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Tips and tricks to avoid implant failure in proximal femur fractures treated with cephalomedullary nails: a review of the literature

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Abstract

Objective: To describe the surgical aspects potentially contributing to hardware failure of cephalomedullary nails.

Data Sources: A search of the Embase, PubMed (MEDLINE), Web of Science, and the Cochrane library for reports of hardware failures after intramedullary fixation of proximal femur fractures. Issues of cut out and cut through phenomena related to technique were excluded. Expert opinion of 3 surgeons, each trained on several fixation systems at Level | trauma centers is reported.

Data Extraction: Three authors extracted data using a predesigned form. Implant type, reported failure mechanism, and associated factors with implant failure were recorded as well as potential bias.

Results: Of 2182 search results screened, 64 articles were deemed relevant for our research question and were included. The authors identified factors associated with implant failure: preoperative patient and fracture characteristics, intraoperative reduction, implant handling, and postoperative nonunion. Issues were identified as independent modifiable intraoperative risk factors: inadequate fracture reduction, varus position of femoral neck, direct damage of the cephalomedullary nail aperture by eccentric drilling related to guide sleeve handling, and implant design mechanism failures.

Conclusions: Multiple factors associated with intraoperative handling can influence the healing of proximal femur fractures. Although many of these have been well described and are taught in fracture courses, surgeons should be aware of subtle intraoperative complications reported in the literature that can weaken implants and add to the likelihood of early failure.

Level of Evidence: IV

Keywords: cephalomedullary nails, early failure, intraoperative complications, proximal femur fractures

1. Introduction

The majority of proximal femur fractures occur in patients above age 75.[1] These fractures are one of the leading causes for hospital admission in elderly patients and the top reason for their admission to an orthopedic ward. These fractures are becoming increasingly prevalent, with an estimated incidence of 2.1 to 7.3 million by 2050.[2] The goal of care for patients with these fractures is to restore function and ability to weight bear. Given the poor physiologic reserve of these patients, it is also essential to minimize surgical and medical complications.

Cephalomedullary nails have become a common implant used to treat various types of proximal femur fractures.[3,4] A number of implants from different manufacturers are at the surgeon's disposal to treat these fractures. Current evidence is inconclusive as to the superiority of a particular design of cephalomedullary device in treating these fractures.[5]

The failure of fixation around the implant has been extraordinarily well described, with implant cut-out occurring in approximately 5%.[5] Nail breakage has traditionally not been in the focus of papers on cephalomedullary nailing as the rate appears to be negligibly low. A number of recent articles have highlighted the potential for fatigue failure of the cephalomedullary nail in approximately 1% of cases, which may be related to intraoperative technique rather than design factors.[6] It is known that notching of the cephalic screw aperture can result from iatrogenic intraoperative damage from inappropriate drill alignment. An Australian laboratory analysis of 13 patients with 16 cases of implant failure at the TFN-ADVANCED Proximal Femoral Nailing System (TFNA, Depuy Synthes, Oberdorf, Switzerland) nail aperture suggested that these failed without signs of such damage, but this has yet to be confirmed in the literature.[7] One further study assessed implant reports in the FDA MAUDE database and reported earlier failure of the TFNA versus the Gamma (Stryker, Kalamazoo, Michigan) nail—but another study of a US healthcare database suggested similar failure rates and implant survival time compared to non-TFNA

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nails.[8,9] All implants undergo thorough preclinical testing; it remains to be seen whether implant design plays a role in cases of postoperative implant failures, or if these are predominantly due to intraoperative factors.

The authors of this manuscript are aware of this ongoing discussion and have felt that a certain learning curve for surgeons in training, or experienced surgeons that retrain to a different implant should be considered as well. Therefore, the current review summarizes the surgical aspects potentially contributing to hardware failure of cephalomedullary nails, associated with intraoperative handling issues.

2. Methods

This article represents level IV evidence from a group of experienced surgeons and biomechanics experts that were involved in development groups for implants (KS and HCP), involved in biomechanical testing (BG and LEV) and trained on different devices (JLP, LEV, KS, and HCP).

2.1. Screening and assessment of eligibility

Two reviewers (LEV and JLP), both with methodological expertise, and 3 authors with content expertise (HCP, KS, and BG), independently reviewed the titles and abstracts of articles identified in the literature searches to determine if the articles should be considered for inclusion. Articles were included if they discussed failure of cephalomedullary nail fixation in proximal femur fractures. Articles were excluded for use of an implant other than a cephalomedullary nail, or if they discussed nail cut-out or cut-through related to technique. A search of Embase, PubMed (MEDLINE), Web of Science, and the Cochrane library was conducted. The search terms were: (cephalomedullary OR "femoral nail" OR "TFN*" OR "PFN*" OR "gamma nail*" OR "Intertan" OR "natural nail") AND ("break*" OR "fail*" OR " implant fracture" OR "Nail fracture") NOT biomechanical [Title] published after 2000 to assess modern nail design. In the Cochrane database, the search was cephalomedullary and separately for femur nail. The retrieved search results for Pubmed (554), Web of Science (811), Embase (807), Cochrane Reviews (10) were screened for content related to implant failure in the title and abstract. The authors independently reviewed the 64 full-text articles that were identified to meet inclusion criteria. Any conflicts were discussed to achieve consensus. A predesigned form was used to record the implant type, reported failure mechanism, and associated factors with implant failure and potential bias were recorded.

3. Results

A total of 2182 search results were screened and 64 full text manuscripts were included. Manuscripts on the topic of implant failure included case series, case reports, and expert reviews (Table 1). The reviewing authors of this manuscript (LEV and JLP), identified the main reasons reported for implant failure. Failure of the intramedullary implant itself has been linked to patient factors, intraoperative malreduction, iatrogenic implant damage, and nonunion.[8,10] These relevant causes of postoperative implant failure are listed in Table 2.

Table 1

Publications discussing implant failure.

Publication type	Number of publications	Level of evidence
Case report	11	IV
Case series	20	IV
Expert review	5	V
Retrospective cohort or Database study	16	III
Prospective trial	6	II
Systematic review	6	I/II

Table 2

Common causes of implant failure.

Preoperative—patient and fracture factors
- a. Pathological fractures—malignancy, bisphosphonate fractures
- b. Unstable fracture type—subtrochanteric, reverse oblique

Intraoperative—implant factors
- a. Direct damage of entry port for cephalomedullary nail by eccentric drilling
  - Intraoperative rotation of handle (all brands) (Fig. 1A)
  - Incomplete soft tissue sleeve application (all brands) (Fig. 1B)
- b. Implant design
  - Blockage of engaged screws in case of double screws (eg, Intertan)
  - Malrotation of cephalomedullary screw, thus preventing gliding (eg, Gamma nail)
  - Failure of sliding mechanism, if position diverging (eg, Veronail)
- c. Implant selection
- d. Intraoperative technique

Postoperative implant fatigue—delayed or nonunion
- a. Incomplete fracture reduction
- b. Varus position of femoral neck
- c. Large osseous gaps, for example, reverse oblique

4. Discussion

Failure of any cephalomedullary nail overwhelmingly occurs at the proximal aperture for the lag screw by design. This weakness can be emphasized, when intraoperative drilling is imprecise and damages the aperture. Thereby, damage of the nail by uncentered drilling can exacerbate the problem of nail breakage in all types of nails. Both issues are benchtop tested during the development of any cephalomedullary nail.

From a biomechanical point of view, the intramedullary nail acts as an internal splint along the anatomical axis of the bone and provides angular fixation in a relative stability construct. The implant is ideally load sharing, with fracture cortical contact and distribution of load along the locking screws and along its length at the nail bone interface. The function of the nail is to maintain length, alignment, and rotation until fracture union.[11,12] In trochanteric fractures, the nail allows for "controlled collapse" of fragments to achieve bone-on-bone stability, with a shorter lever arm and less eccentric load compared to a dynamic hip screw. Acceptable fracture reduction is a prerequisite to optimal lag screw positioning. [13]

4.1. Preoperative factors

The failure of intramedullary nails has been associated with preoperative patient factors and specific unstable fracture types. In an early series, Johnson et al[10] reported 41% of cases of implant failure which were related to pathological fracture. In these cases, the largest possible diameter nail should be utilized, and the patient should be carefully followed, as the implant cannot be assumed to outlive the patient.[10,14] Special emphasis regarding failure of implants has been associated with reverse oblique and especially subtrochanteric fractures.[10,15,16] These unstable fracture types are definite indications for the use of a cephalomedullary nail over an extramedullary implant. The morphology and fracture mechanics mean a surgeon can place these implants under higher stress, when compared with stable fracture types which can shorten against a stable bony buttress to support load sharing. Many surgeons would advocate for the use of a long cephalomedullary nail in these unstable fracture patterns, which might encourage more even load distribution. Although the literature is inconclusive.[17] Interestingly, almost half the implants used in the Australian TFNA paper were reported to be short nails, which is surprising, as the fracture types appeared to represent predominantly unstable patterns.[7]

4.2. Intraoperative factors

One of the main goals of intramedullary nailing of the proximal femur is to achieve healing in an anatomical position. Implant breakage before healing has been associated with malreduction or improper implant positioning in unstable intertrochanteric fractures and subtrochanteric fractures.[10,15] In intertrochanteric fractures, anatomical reduction is pivotal before reaming to allow proper nail placement. In the majority of fractures this can be achieved with traction, internal rotation and adjustment of adduction/abduction. It is important to be aware of more complex fracture types, which can involve the proximal fragment telescoping to lie within the medullary canal that may require specific reduction techniques.[18] It is important for the surgeon to know the selected implant and indicated starting point. The majority of current cephalomedullary devices are with trochan-teric entry, and the starting point should be just medial to the tip of the greater trochanter. The patients' soft tissue and typical lower density bone will tend to push sequential reamers laterally in the greater trochanter. Placing the ring of a Kocher clamp or similar instrument around the guide wire and applying a lateral to medial force can help medialize the reamer, preventing an eccentric starting position and varus positioning. Alternatively, a hollow reamer can be used to make and remove a bone plug exactly where the nail should be inserted. Scissoring the legs rather than lithotomy position of the contralateral leg may prevent rotation of the body and pelvis around the perineal post, which can make proper entry placement difficult. Subtrochanteric fractures can be especially difficult to reduce, and in varus malreduction the implant is loaded rather than the fracture which results in higher rates of implant failure (Fig. 1).[10,19] These fractures present with significant initial displacement of flexion, abduction and external rotation, and sagittal displacement can be made worse in traction. There are specific starting points indicated in subtrochanteric nailing. If a cephalomedullary nail is used in an older patient, the starting point should be more medial and anterior than for a trochanteric fracture to aid in valgizing the proximal fragment. A piriformis entry reconstruction nail is indicated in younger patients and more distal subtrochanteric fractures, the starting point should be more anterior in the piriformis fossa than for a shaft fracture. Too lateral an entry point will result in varus position, if this occurs medialization of the entry point can be achieved with lateral placement at the entry site of a plate, chisel, or fibular strut. Conversely, medial communication can result in inadvertent over reaming of the comminuted segment distal to the isthmus which can also result in varus positioning. In this setting focused lateral reaming can be achieved by pushing the lateral fragment with a ball and spike, or pulling the guide wire or medial fragment with a bone hook, which preserves the nail trajectory.

There are cases of early failure of cephalomedullary implants that may be related to iatrogenic damage at the aperture. A study of FDA medical device reports found that almost all early failures of Gamma (Stryker, Kalamazoo, Michigan) cephalomedullary nail had signs of notching at the aperture from eccentric drilling into the implant.[8] The medial calcar has the highest mechanical load in the body, and in finite element analysis studies notching was shown to reduce the stability of the implant by half.[20] This can result from attempts to change the rotation of the nail and guide sleeve after a soft tissue approach has been made. Rotating the guide sleeve without making a new incision through the soft tissue and the taught iliotibial band can cause the drill or reamer to damage the aperture (Fig. 2). The effect of different soft tissue tensions deflecting guide wire targeting has been demonstrated experimentally for some nail designs.[21] The proper attachment and alignment of the guide must be confirmed before nail insertion, or subtle misalignment may cause inadvertent damage.

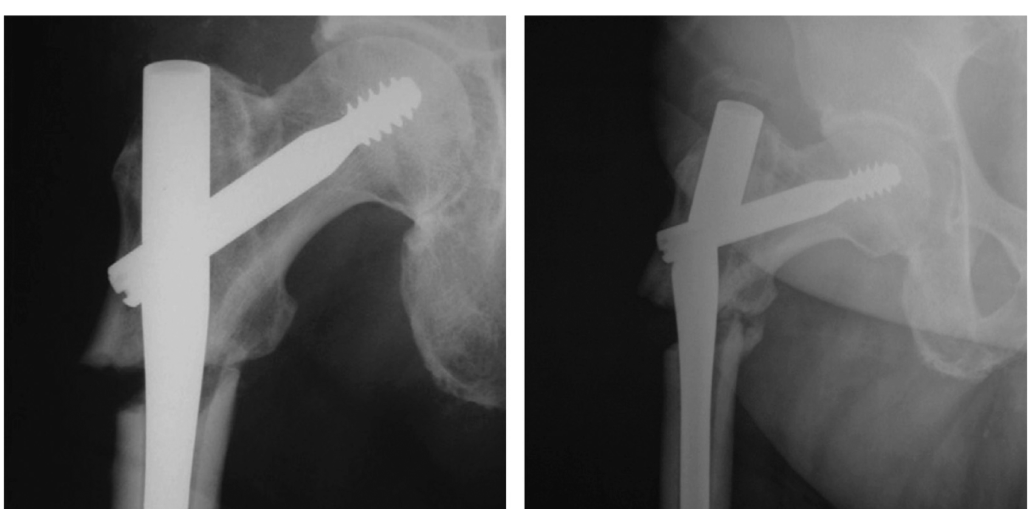

Figure 1. Nail failure at proximal aperture. (A) The fracture Is locked In distraction and varus. Note the typical lateral starting point of the nail. (B) The malalignment and distraction placed excessive load on the implant, resulting in failure at the proximal aperture. Reprinted with permission from Haidukewych GJ. Intertrochanteric fractures: ten tips to improve results. *J Bone Joint Surg Am.* 2009;91:712–719.

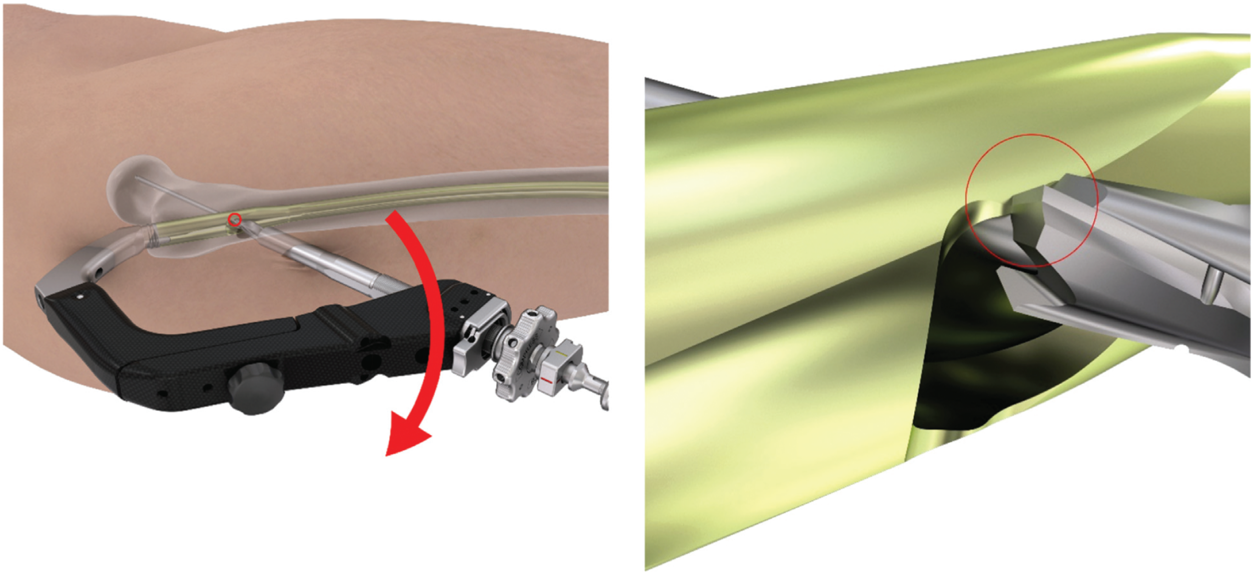

Figure 2. Eccentric drilling can occur through 2 different main mechanisms: (A) when the handle is rotated with the implant in place in order to make corrections, the tip of the drill may rotate sideways (B) when the soft tissue sleeve is not in contact with the lateral cortex, especially with large soft tissue layers.

There are differences in implant design, function, and potential subsequent intraoperative issues that must be understood by the surgeon. The Intertan (Smith & Nephew, London, United Kingdom) nail consists of 2 interdigitating cephalic screws which are proposed to improve rotational stability. Care must be taken with guide pin positioning, and screw insertion as convergent or divergent wires or rotation from screw torque can cause the screws to lock or diverge—as was noted in a prospective trial (Fig. 3).[22] In the authors' experience, the interlocking screws designed to create linear compression across the fracture can fail to engage properly. This intraoperative issue can prevent proper compression and removal of the screws can be difficult. The Veronail (Orthofix, Lewisville, Texas) and ENDOVIS (Citieffe, Minerbio, Italy) utilize 2 separated parallel or convergent cephalic screws. The Z-effect phenomenon has been reported with such designs, whereby the proximal screw rotates medially and the inferior screw migrates laterally and the design has not been in focus anymore.[23–26] In some instances improper positioning of the cephalomedullary screw in the gamma nail may prevent adequate sliding, and has also been suggested to contribute to cutout.[26] In some instances improper positioning of the cephalomedullary screw in the Gamma nail may prevent adequate sliding.

4.3. Postoperative factors

One of the main causes of implant failure can be a nonunion. It can be related to biological or mechanical factors, and commonly both are involved. Typical biological factors include medical issues such as smoking, irradiation, endocrine abnormalities and anti-inflammatory drugs; patients should be medically optimized pre and post surgically.[27] Infection must always be considered as a cause of delayed or nonunion especially in the setting of an open fracture. Intraoperative soft

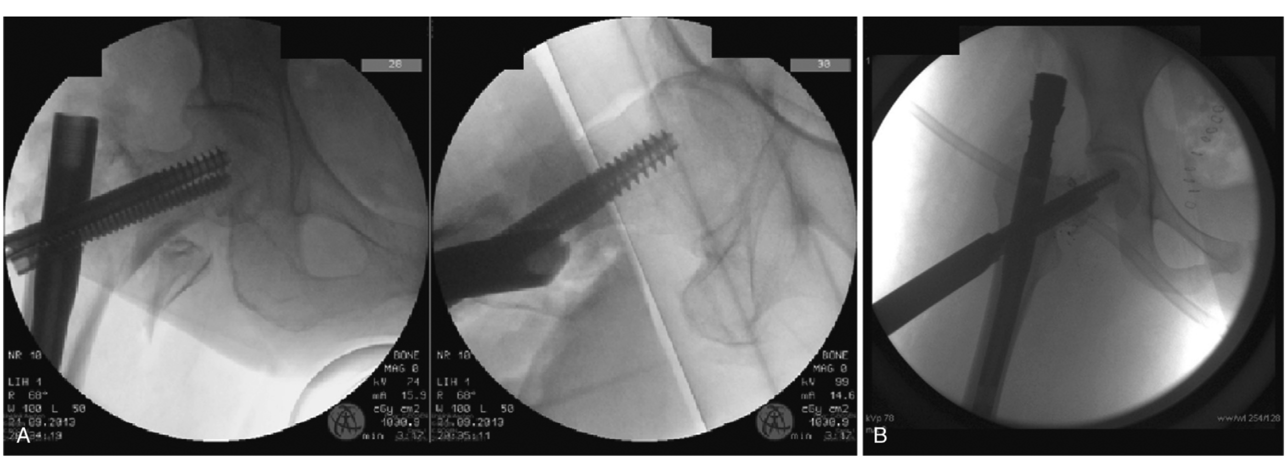

Figure 3. In Intertan, a large, indented hip screw leaves space for a smaller screw that is used for intraoperative reduction. If the alignment of these screws is not perfect, the small screw can engage into the large 1 and may not be applying the reduction maneuver. (A) If the engagement occurs early, further advancement of the small screw may be impossible and it may be even difficult to remove the second screw (B).

tissue striping should be minimized to preserve the biology, utilizing percutaneous reduction clamps where possible—but the surgeon should proceed to an open approach if required to achieve proper mechanical alignment. In subtrochanteric fractures nonunion has been associated with postoperative varus malalignment and lack of medial cortical support.[28] In the setting of comminution or poor reduction, there may be lack of cortical contact, large fracture gap, and excessive interfragmentary motion leading to high strain preventing bone healing according to Perren's theory.[29] Distal locking screw breakage has also been reported to commonly occur before implant failure at the nail itself.[10,15,28] This may be a symptom of nonunion and excessive interfragmentary motion, and a warning sign for impending failure of the implant itself, rather than a cause.

5. Conclusions

In conclusion, proximal femur fractures remain a challenge due to the typical poor bone quality and diminished physiologic reserve of typical patients. Implant related failure occurs in approximately 1% of the patients treated with/by cephalomedullary nailing and will become more widely encountered as the number of hip fractures is going to increase globally over the coming decades. There are reported associations with preoperative patient and fracture characteristics, intraoperative handling and postoperative nonunions. Although many of the factors that can influence the healing of proximal femur fractures have been well described and are taught in fracture courses, surgeons should be aware of subtle intraoperative complications reported in the literature that can weaken implants and add to the likelihood of early failure. The understanding of implant biomechanics, adequate fracture reduction, and proper instrumentation technique optimize patient outcomes by reducing the risk of implant failure. Special emphasis should be placed on the effort to avoid intraoperative notching of the implant.

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