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Implant-related complications in the treatment of unstable intertrochanteric fractures: meta-analysis of dynamic screw-plate versus dynamic screw-intramedullary nail devices

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Abstract The choice between dynamic screw-intramedullary nail (DSIN) devices and dynamic screw-plate (DSP) devices for the fixation of unstable trochanteric fractures remains controversial. This study presents a meta-analysis of fixation failures in unstable trochanteric femoral fractures using DSP devices or DSIN devices. Two independent assessors selected randomised controlled trials using a range of electronic databases, as well as reference lists of selected articles. A study quality checklist was used. The occurrence of fixation failure, in particular cut-out, was the primary subject of analysis using descriptive statistics and random-effect meta-analyses. Seventeen trials were identified. Meta-analyses showed no significant difference in the frequency of implant-related complications between the two types of devices. Iatrogenic femoral fractures associated with the use of DSIN devices represent a rare, but persistent, risk. There was a tendency for less frequent cut-out with intramedullary devices compared with DSP devices.

Résumé Le choix entre clou centro-médullaire avec vis dynamique et vis-plaque dynamique pour la fixation des fractures trochantériennes instables reste controversé. Cette étude présente une méta-analyse d'échecs de la fixation des fractures trochantériennes instables utilisant ces deux procédés. Deux observateurs indépendants ont sélectionné des études cliniques randomisées utilisant plusieurs bases de données électroniques, aussi bien que les listes de référence des articles sélectionnés. Une liste de contrôle de la qualité de l'étude a été utilisée. L'événement d'échec de la fixation, en particulier la protrusion articulaire, était le sujet fondamental d'analyse. Dix-sept

études cliniques randomisées ont été identifiées. La méta-analyse n'a montré aucune différence notable dans la fréquence des complications liées à l'implant entre les deux types de matériel. Les fractures fémorales iatrogènes associées à l'usage de matériel centro-médullaire représentent un risque rare, mais persistant. Il y avait une tendance à des protrusions articulaires moins fréquents avec le système intramédullaire comparé avec les vis-plaque dynamiques.

Introduction

Proximal femoral fractures predominantly occur as low-energy injuries in elderly patients [18], and their number is increasing. Many implants and surgical techniques have been proposed for the surgical treatment of extra-capsular fractures [16]. Currently, the most popular implants for internal fixation of extra-capsular fractures are the dynamic screw-plate (DSP) devices. Fractures classified as unstable, however, have a higher risk of complications (e.g. cut-out) and mechanical failure in comparison with stable fractures. Although several systematic reviews of treatment options for extra-capsular fractures have been published in the Cochrane Library (e.g. [24, 25]), a critical comprehensive review of the unstable fracture sub-group was missing.

Systematic reviews are essential tools to provide evidence related to a particular field and are more objective than traditional narrative reviews [6]. Meta-analyses have the additional advantage of focusing on comparative studies, thus avoiding the inherent biases associated with case series. It is a method of summarising results of different studies quantitatively into single-effect measures estimated with higher precision. By pooling the study findings, conflicting results may be resolved [7], or alternatively, the need for further clinical studies may be strengthened by lack of evidence.

The purpose of this systematic review was the critical appraisal and summary of studies comparing DSP and dynamic screw-intramedullary nail (DSIN) devices used

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Table 1 Quality assessment of trials comparing dynamic screw-intramedullary nail devices (DSIN) with dynamic screw-plate (DSP) devices. ^a Studies ranked according to the year of publication. ^b Quality checklist is presented in Table 2

Study name ^a	Year	Country	1 ^b Treatment allocation	2 Surgeon experience	3 Care program— mobilisation	4 Blind outcome	5 Patient follow-up	6 Patient losses	7 Analysis
Bridle [4]	1991	UK	4	—	—	0	3	34%	2
Leung [19]	1992	Hong Kong	1	—	Mobilisation as early as pain permits	0	3	18%	2
Guyer [11]	1993	Switzerland	2	1	FWB at day 3 whenever possible	0	2	40%	2
Pahlplatz [22]	1993	Netherlands	2	1	—	0	3	15%	0
Fornander [8]	1994	Sweden	2	2	—	0	3	19%	2
Goldhagen [10]	1994	USA	1	0	FWB after 4–6 weeks for DSP	0	3	13%	1
Butt [5]	1995	UK	1	—	—	0	0	7%	2
O'Brien [21]	1995	Canada	3	—	—	0	1	33%	1
Kukla [17]	1997	Austria	4	—	FWB asap unless fracture A2/A3	0	3	26%	2
Baumgaertner [3]	1998	USA	3	0	—	0	0	20%	2
Hardy [12]	1998	Belgium	1	0	Sitting at day 2, FWB at day 4	0	3	30%	2
Madsen [20]	1998	Norway/Finland	2	0	FWB asap	0	3	18%	1
Park [23]	1998	Korea	1	—	FWB at 2 weeks—later for unstable DSP	0	1	—	2
Hoffmann [14]	1999	Germany	4	1	—	0	1	20%	1
Adams [1]	2001	Scotland	4	2	Similar for both groups	1	3	38%	2
Harrington [13]	2002	UK	4	2	FWB was allowed from the outset	1	3	38%	2
Ahrengart [2]	2002	Sweden	4	2	—	0	6	29%	2

in the treatment of intertrochanteric femoral fractures, the main focus being on the occurrence of fixation failure and cut-out (primary outcome) in unstable fractures.

Materials and methods

Eligibility criteria

Randomised clinical trials comparing treatment with DSP (e.g. the dynamic hip screw) or DSIN (e.g. the Gamma nail) in patients with intertrochanteric femoral fractures were included. We rejected articles for which the proportion of unstable fractures could not be extracted. Restriction was made to articles in French, English and German.

Study identification, reviewer agreement and study methodological quality

We searched relevant references in MEDLINE, EMBASE, the Cochrane Controlled Trials Register, the Cochrane Musculoskeletal Injuries Group (CMSIG) Trial Register, and the Cochrane Library up to December 2002. Additional studies were searched via reference lists as well as through contact with members of the CMSIG. Two independent assessors reviewed all abstracts in order to select relevant studies. Any disagreements were resolved by consensus.

All selected studies were assessed by the first author for methodological quality using the checklist of the updated review of

Parker and Handoll [24] (Leeann Morton, CMSIG, personal communication). Quality dimensions are presented with results in Tables 1 and 2.

Data extraction and analyses

Data relating to study characteristics, population demographics, fracture type, prognostic factors, operative details and surgical and functional outcomes were extracted using an MS Excel template. A second reviewer checked the accuracy of data extraction. The total number of fractures operated on was used as a denominator to calculate the proportions for implant-related complications.

Analyses were mostly descriptive. We conducted meta-analyses when appropriate using the softwares RevMan 4.1 and MetaView 4.1 (The Cochrane Collaboration, UK) with random effect models to compute overall relative risks and 95% confidence intervals. Sensitivity analyses were conducted by withdrawing selected studies as appropriate.

Results

Study characteristics and potential for heterogeneity

Classification of unstable fractures

Seventeen randomised controlled trials (RCTs) were included. Sixteen studies used at least one classification

Table 2 Quality checklist pertaining to Table 1

1	Treatment allocation: randomisation of patients to surgical treatments and concealment of allocation 4 = True randomisation (e.g. using random numbers) with concealment of allocation (e.g. when sealed envelopes were used) 3 = True randomisation and concealment of allocation probable 2 = True randomisation probably done (i.e. no mention of the method of randomisation used) 1 = Pseudo-randomised trials (e.g. randomisation according to patient record number)
2	Did the surgeons have experience of the operations they performed in the trial prior to its commencement? 2 = Yes; 1 = participation of registrars/assistants; 0 = Some of the surgeons had no experience
3	Patient mobilisation protocol FWB = Full weight bearing; asap = as soon as possible
4	Were the outcome assessors blind to assignment status? 1 = clearly yes; 0 = probably no or clearly no
5	Type and timing of patient follow-up 3 = Active follow-up at 6 or 12 months; 2 = Active follow-up at 3 months; 1 = Follow-up after 3, 6 or 12 months; 0 = Follow-up undefined
6	Patients lost to follow-up (including mortalities) (%)
7	Did authors check for balance of prognostic factors between groups in an RCT and did they conduct a statistical adjustment when appropriate? 2 = Yes (e.g. using multivariable statistical techniques); 1 = Yes, partly (e.g. with a few factors only such as age and gender, or no statistical adjustment in the case of imbalance); 0 = No

scheme for intertrochanteric fractures. These were the Evans' classification (three papers) modified by Jensen (eight papers), the AO classification (four papers), the classification of Kyle et al. (two papers) and that of Tronzo (one paper). Hoffmann et al. [14] and Adam et al. [1] used both the Evans/Jensen and the AO classification, but we applied the Evans/Jensen classification data in this review. Fornander et al. [8] utilised the modified Evans classification but considered type III as stable, whereas other authors regarded it as an unstable fracture pattern. Their proportion of unstable fractures of 21% (44/208) was the lowest of all papers. For other studies that included both fracture types, the proportion of unstable fractures ranged from 44 (52/145) to 73% (82/100). Madsen et al. [20] and Harrington et al. [13] considered only unstable fractures. The number of patients accrued ranged from 60 to 432 (median 104), the mean age of patients within studies ranged from 73 to 83.5 (median 80.4) years, and the female:male ratio ranged from 1.5 to 5.8 (median 3.3).

Study quality dimensions

Study quality dimensions are presented in Tables 1 and 2. Two trials had no well-defined time to follow-up [3, 5], and three others reported (suspected passive) follow-up after 3 [14], 6 [21] and 12 [23] months. Active examination of patients at 3 and 6 months after operation was conducted in eight trials, but only at 3 [11] or 6 [2, 4, 17] months in the other four trials. Two trials specifically reported that assessors were not aware of the type of implant used in a given patient at the time of follow-up (i.e. so-called blind assessment of outcome parameters) [1, 13]. The proportion of patients lost to follow-up (including mortalities) ranged from 7 to 40% with a median of 26%. The balance between randomised groups with re-

gard to some important patient baseline characteristics was checked in 12 trials. Other trials either failed to do so or did not statistically adjust analyses for imbalance between groups.

Outcome results

There was a varied standard of reporting and use of definitions for many outcome parameters investigated in this review. Using cross-tabulations of study results, we observed no obvious difference between the two types of implant for these outcomes. Results are not presented in detail, but additional information can be obtained from the main author. Implant-related complications were more consistently reported between trials, allowing the implementation of meta-analysis.

Intra-operative complications

Intra-operative complications are presented in Table 3. Risks ranged from 1 to 17% (median 5%) in patients treated with DSIN devices, and from 0 to 11% (median 0%) in patients treated with DSP devices. The majority of reported intra-operative complications of DSIN devices were related to failure to lock the intramedullary nail distally and to iatrogenic fractures, while failures of fracture reduction or fixation/stabilisation accounted for most of the complications with DSP devices. Because some complications, such as failure of distal locking and failure of reduction, might not have been reported in all trials, this analysis is descriptive. Iatrogenic fractures were regularly reported with a use of DSIN devices but at a low frequency.

Table 3 Distribution of intra-operative complications observed during treatment of intertrochanteric fractures with dynamic screw-intramedullary nail (DSIN) and dynamic screw-plate (DSP) devices, respectively. ^a Intra-operative complications were not reported by Pahlplatz, Butt and Madsen

Study ^a	Year	% unstable fractures	DSIN devices				DSP devices										
			N	n	%	Femoral head penetration	Failure of distal locking	Iatrogenic fractures	Device breakage or technical problem	Failure of reduction and fixation of fracture	N	n	%	Femoral head penetration	Iatrogenic fractures	Device breakage or technical problem	Failure of reduction and fixation of fracture
Bridle [4]	1991	59%	49	1	2%	—	—	1	—	—	51	0	0%	—	—	—	—
Leung [19]	1992	73%	93	13	14%	—	3	3	4	3	93	10	11%	—	2	2	6
Guyer [11]	1993	50%	50	2	4%	—	1	1	—	—	50	0	0%	—	—	—	—
Forlander [8]	1994	21%	105	1	1%	—	—	—	—	—	104	3	3%	2	1	—	—
Goldhagen [10]	1994	50%	35	5	15%	—	1	4	—	—	40	0	0%	—	—	—	—
O'Brien [21]	1995	44%	53	2	4%	—	—	2	—	—	49	0	0%	—	—	—	—
Kukla [17]	1997	54%	60	3	5%	—	2	—	1	—	60	6	10%	—	—	—	6
Baumgaertner [3]	1998	51%	67	3	4%	—	—	2	1	—	68	0	0%	—	—	—	—
Hardy [12]	1998	71%	50	5	10%	—	2	3	—	—	50	0	0%	—	—	—	—
Park [23]	1998	58%	30	3	10%	—	—	1	—	2	30	0	0%	—	—	—	—
Hoffmann [14]	1999	64%	56	5	4%	—	3	2	—	—	54	2	4%	—	2	—	—
Adams [1]	2001	48%	203	2	1%	—	—	2	—	—	197	0	0%	—	—	—	—
Harrington [13]	2002	100%	50	1	2%	—	—	1	—	—	52	0	0%	—	—	—	—
Ahrensart [2]	2002	48%	210	36	17%	—	21	5	5	5	216	11	5%	—	2	2	7

Table 4 Distribution of post-operative implant-related complications reported following treatment of intertrochanteric fractures with dynamic screw-intramedullary nail (DSIN) and dynamic screw-plate (DSP) devices, respectively. ^a Post-operative complications were not reported by Pahlplatz

Study ^a	Year	% unstable fractures	DSIN devices				DSP devices							
			N	n	%	Cut-out	Femoral fractures	Other failure of fixation	N	n	%	Cut-out	Femoral fractures	Other failure of fixation
Bridle [4]	1991	59%	49	7	14%	2	4	1	51	3	6%	3	—	—
Leung [19]	1992	73%	113	4	4%	2	2	—	113	3	3%	3	—	—
Guyer [11]	1993	50%	50	2	4%	1	—	1	50	3	6%	3	—	—
Forlander [8]	1994	21%	105	7	7%	3	2	2	104	5	5%	3	—	2
Goldhagen [10]	1994	50%	35	3	9%	2	1	—	40	0	0%	—	—	—
Butt [5]	1995	44%	47	11	23%	—	8	3	48	3	6%	—	—	3
O'Brien [21]	1995	44%	53	4	8%	3	1	—	49	1	2%	1	—	—
Kukla [17]	1997	54%	60	0	0%	—	—	—	60	0	0%	—	—	—
Baumgaertner [3]	1998	51%	67	5	7%	2	3	—	68	2	3%	2	—	—
Hardy [12]	1998	71%	50	0	0%	—	—	—	50	1	2%	—	—	1
Madsen [20]	1998	100%	55	4	7%	2	2	—	44	3	7%	3	—	—
Park [23]	1998	58%	30	1	3%	1	—	—	30	2	7%	1	—	1
Hoffmann [14]	1999	64%	56	0	0%	—	—	—	54	2	4%	—	—	2
Adams [1]	2001	48%	203	10	5%	8	2	—	197	7	4%	4	1	2
Harrington [13]	2002	100%	50	2	4%	1	1	—	52	2	4%	1	—	1
Ahrensart [2]	2002	48%	210	14	7%	14	—	—	216	4	2%	4	—	—

Comparison: 01 DSIN versus DSP devices

Outcome: 01 Post-operative cut-out

Fig. 1 Meta-analysis of post-operative cut-out after the treatment of intertrochanteric fractures with dynamic screw-intramedullary nail devices (DSIN) or with dynamic screw-plate (DSP) devices

Post-operative complications

Post-operative implant-related complications (including cut-out, femoral fractures and other failures such as re-fracture/dislocation and pull-out of the side plate) reported for 16 studies are described in Table 4. Risks ranged from 0 to 23% (median 6%) in patients treated with DSIN devices, and from 0 to 7% (median 3%) in patients treated with DSP devices. Main complications after treatment with DSIN devices were late fractures, mostly around the tip of the nail—in particular in one study [5]—and cut-out in a recent study [2].

A meta-regression analysis of the occurrence of these complications showed no significant association between the relative risks computed for individual studies and the percentage of unstable fractures. Overall, surgeons had a significant 1.7 times higher risk (95% CI 1.2–2.5) of experiencing (and reporting) post-operative implant-related complications with DSIN devices compared with DSP devices. Two studies showing significantly more complications with DSIN devices were of overall lower methodological quality than others [5,

10]. Removing these studies did not change the overall effect.

A meta-analysis of the occurrence of cut-out is presented in Fig. 1. This analysis shows no significant difference of occurrence between DSIN and DSP devices. This analysis, however, considers the sub-group of studies from which only data related to unstable fractures could be obtained. There are inconsistent results between this group of studies and the other, with a tendency that DSIN devices caused a lower proportion of cut-out than DSP devices when considering data for unstable fractures only (overall relative risk = 0.51; 95% CI=0.17–1.5) and the reverse results from mixed data (overall relative risk = 1.7; 95% CI=1.0–3.0).

Discussion

Unstable fractures are difficult to manage because of enormous mechanical stresses at the proximal femur. In this systematic review, we considered the best current evidence on treatment of unstable intertrochanteric fractures from studies comparing DSP and DSIN devices. We identified 17 randomised studies meeting our selection criteria, which is greater than other systematic reviews in orthopaedics. This enhances the strength of the evidence presented.

We have considered methodological quality dimensions related to the internal validity of studies. For instance, regarding the type and timing of outcome assessment, we considered whether patient follow-up was active (i.e. significant efforts were made to examine all patients at given pre-specified time points) or passive (i.e. no effort was made to examine patients at the same time points). Active follow-up is preferred because if outcome measures are not systematically assessed within the same time frame the data is weak and subject to intense detection bias. Nevertheless, it is believed that at least 6 months of rehabilitation should be allowed for patients with unstable fractures before assessing the final clinical outcome [26]. Five trials had methodological weakness on that front [3, 5, 14, 21, 23].

Various classifications used to distinguish between stable and unstable fractures were used. Although their reliability was questioned [9, 15], definitions of unstable fracture were fairly similar with regard to the lack of medial support. The reported percentage of unstable fractures was the best measure available for this review.

The present evidence suggests that DSIN devices are associated with a higher risk of intra-operative complications than DSP devices. We could not assess whether this difference was related to fracture stability, but the most common complications more specific to the surgical technique of DSIN devices were failure of “distal locking” and “iatrogenic fracture”. Iatrogenic fractures seem to be a rare but recurring problem. Some of these fractures were attributed by certain authors to the limited experience of the surgeons [3, 12, 14], but even with experience and a well-defined surgical technique, the problem of femoral-shaft fractures can persist without appropriate surgical planning and respect of the surgical procedure [1, 13].

The significant 1.7 times increased risk of experiencing (and reporting) a post-operative failure of fixation with DSIN devices compared with DSP devices observed in this review is probably related to the occurrence of femoral fractures with DSIN devices. The study of Butt et al. [5] had the most impact on the meta-analysis result. It reported eight femoral fractures in 47 patients treated with DSIN devices. In a meta-regression, we found no significant relationship between effect estimate from individual studies and the percentage of unstable fractures within studies. However, the most recent trial reported by Harrington et al. [13] was methodologically well conducted, included unstable fractures only and failed to show a significant difference in fixation failures between the two types of implants. In a more recent trial, Ahrengart et al. [2] reported a high risk of cut-out following the use of the Gamma nail, which they associated with the sub-optimal placement of the lag screw in the femoral head. This highlights the importance of the surgical technique.

Consistent with the observation of Parker and Handoll [24], there was no significant difference in the risk of cut-out between DSIN and DSP devices, although a dis-

crepancy between study sub-groups is notable. Results favoured DSIN devices when considering data from unstable fractures only, but favoured DSP devices when data from studies mixing stable and unstable fractures were analysed. This suggests that DSP devices may be superior in stable fractures, and that mixing stable and unstable fractures in the same study may “dilute” evidence of a potentially beneficial effect of DSIN devices with regard to the risk of cut-out.

This review failed to identify a clear significant clinical advantage of one device (DSIN or DSP) over the other for the treatment of unstable intertrochanteric fractures, although overall implant-related complications occurred more frequently with DSIN devices. This could be related to the problem of “case-mix” and heterogeneity of trial protocols. This review provides a strong rationale for more clinical research specifically conducted in unstable fractures.

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