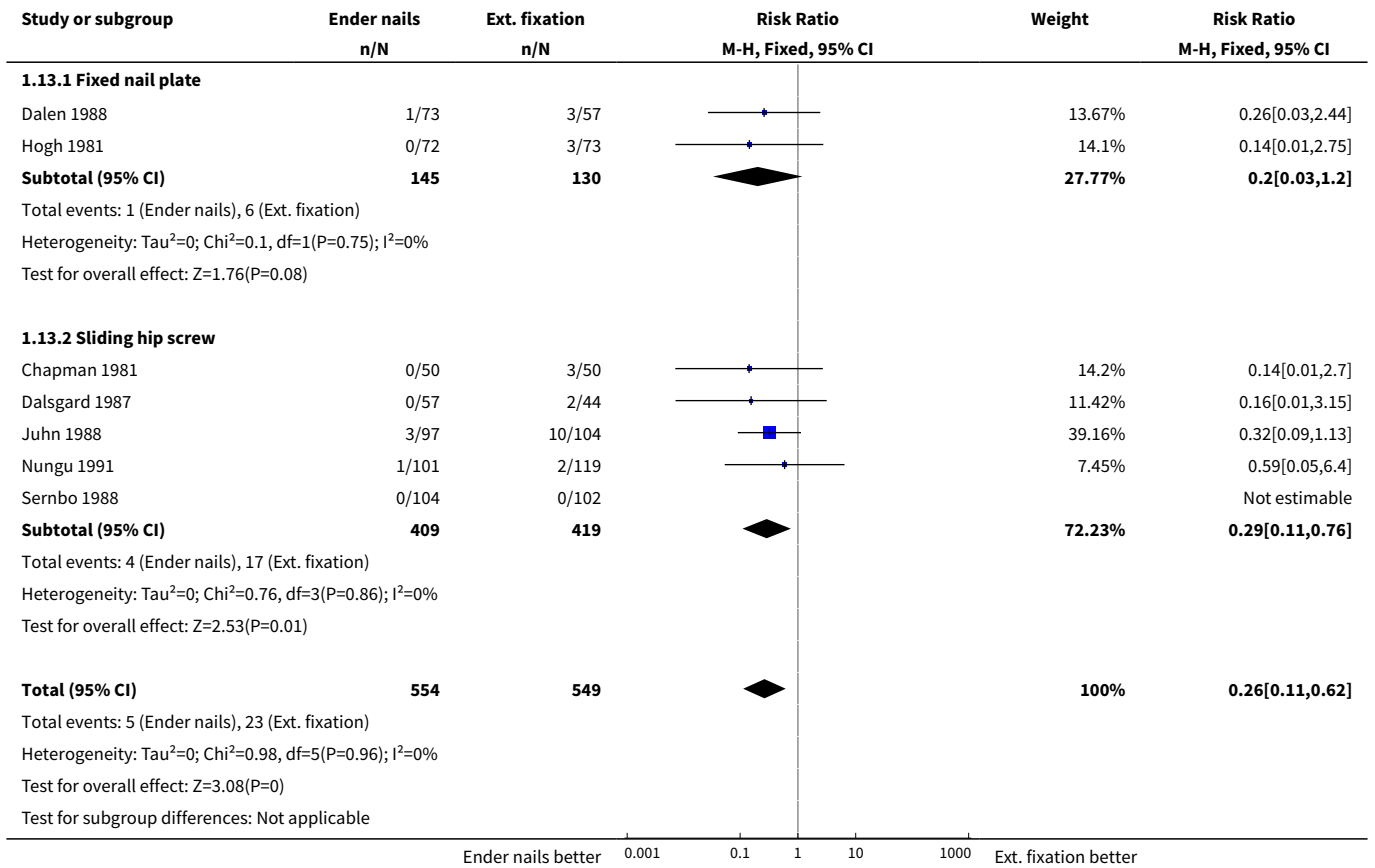




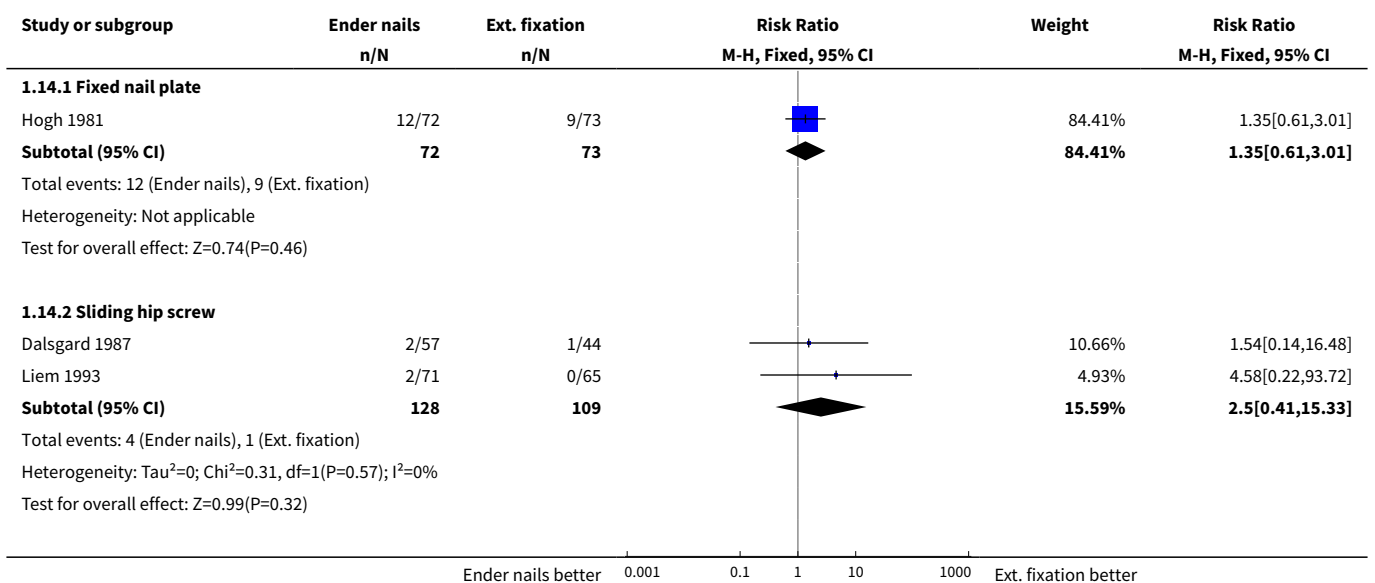
**Analysis 1.12. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 12 Superficial wound infection.**

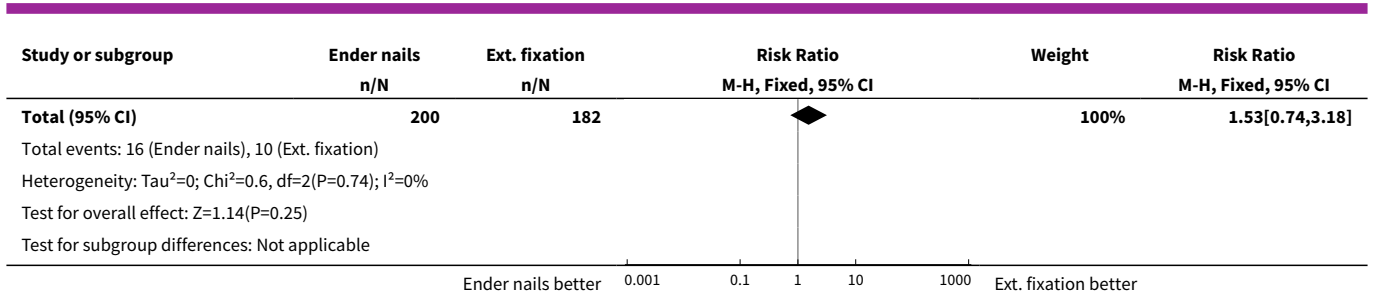


**Analysis 1.13. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 13 Deep wound infection.**

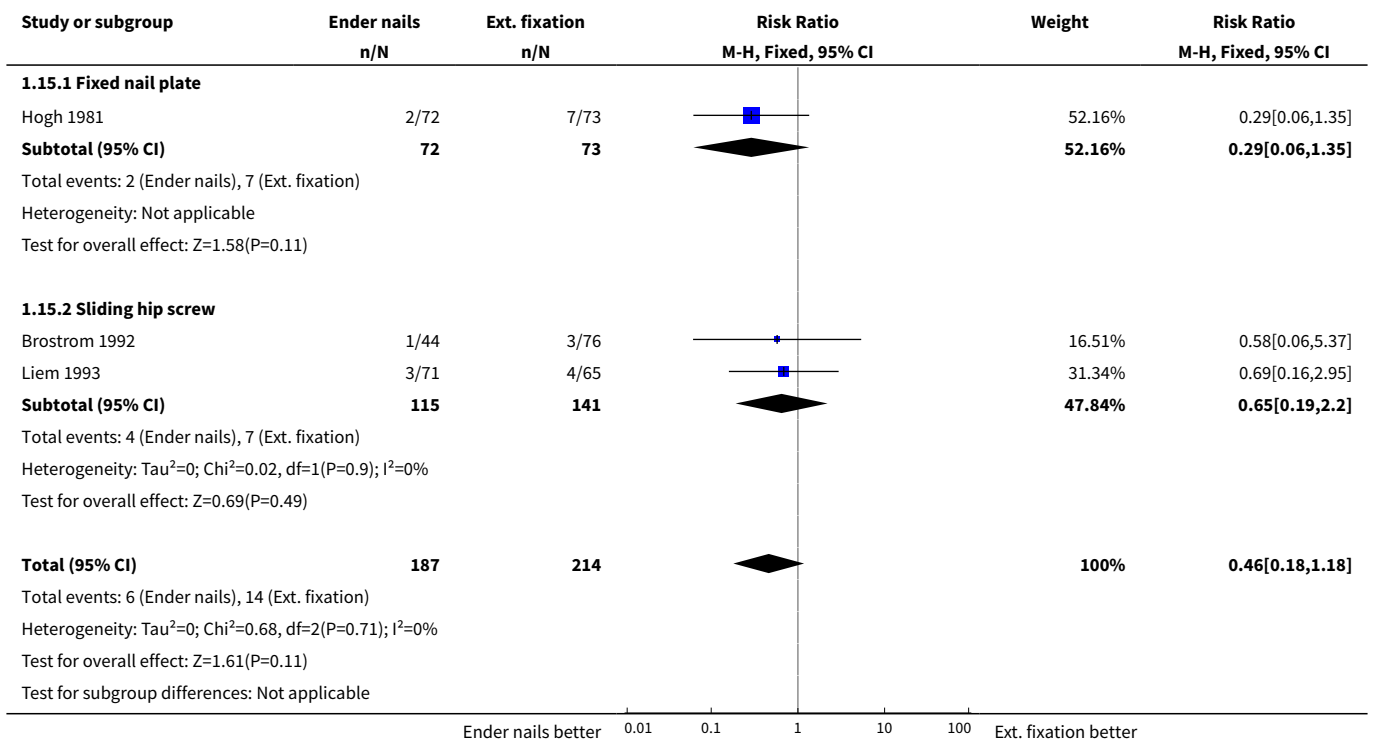


**Analysis 1.14. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 14 Pneumonia.**

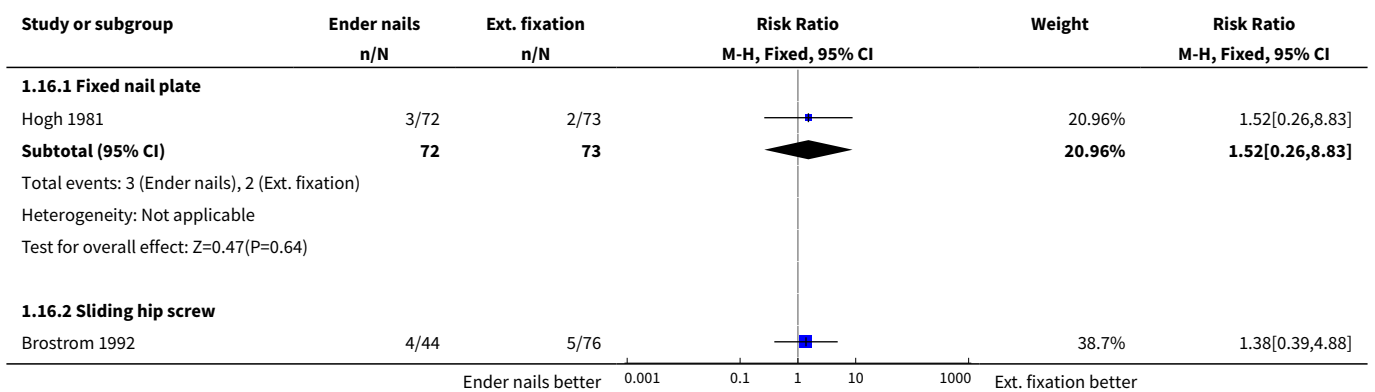




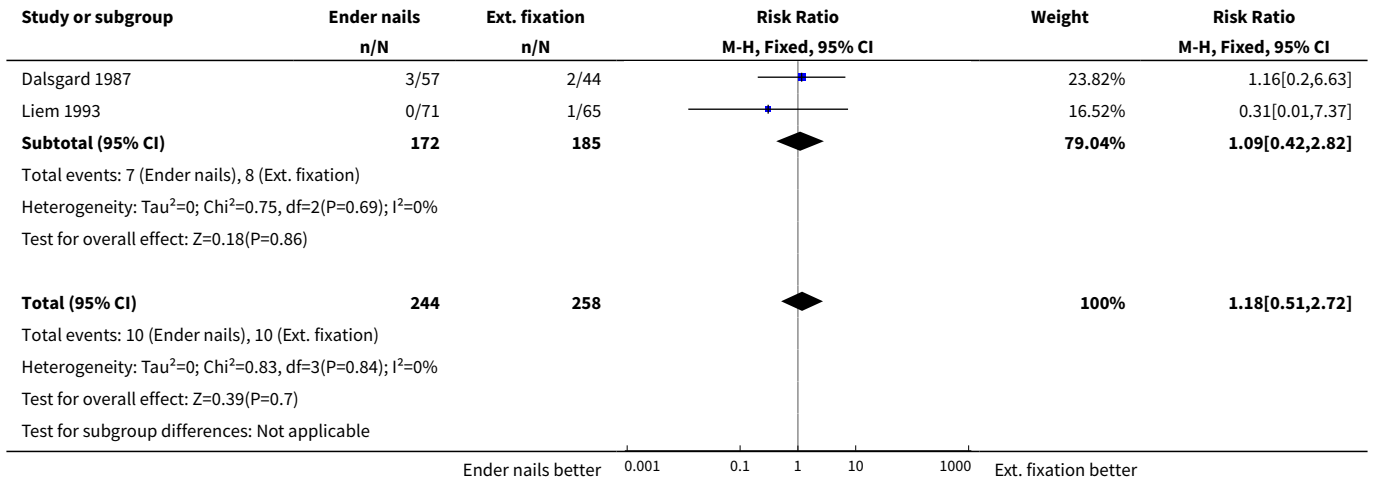
**Analysis 1.15. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 15 Pressure sores.**



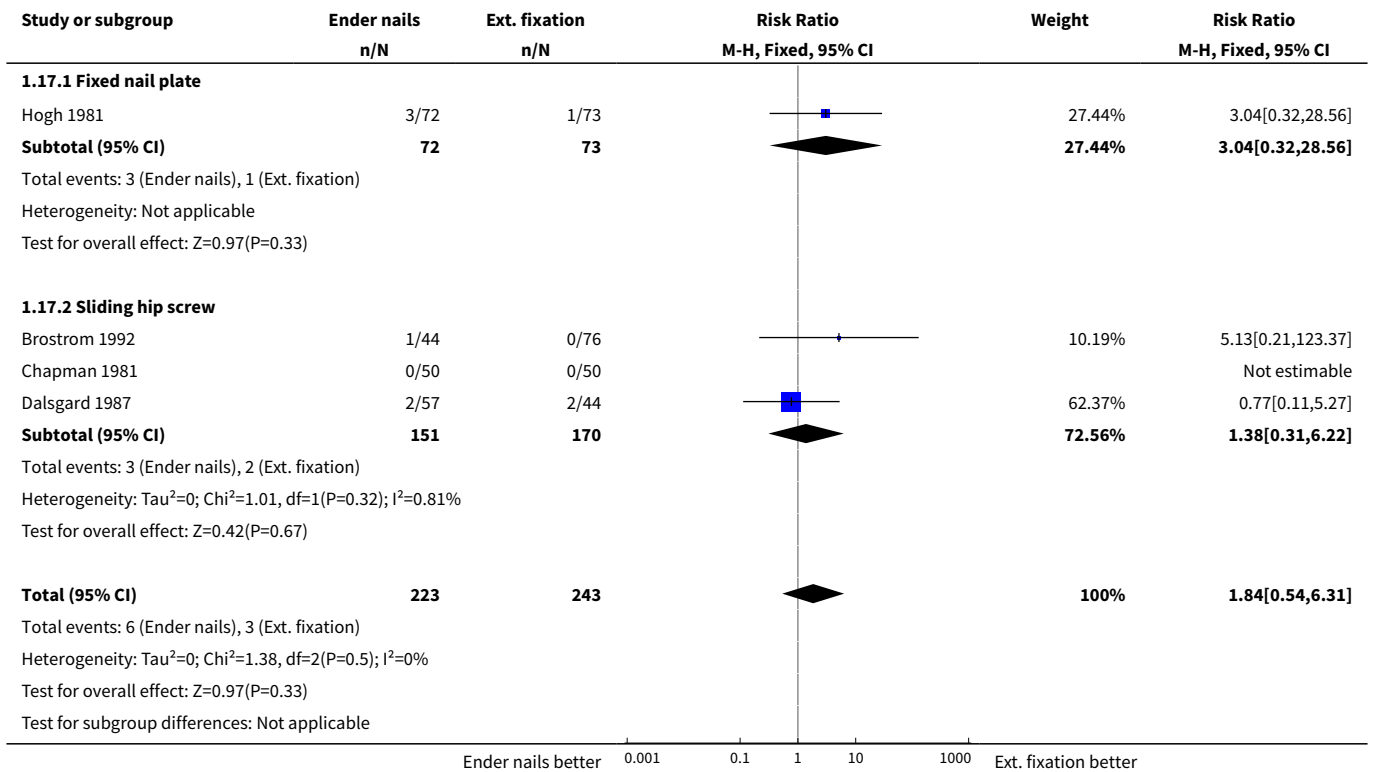
**Analysis 1.16. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 16 DVT (deep vein thrombosis).**



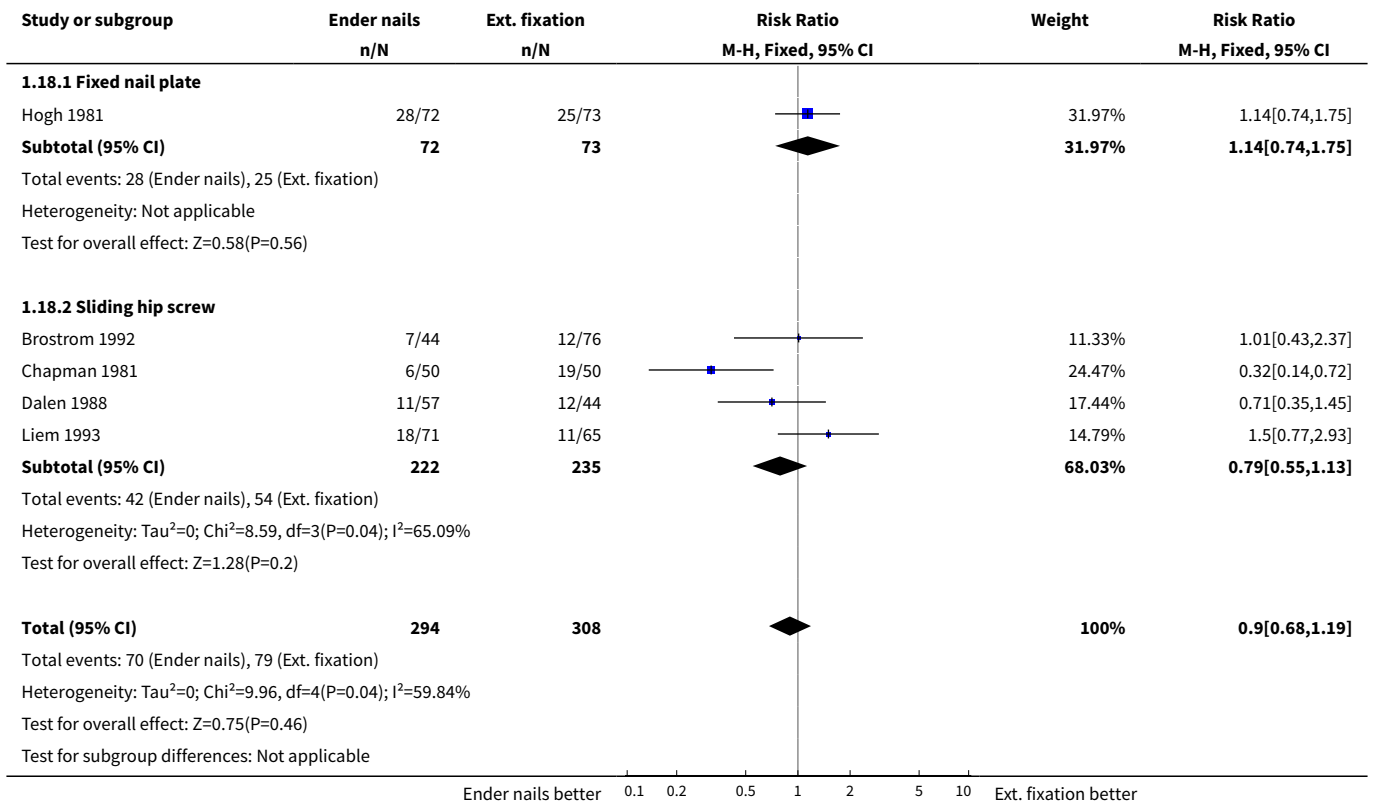




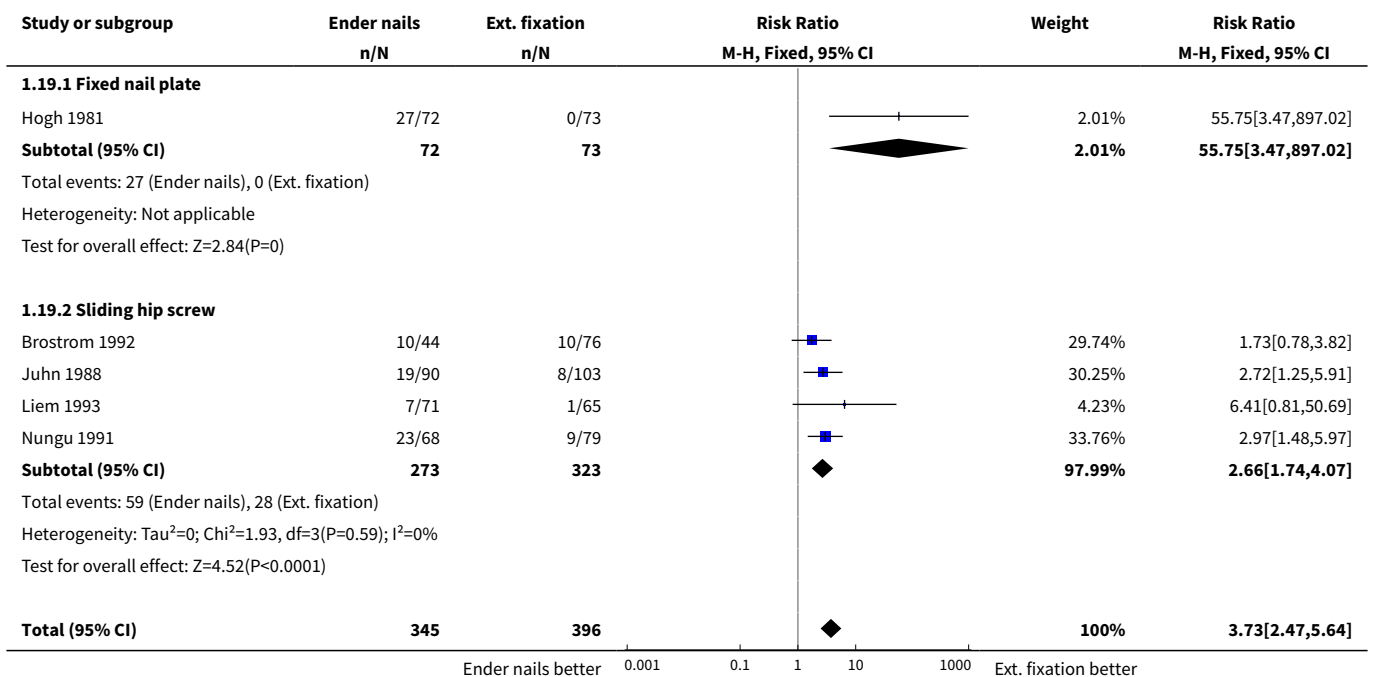
**Analysis 1.17. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 17 Pulmonary embolism.**

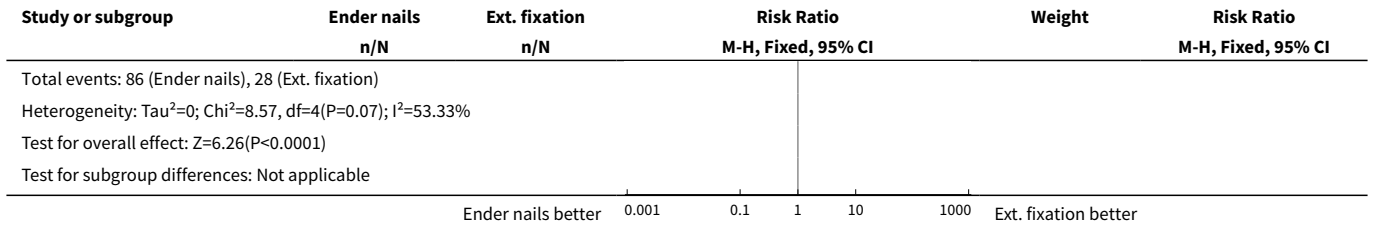


**Analysis 1.18. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 18 Any medical complications.**

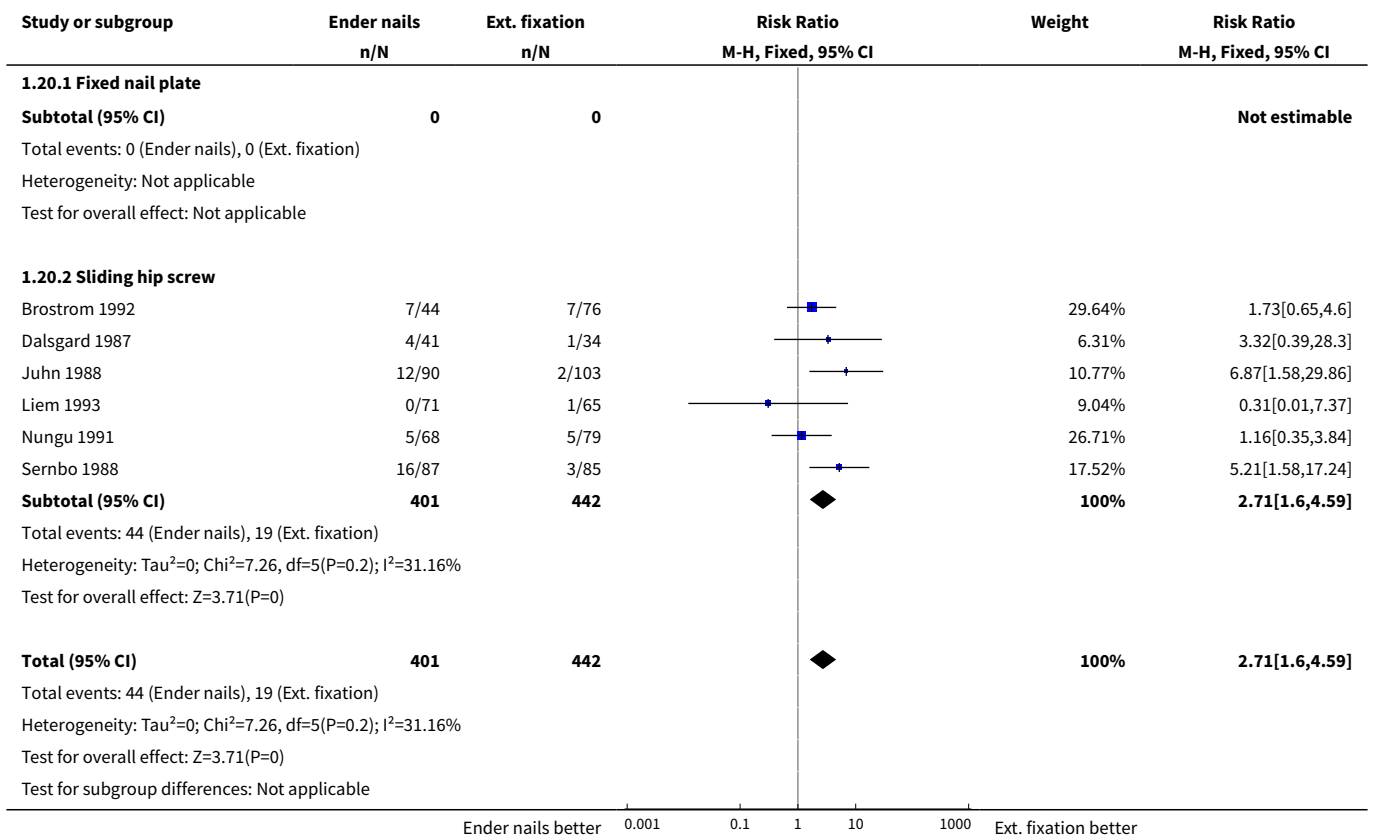


**Analysis 1.19. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 19 External rotation deformity.**

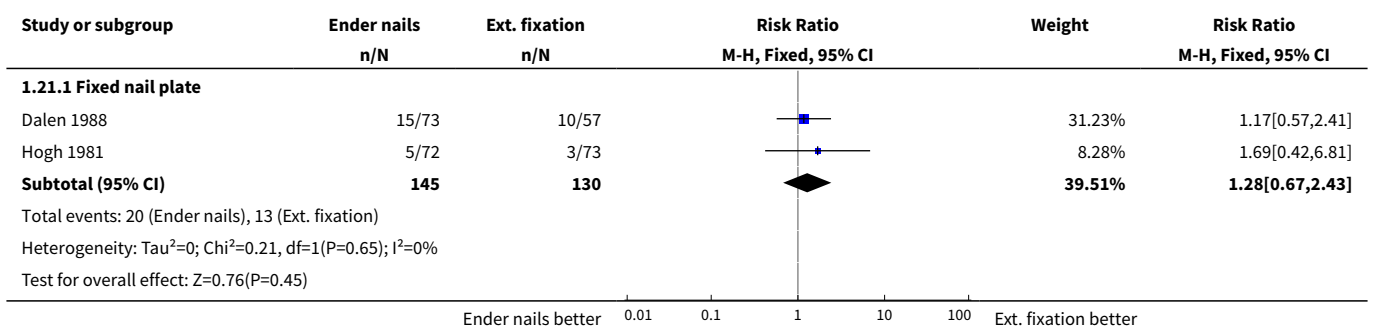


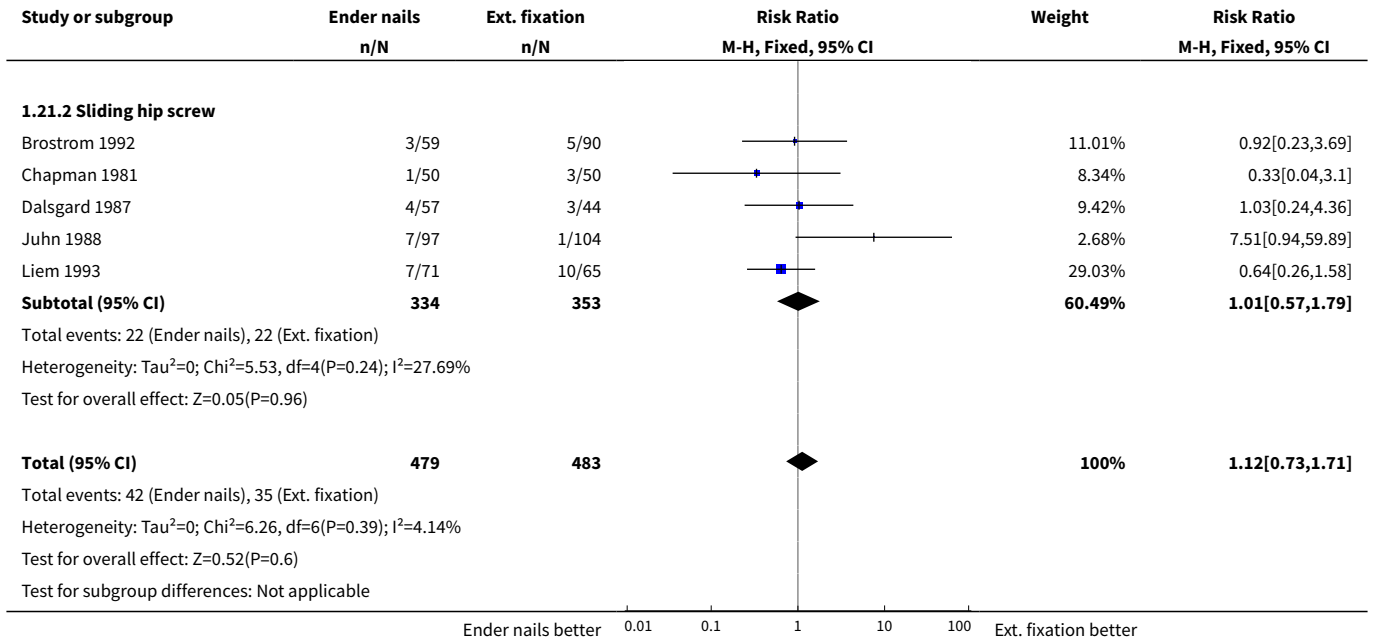


**Analysis 1.20. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 20 Shortening of leg.**

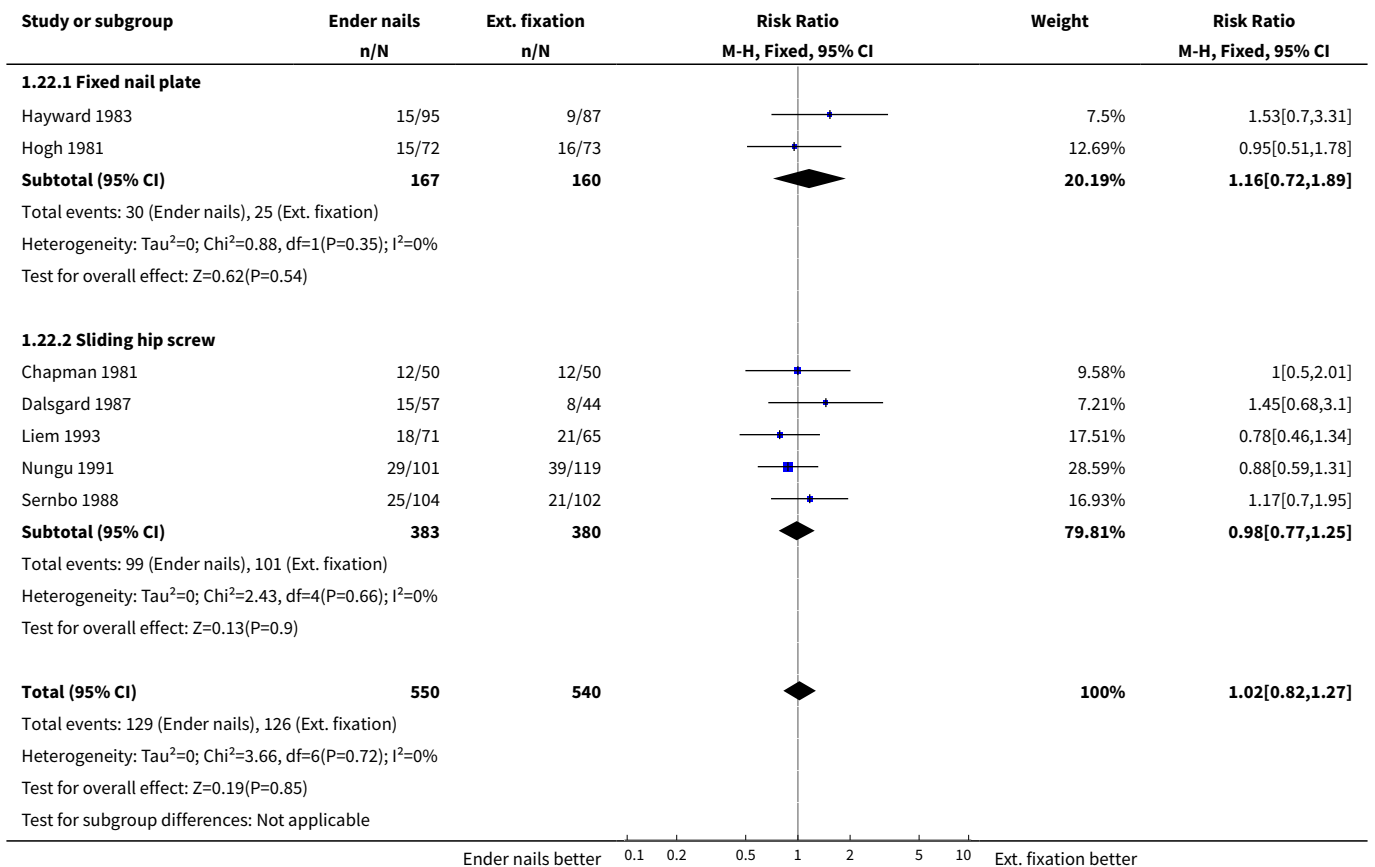


**Analysis 1.21. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 21 Mortality: short term (<2 months).**

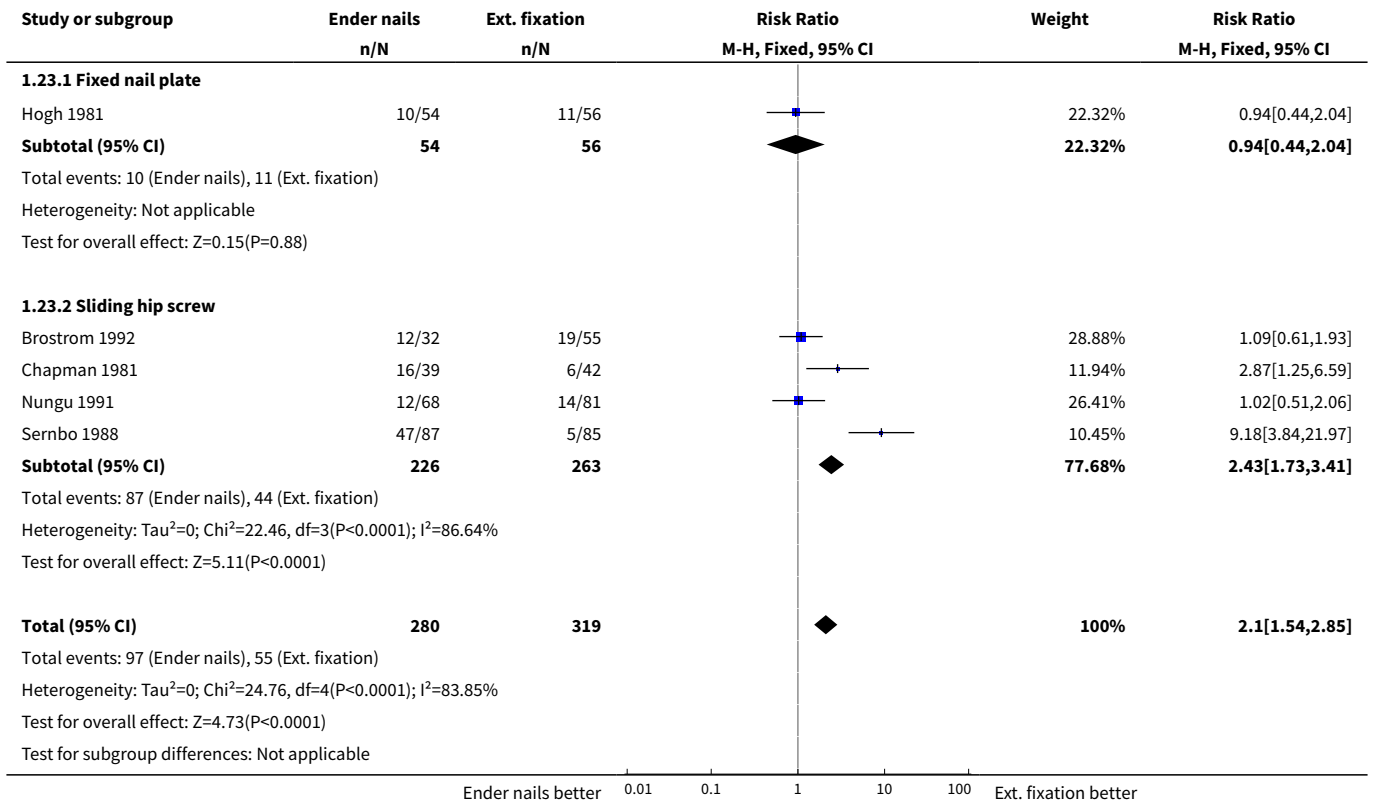




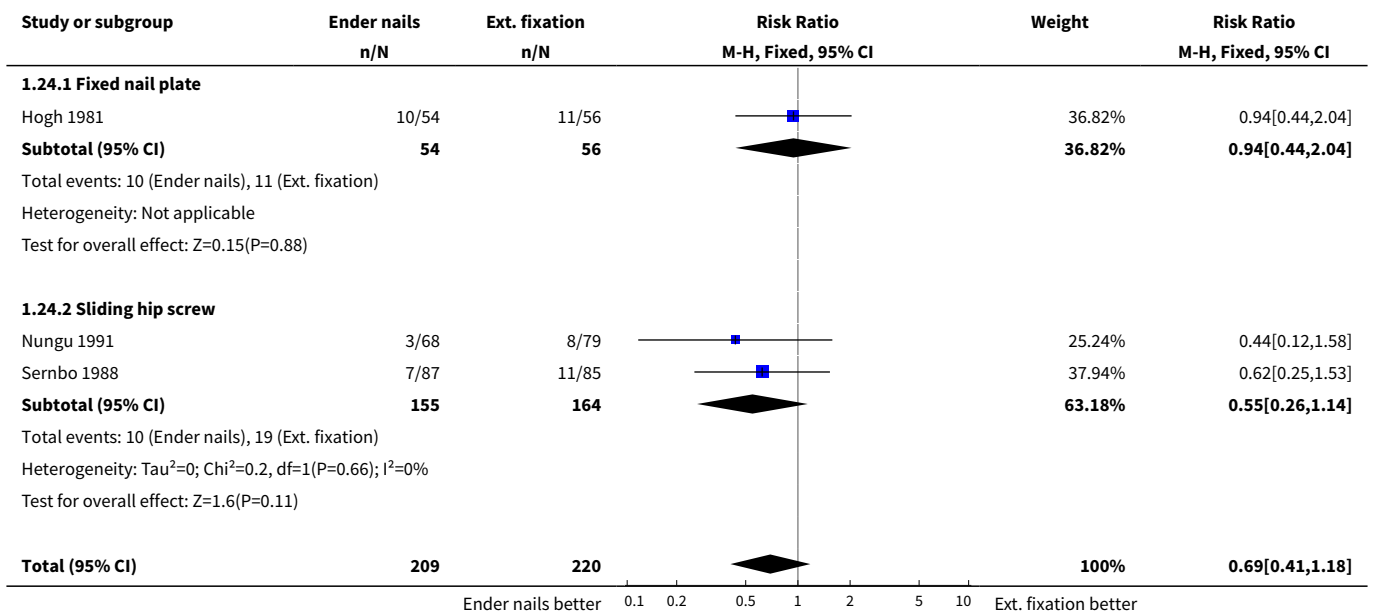
**Analysis 1.22. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 22 Mortality: long term follow up.**

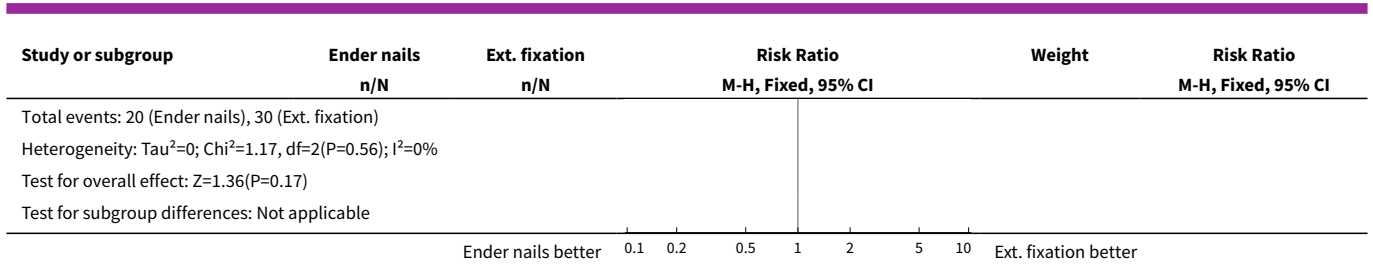


**Analysis 1.23. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 23 Pain at follow up: any (knee, hip).**

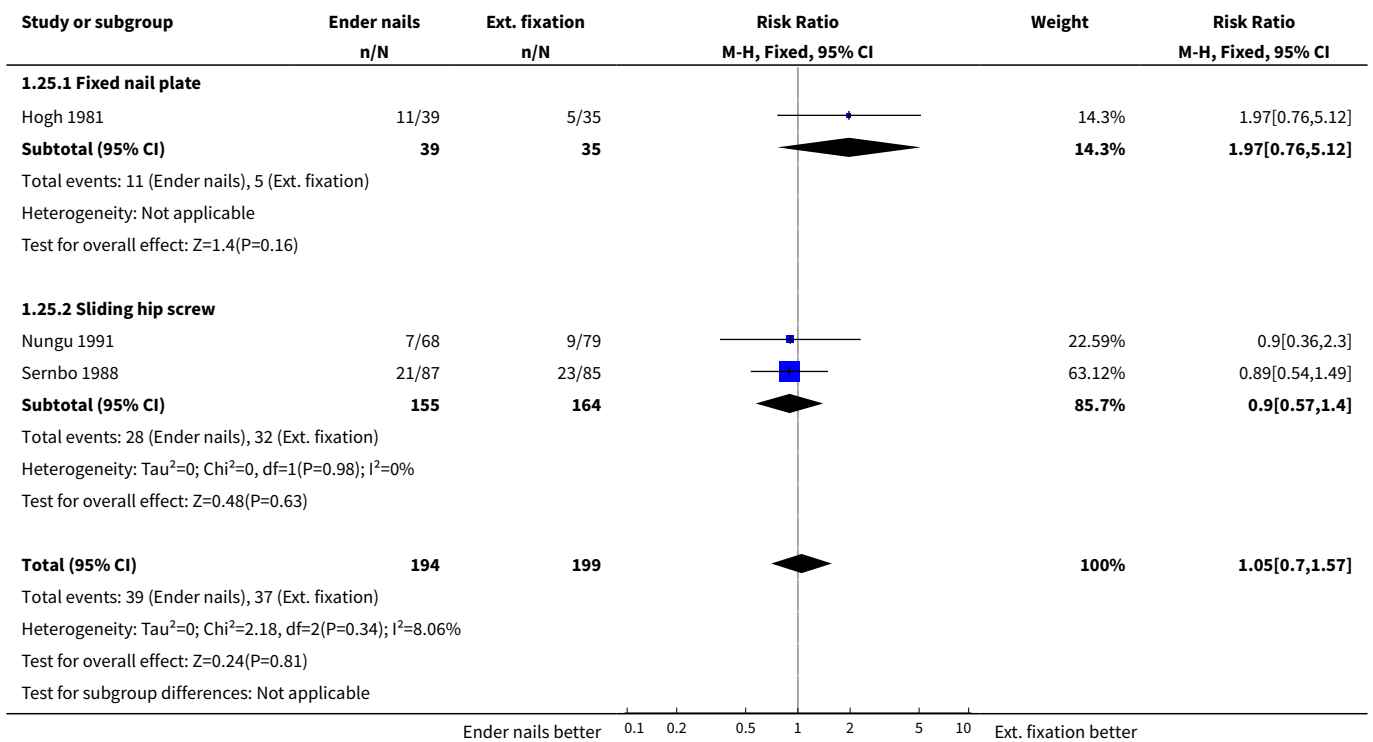


**Analysis 1.24. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 24 Pain at follow up: hip pain.**

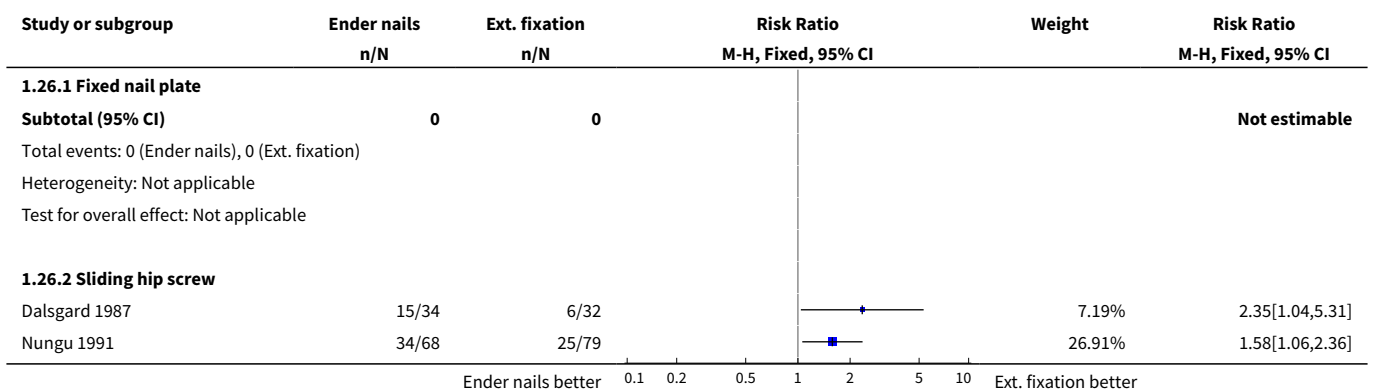


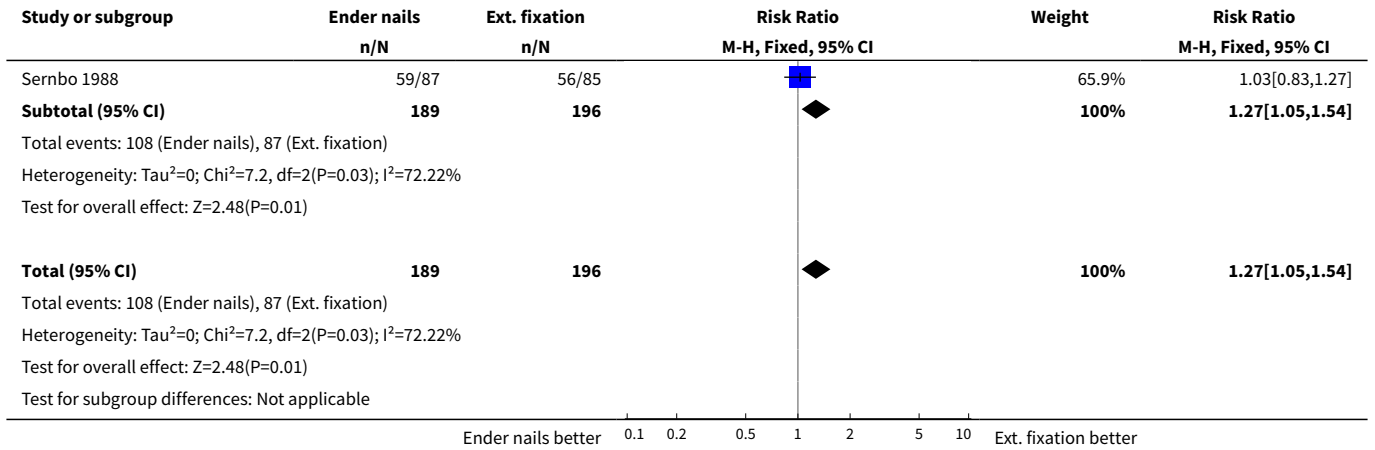


**Analysis 1.25. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 25 Failure to return previous residence.**



**Analysis 1.26. Comparison 1 Ender nails versus extramedullary fixation implants, Outcome 26 Deterioration in walking function.**

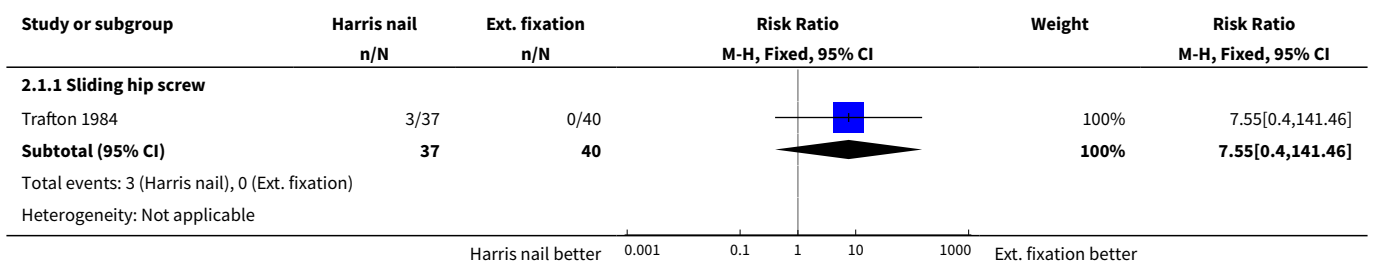


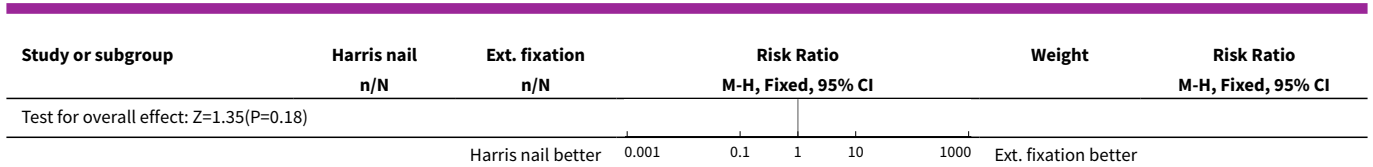


**Comparison 2. Harris nail versus extramedullary fixation implants**

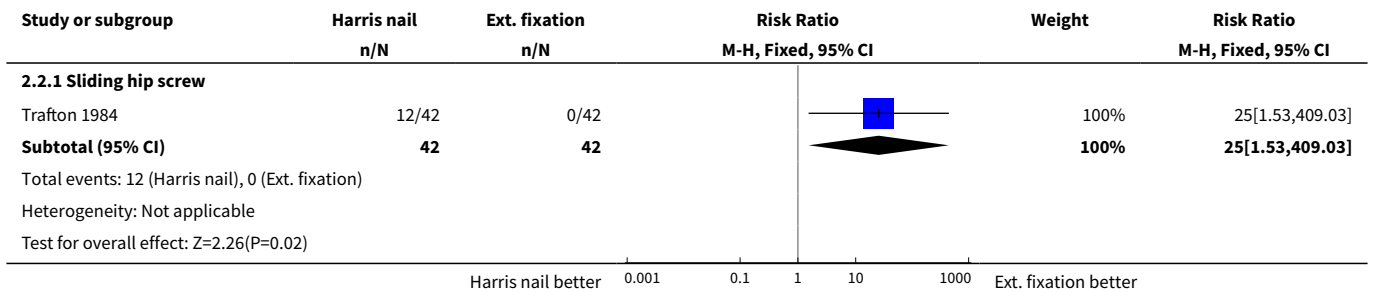
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<b>1 Non-union</b>	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Sliding hip screw	1	77	Risk Ratio (M-H, Fixed, 95% CI)	7.55 [0.40, 141.46]
<b>2 Fixation failure rate</b>	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Sliding hip screw	1	84	Risk Ratio (M-H, Fixed, 95% CI)	25.0 [1.53, 409.03]
<b>3 Reoperation</b>	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Sliding hip screw	1	84	Risk Ratio (M-H, Fixed, 95% CI)	3.5 [0.77, 15.88]
<b>4 Mortality: long term</b>	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Sliding hip screw	1	84	Risk Ratio (M-H, Fixed, 95% CI)	2.5 [0.51, 12.17]
<b>5 Failure to regain mobility</b>	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 Sliding hip screw	1	77	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [0.91, 2.89]

**Analysis 2.1. Comparison 2 Harris nail versus extramedullary fixation implants, Outcome 1 Non-union.**

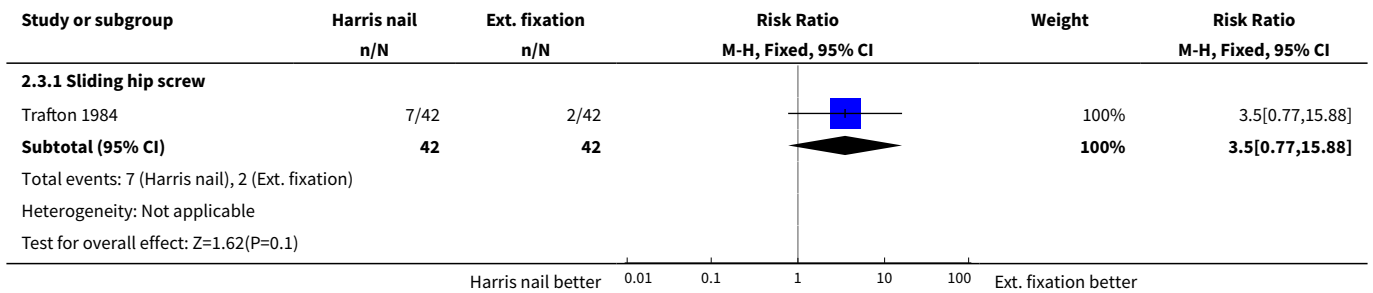




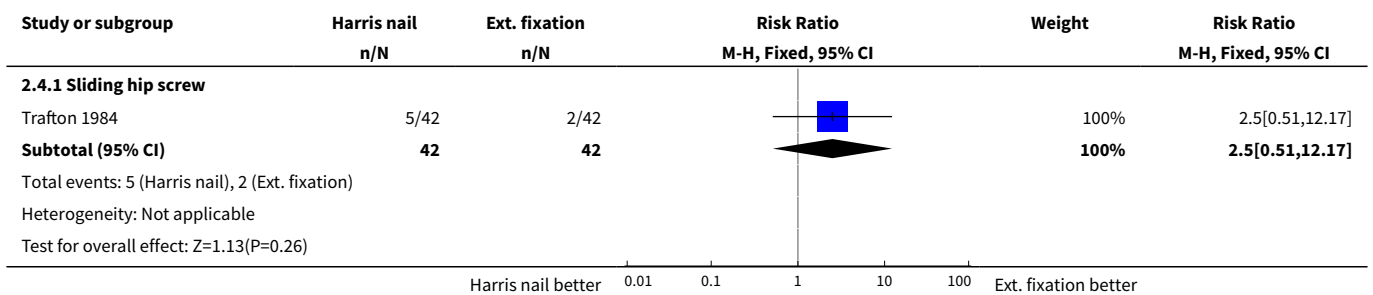
**Analysis 2.2. Comparison 2 Harris nail versus extramedullary fixation implants, Outcome 2 Fixation failure rate.**



**Analysis 2.3. Comparison 2 Harris nail versus extramedullary fixation implants, Outcome 3 Reoperation.**

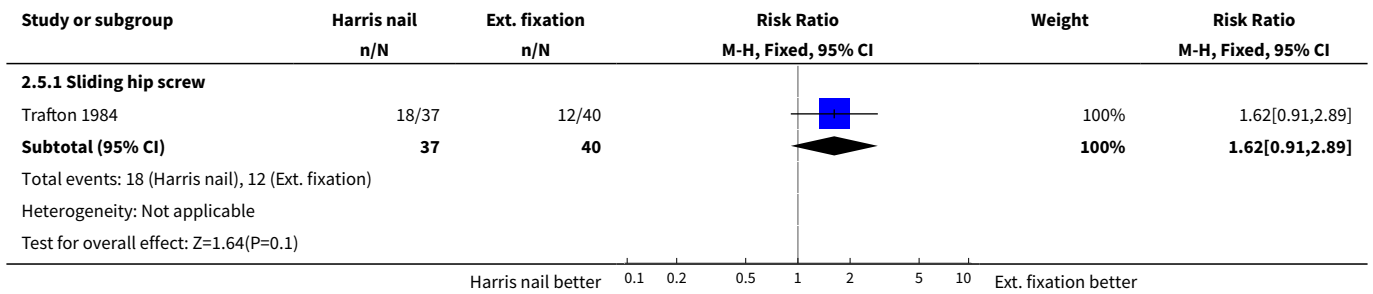


**Analysis 2.4. Comparison 2 Harris nail versus extramedullary fixation implants, Outcome 4 Mortality: long term.**





**Analysis 2.5. Comparison 2 Harris nail versus extramedullary fixation implants, Outcome 5 Failure to regain mobility.**



**APPENDICES**

**Appendix 1. Search strategy for MEDLINE (OVID-WEB)**

1. exp Hip Fractures/
2. hip\$ or femur\$ or femoral\$ or trochant\$ or petrochant\$ or intertrochant\$ or subtrochant\$ or intracapsular\$ or extracapsular\$) adj4 fracture\$).tw.
3. or/1-2
4. (pin\$1 or nail\$ or screw\$1 or plate\$1 or arthroplast\$ or fix\$ or prothes\$).tw.
5. Internal Fixators/ or Bone Screws/ or Fracture Fixation, Internal/ or Bone Plates/ or Bone Nails/
6. Arthroplasty/ or Arthroplasty, Replacement, Hip/
7. or/4-6
8. and/3,7

**Appendix 2. Search strategy for EMBASE (OVID-WEB)**

**EMBASE**

1. exp Hip Fracture/
2. ((hip\$ or ((femur\$ or femoral\$) adj3 (neck or proximal))) adj4 fracture\$).tw.
3. or/1-2
4. exp Randomized Controlled trial/
5. exp Double Blind Procedure/
6. exp Single Blind Procedure/
7. exp Crossover Procedure/
8. Controlled Study/
9. or/4-8
10. ((clinical or controlled or comparative or placebo or prospective\$ or randomi#ed) adj3 (trial or study)).tw.
11. (random\$ adj7 (allocat\$ or allot\$ or assign\$ or basis\$ or divid\$ or order\$)).tw.
12. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj7 (blind\$ or mask\$)).tw.
13. (cross?over\$ or (cross adj1 over\$)).tw.
14. ((allocat\$ or allot\$ or assign\$ or divid\$) adj3 (condition\$ or experiment\$ or intervention\$ or treatment\$ or therap\$ or control\$ or group\$)).tw.
15. or/10-14
16. or/9,15
17. limit 16 to human
18. and/3,17

## WHAT'S NEW

Date	Event	Description
5 September 2008	Amended	Converted to new review format.

## HISTORY

Protocol first published: Issue 3, 1996

Review first published: Issue 4, 1998

Date	Event	Description
15 September 2004	New citation required but conclusions have not changed	<p>This minor update (Issue 2, 2005) included:</p> <ol style="list-style-type: none"> <li>(1) Extension of literature search to September 2004.</li> <li>(2) Explicit confinement of scope to condylocephalic nails versus extramedullary implants. This reflected the availability of evidence from randomised trials and also the availability of another Cochrane review of comparisons between various intramedullary nails.</li> <li>(3) Change from 99% to 95% confidence intervals for the results of individual trials.</li> <li>(4) Other adjustments were made to text and tables to conform to revised methodology (e.g. use of the I squared statistic) and style guidelines.</li> </ol> <p>For details of previous updates, please see Notes.</p>

## CONTRIBUTIONS OF AUTHORS

Martyn Parker initiated the review, and compiled the first drafts of the protocol and review and subsequent revisions. Helen Handoll located the review studies. All four authors of the first version of the review assessed methodological quality and extracted data from the trial reports. Martyn Parker, Helen Handoll and Bill Gillespie devised the analyses. Helen Handoll checked data entry. Helen Handoll and Bill Gillespie critically rewrote the first draft and subsequent drafts of the first version of the review.

Helen Handoll and Martyn Parker produced the three non-substantive updates so far. Martyn Parker is the guarantor of the review.

## DECLARATIONS OF INTEREST

None known

## SOURCES OF SUPPORT

### Internal sources

- University of Teesside, Middlesbrough, UK.
- Peterborough and Stamford Hospitals NHS Foundation Trust, Peterborough, UK.

### External sources

- No sources of support supplied

## NOTES

Non substantive update published Issue 3, 2000 included:

- (1) Literature search extended to August 1999.

(2) Synopsis added.

Non substantive update published Issue 4, 2002 included:

- (1) Extension of literature search to June 2002.
- (2) Exclusion of newly identified studies: Cobelli 1985, Aparisi 1990.
- (3) Change to relative risks from Peto odds ratios.
- (4) Addition of citations for conference abstracts for four trials - no changes otherwise.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Fracture Fixation, Internal; \*Fracture Fixation, Intramedullary; \*Orthopedic Fixation Devices; Bone Nails; Bone Screws; Hip Fractures [\*surgery]; Internal Fixators

### **MeSH check words**

Humans