Eur J Trauma Emerg Surg (2011) 37:305–312
DOI 10.1007/s00068-011-0091-8

ORIGINAL ARTICLE

Clinical evaluation of end caps in elastic stable intramedullary nailing of femoral and tibial shaft fractures in children

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Received: 18 January 2011 / Accepted: 26 February 2011 / Published online: 19 March 2011

Abstract
Background Elastic stable intramedullary nailing (ESIN) may be complicated by the loss of reduction following push out of the nails at the entry site in unstable femoral and tibial fractures, especially in older and heavier children and following technical failures. An end cap system addressing this complication was evaluated clinically.
Methods In a retrospective case series, 49 femoral and five tibial fractures in 54 pediatric patients treated by ESIN and end caps were documented in two European tertiary centers. End caps were used to interlock standard ESIN nails. The results were evaluated regarding difficulties in the placement and removal of the end cap system, fracture stability and healing, and return to normal activities by analyzing patient charts and X-rays.
Results Fifty-three of 54 fractures were stabilized sufficiently with ESIN and end caps. Loss of reduction was observed in one patient, requiring additional surgery. Six complications were observed, five of which were not related to end caps. There were no significant leg length differences or varus/valgus deformities. A rotational difference of >10°–20° was found in one patient. Removal of the end caps and nails was rated as simple and uncomplicated in 35/37 cases.
Conclusions End caps avoided postoperative instability in the majority of pediatric patients with lower limb shaft fractures, even in heavier, older patients and those with instable fracture types. End caps, however, will not compensate for operative technical insufficiency concerning reduction or nail placement. To maximize the stability of ESIN-instrumented unstable fractures, end caps require properly placed nails.

Keywords End cap system · ESIN · Femoral fracture · Tibial fracture · Pediatric

Level of evidence: level IV therapeutic study.

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Introduction

In children, femoral and tibial shaft fractures present the most frequent traumatic orthopedic inpatient diagnoses [1]. During the last two decades, elastic stable intramedullary nailing (ESIN) has become the method of choice for internal fixation of femoral [2–5] and tibial shaft [6–9] fractures in children aged 4–14 years. However, in unstable fracture types of the lower limb, these implants may prove to be more elastic than stable, especially in patients older than 12 years, with higher body weight, and when combined with intraoperative technical difficulties [10, 11]. Such technical problems may be the use of nails that are too thin, inadequate prebending, too large a cortical opening at the entry site, insufficient proximal and distal crossing of the nails, crossing at the fracture site, and twisting of the nails (the cork-screw phenomenon) [12]. Technical imperfections, unstable fracture type, and heavy body weight may combine to cause push out of the nail

ends at the entry site, with subsequent loss of stability, resulting in shortening or angulation at the fracture site. The rate of this complication, detected by nail migration with subsequent soft tissue and skin irritation, was previously reported to be as high as 5–12% [13–15]. Therefore, a method to lock the nails was sought. Previous methods to lock elastic nails and similar devices required additional incisions to bring in either locking screws [16] or to apply screws at the crossing points of the nails (the "miss-a-nail" technique [17]). The end caps were designed by the members of the pediatric group of the AO Technical Commission and tested at the AO Research Institute in Davos, Switzerland. In vitro testing suggested that the use of end caps increased stability sixfold in a model of an unstable femoral fracture. So far, only a handful of cases treated with this method have been reported [18, 19]. The goal of this study was to evaluate the end cap system for the stabilization of ESIN-treated pediatric lower limb shaft fractures and the prevention of secondary loss of fracture reduction.

Materials and methods

Two European pediatric surgery or pediatric orthopedic referral centers (Bern, Switzerland, and Nottingham, UK) participated in this investigation, including all pediatric lower limb shaft fractures treated with ESIN and end caps between January 2005 and June 2009. Data were collected retrospectively, including patient demographics, fracture classification according to the AO pediatric comprehensive classification of long-bone fractures (PCCF) [17], operative details, intra- and postoperative complications, and date of the child's return to full unrestricted activities. X-rays taken immediately postoperatively, at the end of treatment, and at final examination were evaluated regarding fracture healing, possible malunion, and positioning of the implants. The primary outcome was the occurrence of the loss of reduction/stability, which was defined as any change in fragment position at follow up examination compared to postoperative X-rays.

Follow up results were assessed at 4 weeks and 2–3 months after the operation (end of treatment), and a final examination was performed after removal of the material. In some patients, the final examination was still due at the time of writing of this article. Data were entered into a Windows Access® database. All statistical data are given as mean ± standard deviation, unless otherwise indicated. Statistical data analysis was performed using Stata® software (StataCorp LP, Texas, USA).

Implant description

End caps (produced by Synthes GmbH) are made of the same material as the titanium elastic nails (titanium—6% aluminum—7% niobium alloy), have a length of 25 mm, and an inner diameter of 4.4 mm (designed for nails of 3–4 mm in diameter). The outer diameter is 5.7 mm (7.5 mm maximum diameter at the helix). This end cap can be used for 2.5-mm nails as well. One part of the diameter of the closed end of the end cap is flattened to form the shape of a D, and this allows the cap to be inserted with a custom socket driver. Smaller end caps are now available for fitting with titanium elastic nails of 1.5–2.5 mm in diameter (Fig. 1). In the current study, only the larger end caps were used. The caps are relatively radiolucent due to the thinness of the material, thus, the position of the nail inside the end caps can be visualized intraoperatively by fluoroscopy.

Operative technique

The fracture is reduced in the usual manner under fluoroscopic control and stabilized with ESIN nails. No special considerations have to be made for the use of end caps; however, cutting the nails to the correct length is mandatory. The beveled impactor should be used to introduce the

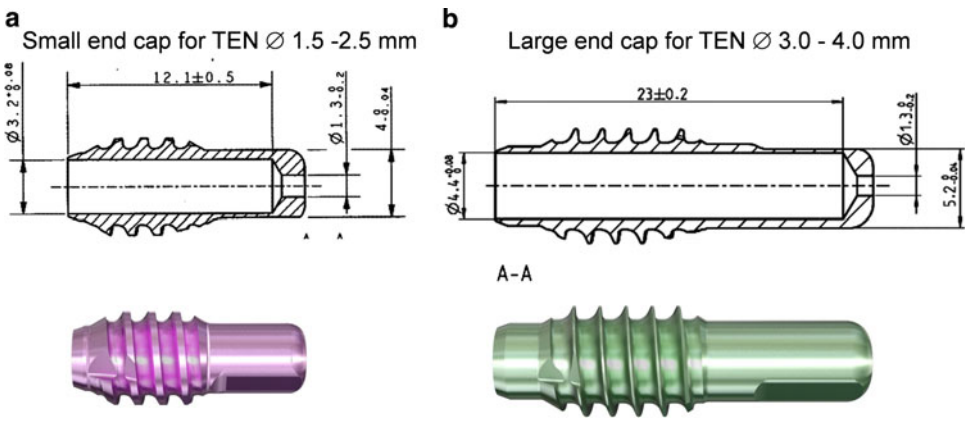

Fig. 1 Dimensions and design of small (**a**, for ESIN up to 2.5 mm in diameter) and large (**b**, for ESIN up to 4 mm in diameter) end caps

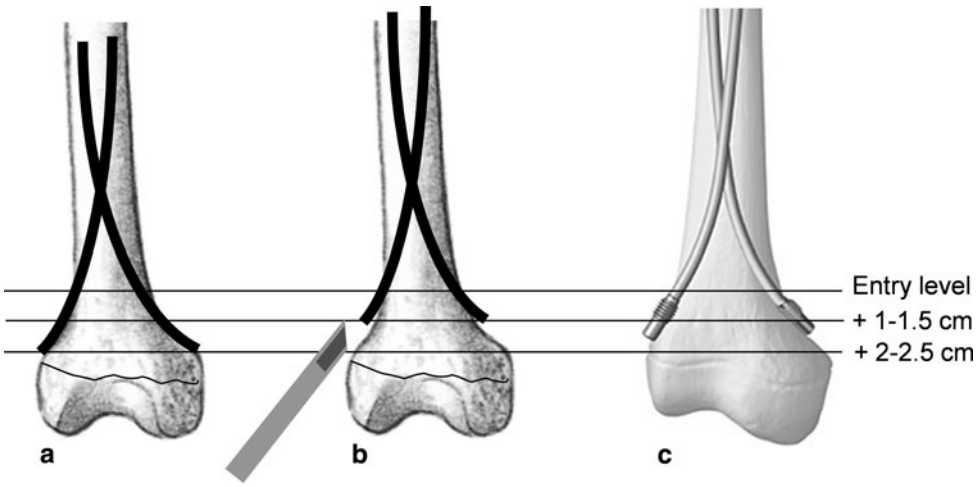

Fig. 2 Method to prepare nail ends for end cap application. **a** Nails are cut at 2–2.5 cm from the entry level. **b** Nails are advanced 1 cm by the beveled impactor and bent slightly outwards. **c** End caps are positioned over the nail ends

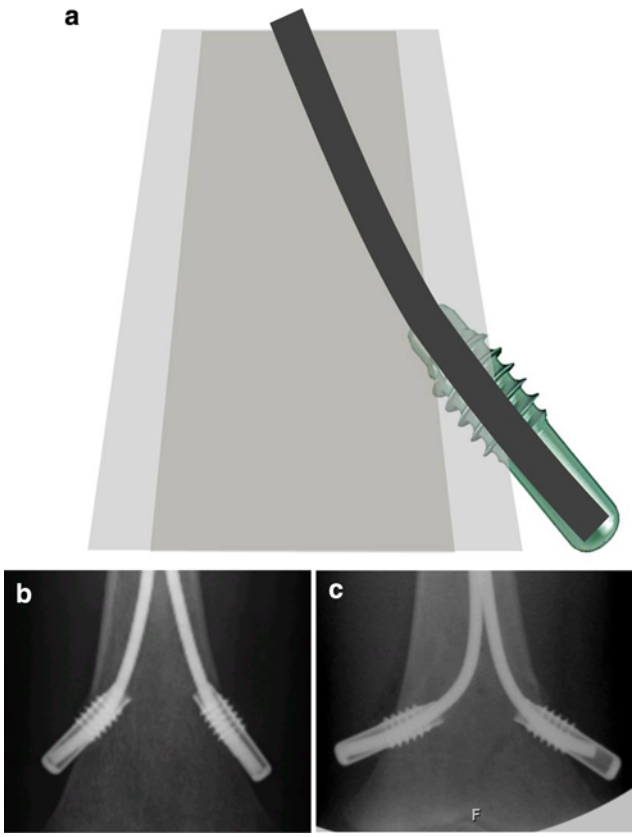

Fig. 3 Correct and incorrect positioning of nails in end caps. **a** Schematic drawing of ideal nail anchoring in the end cap. **b** Two correctly positioned end caps. **c** Nails bent too much, leading to difficult placement of the end cap (*left nail*) or insufficient anchoring of the nail (*right nail*)

nail after cutting them, since its recess corresponds to the portion of the nail that should remain outside the bone to be covered by the end cap (Fig. 2). When the nail is brought to its final position, the external portion should be bent away from the cortical bone a fraction by lifting the impactor. Too much bending may prevent the end caps from sliding over the nail. Too little bending may result in inadequate anchoring of the cap (Fig. 3). If the nail is cut too long, the end cap thread does not grip the cortical bone.

Results

Patients

Fifty-four patients (age range 2–15 years; mean age 8.6 ± 3.7 years) with femoral (49) or tibial (5) shaft fractures were documented, including 46 cases from Berne and eight cases from Nottingham. The cases were treated by a total of 13 surgeons (nine from Berne and five from Nottingham), and the number of cases per surgeon ranged from 1 to 17.

Patient characteristics

The boy to girl odds was 2.4 (38:16) (Fig. 4). The mean body weight of the patients was 37 ± 15 kg (range 17–80 kg). Height measurements were available for 34 patients. The mean height of these patients was 141 ± 21 cm, with a range from 108 to 180 cm, and their mean body mass index (BMI) was 18.1 ± 3.1 (range 13.0–24.7).

Fracture types and type of nailing

There were 46 fractures of the femoral diaphysis (PCCF classification: 32-D) receiving retrograde nailing and end caps, and three other 32-D fractures receiving antegrade nailing plus end caps. Five fractures of the tibial diaphysis (42-D) were treated by antegrade ESIN and end caps. The classification of the fractures is detailed in Table 1.

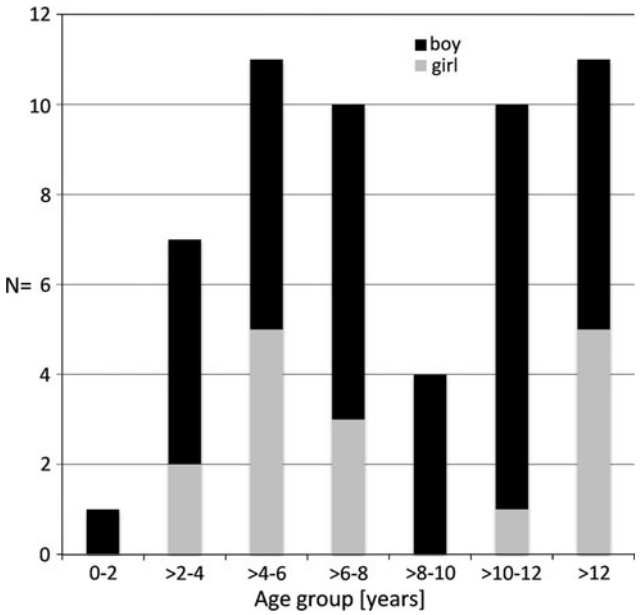

Fig. 4 Age and gender distribution of the patient cohort

Table 1 Distribution of bone segments and fracture types

Bone fractured	AO fracture classification	Total	% of all fractures
Femur	32-D/4.1	3	5.6
	32-D/4.2	5	9.3
	32-D/5.1	26[a]	48.1
	32-D/5.2	15	27.8
Tibia	42-D/5.1	2	3.7
	42-D/5.2	3	5.6
Total		54	

[a] Including two pathological fractures

Timing and detail of operations

Thirty-eight operations (70.4%) were performed on the day of the accident, while 15 operations were performed on the next day (27.8%). Only one (1.9%) operation was delayed for 3 days. In 51 cases, closed reduction of the fracture was possible, and only three fractures were reduced openly (one 32-D/4.2, one 32-D/5.1, and one 42-D/5.2 fracture). The definitive position of the nails prior to application of the end caps was achieved using a beveled impactor in 52 cases (96.3%). In the remaining two cases, the nails were positioned by other instruments.

Nail diameters

Nails of 2.5–4 mm in diameter were used. Most fractures were stabilized by 3- and 3.5-mm nails. Details of the nail diameters with respect to the affected bone segment are given in Table 2.

Table 2 Fracture type/bone segment and nail diameter used

Bone segment fractured	Nail diameter (mm)				Total
	2.5	3	3.5	4	
Femoral diaphysis	2	24	16	7	49
Tibial diaphysis	1	0	3	1	5
Total	3	24	19	8	54

Fitting of end caps

No problems with the insertion of end caps were reported in any of the 54 cases. From radiologic evaluation, adequate contact of the nail end with the end cap was achieved in 53 of 54 cases at the lateral and medial nail each.

Hospital stay

Children stayed in the hospital for a mean of 6.8 ± 7.8 days. The median of the stay duration was 5 days, and the range was 2–39 days. In three cases, hospital stays exceeded 1 SD of the mean stay (>15 days), two of which were not fracture-related but due to other injuries.

Duration and type of mobilization/immobilization

In two patients (4.2%), only passive motion by a physiotherapist was allowed immediately postoperatively. Thirty-one children (57.4%) were allowed to move their injured leg freely but without weight bearing, and 20 children (37%) could bear partial weight. One child (1.9%) was allowed to bear their full weight. Mobilization with partial or non-weight bearing was achieved by walking aids (crutches in patients above 6 years of age or an assistant for younger children). Inside the hospital, mobilization was supported by the use of continuous passive motion (CPM) in 13 (24.1%) or physiotherapy in 39 (72.2%). In two patients, other means (e.g., nurse support) were used to improve mobilization.

Additional means of immobilization such as plaster splints were used in five patients, either for 2–4 weeks for fracture protection ($n = 3$), 2 weeks for pain at the fracture site ($n = 1$), or 4 weeks due to joint instability ($n = 1$).

Time to return to full activity

Full activity was achieved in those 46 patients that were controlled at the end of treatment after a mean of 9.6 ± 4.4 weeks (median 8 weeks, range 4–22 weeks). Among the six patients that needed more than 14 weeks to return to full activity, there were three tibial shaft fractures and three femoral shaft fractures. The age spectrum and

fracture type distribution of the subgroup with delayed full activity was not different from the remaining cohort.

Implant removal

Fifty-two of 54 implants were initially planned to be removed electively, while implant removal was not planned in two. Nail and end cap removal was simple and unproblematic in 35 of 37 cases evaluated.

Complications

There were six complications reported in six patients (6/54 = 11.1%; 95% confidence interval: 2.7–19.5%). Three complications were intraoperative and attributable to insufficiencies in the operative technique. They included one severe insufficient fracture reduction and fixation in external rotation, one nail perforation into a joint, and, in the third, the medial end cap came off because it did not come into contact with the cortical bone. None of the intraoperative complications caused additional surgical treatment.

The other three complications were postoperative, including two losses of reduction (2/54 = 3.7%; 95% confidence interval: 1.1–6.2%) and a delayed healing. All were considered as mild. One loss of reduction, leading to 10° varus deviation visible on X-rays, was caused by a fall 3 weeks after the initial fracture fixation, and the other occurred after physiotherapy due to insufficient fracture fixation in a polytraumatized patient requiring additional external fixation. Delayed healing of one tibial fracture was related to the injury.

Follow up results

The end of treatment was defined in 46 patients at a mean of 64.7 ± 40.8 days after trauma (median 53 days, range 17–220 days). A final examination was performed in 37 patients at a mean of 244.2 ± 127.1 days (median 213 days, range 84–667 days). There were no losses to follow up; in eight patients, the end of treatment had not yet been reached. End of treatment results were obtained in the remaining 46 patients; the final examination, however, was still due in nine of these patients, since the time for implant removal had not been reached upon the writing of this article.

At the end of treatment, fracture healing was classified as visible callus in 10, complete callus bridging in 30, and partial remodeling in six of the patients. At the final examination, fracture healing had progressed to partial remodeling in 11 and full remodeling in 26 cases.

Varus or valgus deviation was evaluated at the last available examination for each case. A varus or valgus deviation greater than 10° was found in none of the 37 cases at the final examination, at the end of treatment ($n = 9$), or after surgery ($n = 8$).

Antecurvation of between 10° and 20° was present in two cases after surgery. This normalized to anatomical alignment in all patients by the final examination ($n = 36$). Recurvation of between 20° and 30° was seen only in one case after surgery and normalized by the end of treatment. In those cases seen only until the end of treatment ($n = 9$) or postoperatively, non ante- or recurvation greater than 10° was seen.

Leg length differences were seen in none of the 37 patients at the final examination. No length differences were encountered among the patients which were only seen at the end of treatment ($n = 9$) or postoperatively ($n = 8$) yet. External rotation of greater than 10° was seen in one patient at the final examination. Rotation was symmetrical in the 53 other patients upon the last available examination. The follow up results of fracture alignment are summarized in Table 3.

Discussion

Study background and study design

Technical difficulties in ESIN may result in angulation at the fracture level, push out of nails at the entry site, and loss of reduction [11, 14, 20, 21]. To compensate for this, prolonged splint immobilization or bed rest are used sometimes, contrary to the concept of ESIN, which should allow for early non-weight bearing mobilization [15]. Rigid interlocking nails of the adult type might be used instead, as soon as the bone marrow canal is wide enough; however, complications have been reported, including valgus of the femoral neck and necrosis of the femoral head. There have been reports of interlocking pediatric nails in older children

Table 3 Fracture fragment position (axial, longitudinal, and rotational deviation) at different time points

Parameter	After surgery $n = 54$	End of treatment $n = 46$	Final examination $n = 37$
Varus/valgus >10°–20°	1	0	0
Varus/valgus ±10°	53	46	37
Ante/recurvation >10°	3	2	0
Ante/recurvation ±10°	51	44	37
Shortening >1 cm	1	0	0
Shortening >0.5–1 cm	3	0	0
Shortening <0.5 cm	50	46	37
Rotation >10°	1	1	1
Rotation <10°	53	45	36

or more instable fractures by placing screws on the crossing points of the nails or by the use of specially designed nails [22]. The use of end caps is the first described method to interlock a standard ESIN. With end caps, stability can be added to ESIN with a minimum of extra effort. The stability of the system was demonstrated in a previously published biomechanical study [23]. In this study, axial stability of ESIN was significantly increased in human cadaveric bones and in plastic model bones by the use of end caps.

This study is a retrospective investigation of the initial use of end caps. The cases were performed by many surgeons of differing experience. The lead investigators in each center were among those who devised and designed the end caps and they gave instructions to their colleagues on their use. These results do, however, represent the learning curve in the use of end caps at these centers. Since the complications related to end caps were mainly due to intraoperative technical problems (of nailing and/or of end cap insertion), there is room for improvement through education, training, and experience [12].

The incidence of difficulty in applying (0/54, 0%) or removing (2/37 or 5%; 95% confidence interval 0–12.7%) the end caps was low. With specific education on the implantation of the caps, these difficulties should be eliminated.

The number of end cap-related complications was also low ($n = 2$). One case was seen with inadequate fixation of the medial end cap which, later on, lost contact to the femur, but without subsequent loss of reduction or relevant soft tissue irritation. Soft tissue/skin irritation by nail ends was not reported in the patients with functioning end caps. This complication, thus, appears to be less frequent than in reports on the use of ESIN without end caps [10, 24, 25]. All failures of the implant were caused by defective technique and not by instability of the implant itself. Loss of reduction did not occur in any case with adequately anchored end caps.

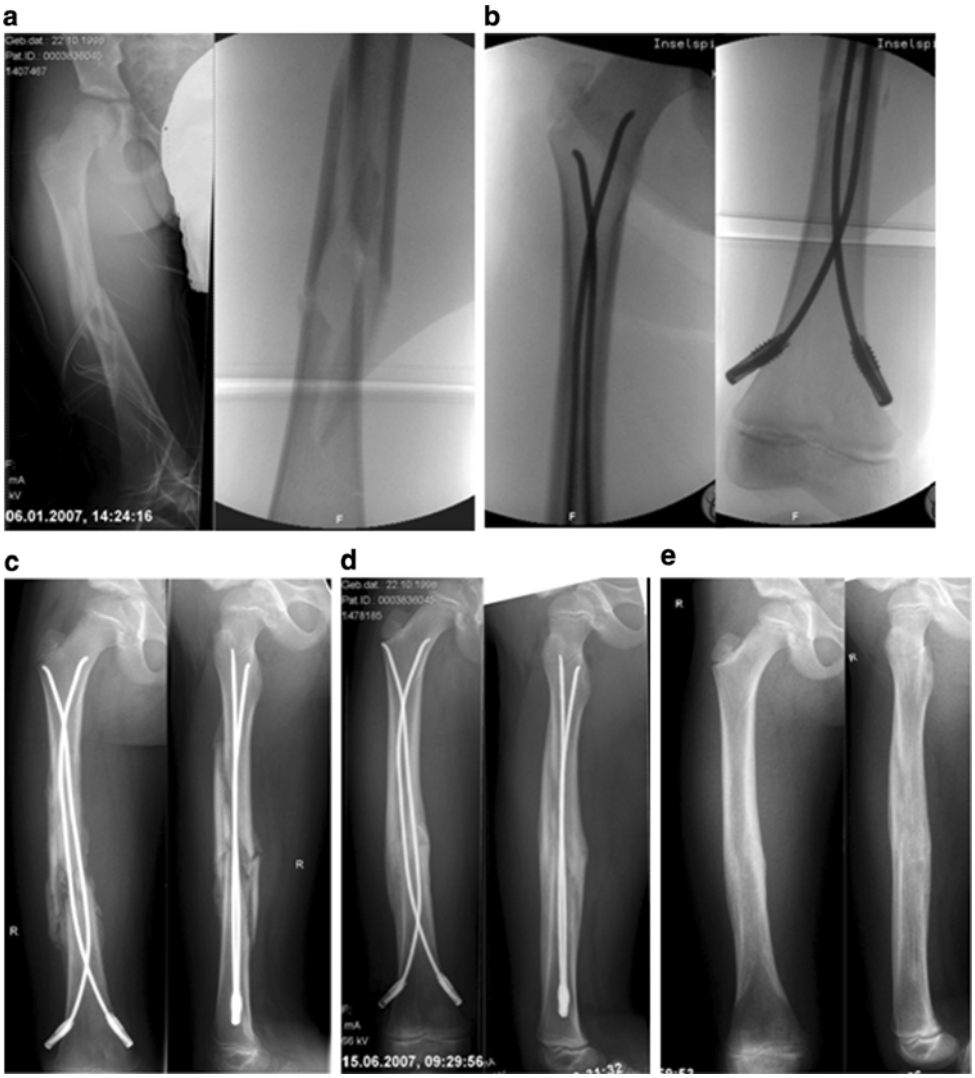

Fig. 5 Proximal femoral shaft long spiral fracture with a large wedge fragment (32-D/5.2) (9-year-old boy, 36-kg body weight) stabilized with ESIN and end caps. **a** Initial X-ray. **b** Intraoperative X-rays. **c** Follow up at 5 weeks after fracture. **d** Follow up at 5 months. **e** Follow up at 8 months after the removal of nails. Proper nail and end cap placement allowed for stable fixation and rapid consolidation, even in a very unstable fracture type

Technical difficulties and complications appeared to be related to not using the recommended beveled impactor. End caps cannot give stability when not adequately anchored in the cortical bone. End caps may improve stability in the majority of otherwise problematic fracture types (oblique, spiral, comminuted) in heavier children. An example of such a fracture is given in Fig. 5. The spectrum of ESIN can probably be somewhat expanded with the use of end caps by increasing the safety of its use in older children and less stable fractures.

Return to full activity

The time to return to full activity is comparable in the current study to results reported by others after ESIN stabilization of lower limb fractures in children of comparable age [20, 26]. This is due to the fact that weight bearing was often only allowed after radiographic signs of fracture consolidation, especially in oblique and unstable fracture types. The potentially increased stability of the nailed fracture by the addition of end caps did not generally translate to earlier weight bearing and activity. This was presumably because the hospitals continued to use the same rehabilitation protocols as prior to the use of end caps. Biomechanical studies, however, indicate that earlier weight bearing is probably possible with end caps as compared to ESIN used alone [27]. The question on whether end caps might be beneficial in all femoral fracture types with respect to earlier weight bearing remains to be studied.

The use of end caps did not lead to an increased rate of delayed and non-union; this had been a concern because of the dramatic increase in stability achieved in the in vitro biomechanical studies.

Removal of end caps and nails

In most cases, removal of the implants was rated simple and uncomplicated. In fact, end caps prevent cortical bone overgrowth over nail ends, and, after removal of the end cap, a small channel remains around the nail at the entry site, which facilitates removal of the nail. In general, ESIN implants are usually removed after the complete consolidation of respective fractures. In a recent study [28], where removal was not intended in a cohort, a rather large subgroup received unplanned removal due to pain and discomfort. Although end caps might decrease discomfort from nail ends protruding into soft tissue, the intention of using end caps is not to avoid removal but, rather, to facilitate it.

The use of end caps as an addition to elastic nailing has been shown in this study to be simple and safe. They have been shown to be easy to apply and remove in the majority of cases. Attention to detail in the original elastic nailing and the end cap application has been confirmed to be important. This study does not demonstrate the increased stability of nailed fractures suggested by our biomechanical studies, as there was no comparison group; however, the results are sufficiently encouraging for this method to be included in comparative studies of either simple elastic nailing or other methods, such as formal interlocking nails or sub-muscular plating.

Acknowledgments This investigation received financial support from the AO foundation (AO Technical Commission), Davos, Switzerland.

Conflict of interest None.

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