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Review

Lacking evidence for performance of implants used for proximal femoral fractures – A systematic review

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ABSTRACT

Introduction: Evaluation of the long-term performance of implants used in trauma surgery relies on post-marked clinical studies since no registry based implant assessment exists. The purpose of this study was to evaluate the evidence of performance of implants currently used for treating proximal femoral fractures (PFF) in Denmark.
Method: PubMed was searched for clinical studies on primary PFF with follow-up ≥12 months, reporting implant-related failure and evaluating one of following: DHS, CHS, HipLoc, Gamma3, IMHS, InterTan, PFN, PFNA or PTN. Limits: English language and publication date after 1st of January 1990.
Results: All studies were evidence level II or III. 30 publications for SHS were found: 13 of CHS, 15 of DHS and 2 of HipLoc. In total CHS was evaluated in 1110 patients (900 prospectively), DHS in 2486 (567 prospectively) and HipLoc in 251 (all prospectively). Fifty-four publications for nails were found: 13 of Gamma3, 7 of IMHS, 5 of InterTan, 10 of PFN, 24 of PFNA and 0 of PTN. In total Gamma3 was evaluated in 1088 patients (829 prospectively), IMHS in 1543 (210 prospectively), InterTan in 595 (585 prospectively), PFN in 716 (557 prospectively), PFNA in 1762 (1018 prospectively) and PTN in 0.
Conclusions: The clinical evidence behind the current implants used for proximal femoral fractures is weak considering the number of implants used worldwide. Sporadic evaluation is not sufficient to identify long term problems. A systematic post market surveillance of implants used for fracture treatment, preferable by a national register, is necessary in the future.

Contents

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Introduction

The treatment of fractures is constantly evolving with introduction of many new implants as well as modifications of current implants. Awareness of need for best possible evidence-based treatment is emerging not least by establishment of clinical guidelines and registries [1]. In the field of arthroplasty, the well-established continuous registration on specific implant level has proven beneficial in detecting implants with inferior survival rates, as exemplified by the high reoperation rate of ASR hip prosthesis first reported by the Australian Orthopaedic Association National Joint Replacement Registry [2]. Traumatology is one of the largest subspecialities in orthopaedic surgery, with hip fractures being the most commonly surgically treated fractures [3]. Despite the fact that procedures for hip fractures have an incidence of approximately 1–2/1000 [4,5], thus having similar frequency as hip arthroplasties [6], no systematic registration of implant performance exist, not for hip fractures or for other fracture-related implants.

The purpose of this study was therefore to evaluate and present the evidence of implant survival and technical failures of the specific implants currently in use for treating a proximal femoral fracture in Denmark.

Methods

A full protocol was written and registered at PROSPERO International prospective register of systematic reviews, University of York (Registration number CRD42015016908).

Implants for treating proximal femoral fractures used by any orthopaedic centres in Denmark (23 departments, covering the entire population of 5,600,000) were identified in January 2015. Only the main types of sliding hips screws (SHS) and antegrade intramedullary nails (IMN) used for proximal femoral fractures (OTA/OA type 31A and 31B) were included for this analysis, thus excluding implants used for caput, subtrochanteric and shaft femoral fractures (OTA/OA type 31C and 32). The following implants were identified:

SHS: Dynamic Hip Screw (DHS, Synthes), Compression Hip Screw (CHS, Smith&Nephew) and HipLoc (Biomet).
IMN: Gamma3 (G3, Stryker), InterTan (Smith&Nephew), Intramedullary Hip Screw (IMHS, Smith&Nephew), Proximal Femoral Nail (PFN, DePuy-Synthes), Proximal Femoral Nail Antirotation (PFNA, Depuy-Synthes) and PeriTrochanteric Nail (PTN, Biomet) (Table 1).

The electronic database of PubMed was searched using the following search lines:

- (Intramedullary nail OR IMHS OR (intramedullary hip screw) OR PFN OR (proximal femoral nail) OR PTN OR (Peritrochanteric Nail) OR Gamma 3 OR PFNa OR (Proximal femoral nail antirotation)) AND (hip fracture OR cephalomedullary fracture OR trochanteric fracture OR femoral fracture OR "Hip Fractures"[Mesh]) (search performed 20th of November 2014).
- (sliding hip screw OR SHS OR (dynamic hip screw) OR DHS OR (compression hip screw) OR CHS OR HipLoc) AND (hip fracture OR cephalomedullary fracture OR trochanteric fracture OR femoral fracture OR "Hip Fractures"[Mesh]) (search performed 10th of January 2015).

Furthermore the Cochrane library was searched.

In addition, the reference lists of included studies and all related review articles were checked for further publications fulfilling the inclusion criteria. Language was restricted to English and publication date to after 1st of January 1990. The inclusion criteria are as follows:

- Clinical studies on patients with primary trochanteric (OTA/OA 31A) or femoral neck fracture (OTA/AO 31B), excluding pathological fractures.
- Retrospective studies, prospective studies and randomised trials are included.
- Interventions included as listed above.
- Implant related failure reported as an outcome.
- Follow up of at least 12 months.
- Studies with clearly specified implants, excluding publications where specific type of implants used was unclear or grouped together without possibility to evaluate implant-specific failure.
- Studies evaluating only augmented PFNA were excluded since this technique is not commonly used in Denmark.
- Osteotomy is considered outdated thus publications using this technique were excluded.

Two authors (AN and HP) independently undertook the screening of studies. An initial screening of titles and abstracts was performed to remove those that were obviously outside the scope of the review. When the title or abstract could not be rejected with certainty, the full text article was obtained for further evaluation. Two independent authors (AN and HP) evaluated the full text articles identified during the initial screening process. In 28 cases disagreement was solved by discussion between the two authors. In one case a third author was consulted (KG).

Data were extracted for all studies that met the inclusion criteria. For each study, two review authors (AN and KG) independently completed data extraction forms that were tailored to the requirements of this review. All disagreements were resolved by discussion between the two review authors. In all cases consensus was made by discussion between the two authors.

The following information was extracted from each publication:

- Year of publication
- Specific type of implant
- Time-period of intervention (when the patients were operated)
- Type of fracture
- Number of patients
- Number of females
- Age of patients
- Follow up time

Level of evidence was evaluated for each study in accordance with OCEBM Levels of Evidence Working Group, "The Oxford 2011 Levels of Evidence", Oxford Centre for Evidence-Based Medicine, [7] (accessed 6th of March 2015).

After completion of the searches the manufacturing companies were contacted and asked if any changes or updates had been made

Table 1
Implants used in Denmark.

Sliding hip screws
Compression Hip Screw (Smith&Nephew)
Dynamic Hip Screw (Depuy-Synthes)
HipLoc (Biomet)
Intramedullary nails
Gamma3 (Stryker)
InterTan (Smith&Nephew)
Intramedullary Hip Screw (Smith&Nephew)
Proximal Femoral Nail (Depuy-Synthes)
Proximal Femoral Nail Antirotation (Depuy-Synthes)
PeriTrochanteric Nail (Biomet)