

## Minimally invasive fracture stabilization of distal femoral fractures with the LISS: A prospective multicenter study

### Results of a clinical study with special emphasis on difficult cases

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#### Summary<sup>1</sup>

The LISS-DF (Less invasive stabilization system–distal femur) is a new type of implant system for the treatment of distal femoral fractures according to the principles of “Minimally Invasive Surgery”. A plate, pre-contoured to the anatomy, is inserted through a minimally invasive incision into the epiperiosteal space by means of an aiming device after indirect, closed fracture reduction. The implant is stabilized by insertion of screws which lock into the plate holes and prevent tilting. This is performed with the aid of an aiming device and through stab incisions. It is not necessary for a large area to be exposed at the fracture site.

As part of an AO prospective multicenter study, the new system was applied to 112 patients with 116 fractures. The time to follow-up was on average 13.7 months (minimum 7 months, maximum 33 months). Fractures treated were distal femoral shaft and supracondylar femoral fractures.

Eight patients died during the study of causes unrelated to the implant. Of the remaining 104 patients with 107 fractures, 96 patients with 99 fractures were available for complete follow-up (93% follow-up rate). In 90% of all cases treated and followed up, the fracture had consolidated during the period of observation.

Twenty-three revision operations were necessary in 21 patients. In two cases, implant failure occurred as the

result of a pseudarthrosis. The complications can be attributed in nearly all cases to the severity of the trauma and/or a lack of experience when applying the new style implant to a wider range of indications.

The results of the study show that with a sound knowledge of the operative technique and careful pre-operative planning this system represents an excellent, safe procedure for the treatment of almost all distal femoral fracture types including periprosthetic fractures of the distal femur. There is generally no need for primary cancellous bone grafting.

**Keywords:** LISS, internal fixator, distal femoral fractures, clinical study, minimally invasive operative technique

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#### Introduction

The LISS is a new internal fixator which combines the biomechanical properties of a lateral fracture stabilization on the distal femur with the principles of optimized bone-to-implant contact. The complexity of indirect reduction techniques and a minimally invasive, fracture bridging, operative techniques make considerable demands on the surgeon. For this reason, during preparation of the clinical study, special emphasis was placed on training the participating surgeons. Seminars were

<sup>1</sup> Abstracts in German, French, Italian, Spanish, Japanese and Russian are printed at the end of this supplement.

held to teach handling and the basic concept of the new internal fixator (Figs 1 and 2).

**Materials and Methods**

After completion of mechanical testing of the implant, patient recruitment commenced in December 1996 as part of a prospective, multicentre clinical study. From December 1996 to November 1998 in 9 European centres, 112 patients with 116 fractures were treated with the new system. The application of indirect reduction techniques dispensed with the need for primary cancellous bone grafting. Depending on the type of fracture and the concomitant injuries. The objective was to achieve early functional mobilization as soon as possible as part of the postoperative aftercare programme. Weight-bearing was increased for each individual depending on clinical and radiological signs of healing.

All centres recorded the data relating to the operation, the follow-up assessments, and any observed adverse

events on a special form for documentation. The fractures were categorized according to the AO Fracture Classification [1], soft tissue injuries according to Gustilo [2] and/or the AO Soft Tissue Classification [3]. Evaluation of the radiographs was performed by a central body of experienced surgeons. The inclusion criteria were distal femoral fractures of all degrees of severity in patients with a mature skeleton. The follow-up took place over a period of one year and was completed in December 1999.

**Patient sample**

The patient sample was comprised of 64 women and 48 men aged between 17 and 99 years. The average age was 54 years. There were peaks in distribution over three age groups in the 4th and 6th decades, and in patients over 80 years of age. Obvious osteoporosis was found in the latter group.

**Trauma:**

The implant was applied in 60 cases of isolated fracture, 19 cases of multiple fractures and 37 cases of polytrauma.

Eighty-five supracondylar or intracondylar femoral fractures (AO 33) and 31 distal femoral shaft fractures (AO 32) were treated. There were 49 Type A, 20 Type B, and 57 Type C fractures. The proportion of intraarticular C-3 fractures was 20% (n=23).

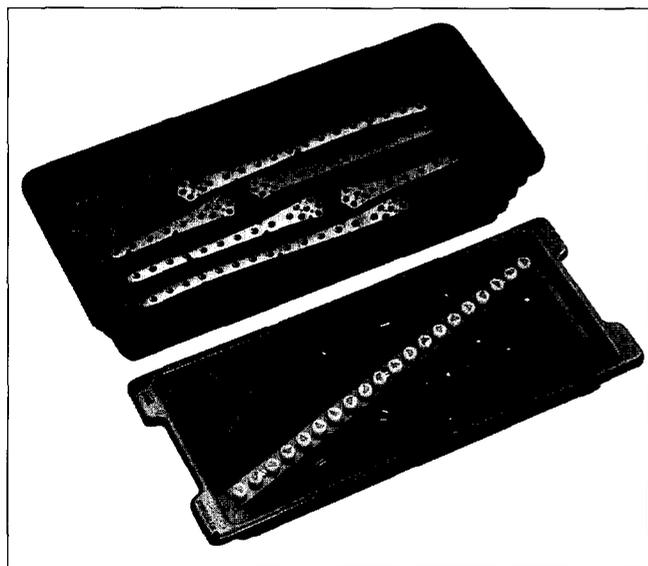
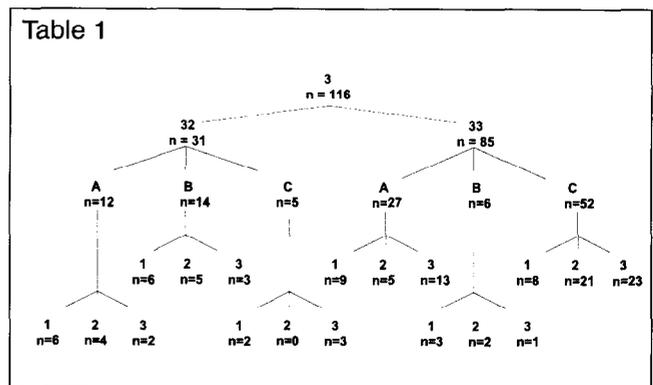


Fig. 1: LISS set for radiolucent aiming device.



Fig. 2: The LISS-DF has been adapted to the anatomical form of the distal femur.



There were 12 cases of periprosthetic fractures and 6 patients had initially been unsuccessfully treated with other implants. The proportion of open fractures was 29 % (n=34), 11 patients presented with third degree open soft tissue injuries.

**Operation data**

Definitive fracture treatment was performed on 48 patients within the first 24 hours of the accident; in 25 cases within the next 4 days, and in 43 cases after more than 5 days.

Fracture reduction was performed manually in the majority of cases (n=73). To assist with this, an external fixator was applied (n=25), a distractor (n=6), the reduction table (n=3), or a combination of these procedures (n=9). It became apparent during the study that a fixator was being used increasingly as a reduction and temporary holding device.

Insertion of the implant was performed by 38 different surgeons. This fact, and the wide spectrum of indications, often involving the first clinical application of the system, explain the large differences in operating times (40-300 minutes) and intraoperative radiographic screening times (0.5-30 minutes).

During the study, a 13-hole implant was used in 50 cases, a 9-hole implant in 52 cases, and a short 5-hole implant in 14 cases. During the study the longer implants were increasingly preferred by the surgeons. The implant was stabilized with, on average five screws, each in both the distal and the proximal fragments (min. 3, max. 9 screws). In 45 cases, additional implants such as cortical lag screws, cancellous bone screws, and small fragment screws were inserted.

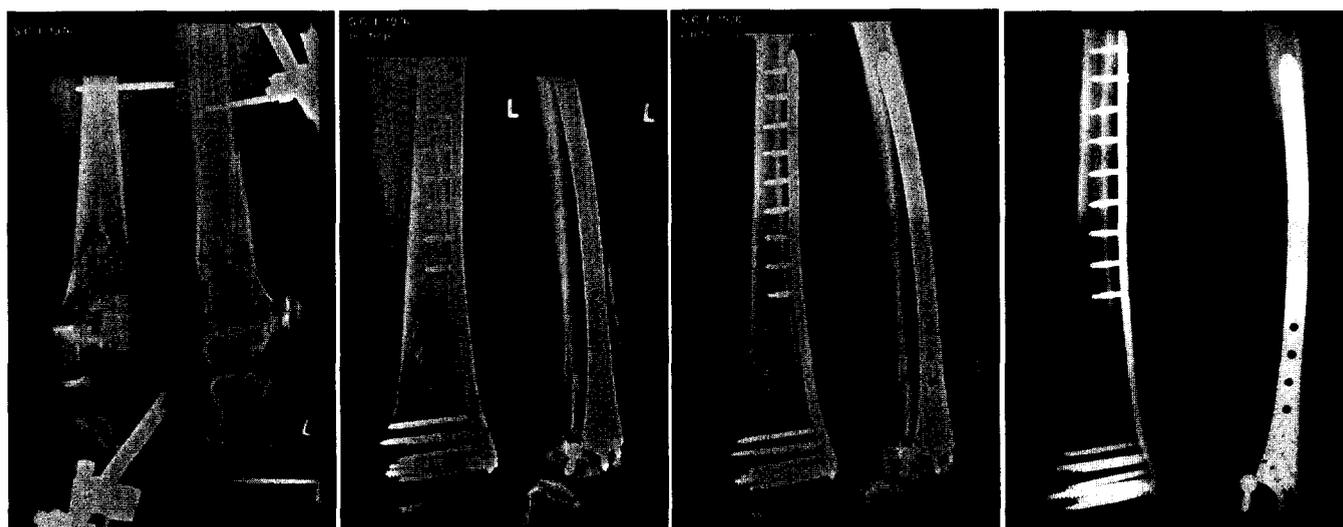
## Results

Follow-up covered a period of 13.7 months on average (min. 7 months, max. 33 months). Of the 112 patients treated, eight patients with 9 fractures died before healing was complete without there being any recognizable relationship between the cause of death and the implant. Of the remaining 104 patients with 107 fractures, 96 patients with 99 fractures were followed up until healing was complete or until the observation period ended. This amounts to a follow-up rate of 93%. Seven patients

could not be located for follow-up; one patient refused to attend the follow-up assessment without giving any explanation (Fig. 3a-d).

In 102 cases, the postoperative radiographic assessment showed correct position of the implant. In the remaining 14 cases, either a slight ventral (n=8) or dorsal (n=1) position of the proximal end of the implant in relation to the femoral shaft was observed; in five patients the distal end of the implant had not been situated optimally on the condyle. Assessment of the fractures in terms of valgus/varus alignment as seen on the postoperative radiograph indicated correct axial alignment in 93 cases. In 21 cases there was a deviation of 5-10°, and in two cases a deviation of about 10-20° from the anatomical axis. Evaluation of fracture alignment in the sagittal plane indicated correct axial alignment in 103 cases, 10 cases of a 5-10° deviation, and three cases of a 10-20° deviation. In eight patients, a combined malalignment of both valgus and hyperextension of the distal fragment was observed. With regard to axial deviations, a clear predominance of complex intra-articular fractures was seen.

At the end of the investigation period, 91% (n=90) of the 99 fractures seen at follow-up had healed and were stable (completely bridged fracture capable of full weight-bearing). In four cases, definitive fracture healing was not achieved by the end of the investigation period; in five further cases a reconstructive procedure was performed by the treating physician. The range of motion of the knee joint measured using the neutral-0-method varied depending on the type of fracture [Injury 1995; 26(S1)]. The results for the various types of fracture were on average 108°/0/0 (32-A), and 120°/0/0 (32-B, 32-C, 33-A and 33-B), and 107°/0/0 (33-C). Thirty-three C3 fractures with an average bending range of 107°



3a: Preoperative radiograph; 3b: postoperative radiograph. 3c: 2 months postoperatively; 3d: fracture healing 6 months postoperatively.

Fig. 3: 22-year-old patient with an isolated, II° open 33 C2 fracture. Primary fracture stabilization with an external fixator; definitive fracture treatment 5 days after the accident with a 13-hole LISS.

after complete fracture healing showed the greatest bending deficit.

During the observation period, 23 revision operations had to be performed on 21 patients. The analysis will be presented below.

General postoperative complications included symptoms of hemiplegia in an 85-year-old female patient, one case of post-operative dementia in a 91-year-old female patient, one deep vein thrombosis of the leg with subsequent non fatal, pulmonary embolism, and one case of gastrointestinal bleeding.

### **Analysis of the complications and the necessary revision operations:**

The revision operations were required for the following reasons:

- 6 non/delayed unions (bone grafted)
- 4 cases of implant loosening
- 2 cases of implant breakage
- 7 debridments to deal with infection
- 3 arthrolyses
- 1 correction osteotomy

### **Cancellous bone grafts**

The need for cancellous bone grafting can be attributed in all cases to the complexity of the trauma (intra-articular C3 fractures and II° and III° open fractures), or to the severity of the concomitant injuries. One example is the case of a 28-year-old polytraumatized female patient with distal femoral fractures of both legs. Both were treated with a LISS plate. Paraplegia severely limited mobilization and four months after the operation delayed fracture healing was diagnosed for both legs. This meant that secondary cancellous bone grafting was necessary. Fracture healing subsequent to the revision operation was uneventful.

### **Implant loosening:**

Analysis of implant loosening revealed various causes, but loosening only affected the main proximal fragment. The following mechanisms were identified as causes:

1. An existing ipsilateral implant (Pohl eye screw) for the treatment of an earlier proximal femoral fracture that made the use of a short LISS plate unavoidable and prevented optimal implant stabilization.
2. Ventral position of the implant on the femoral shaft and too great a distance between the implant and the femoral shaft, leading to insufficient fixation of the implant with the unicortical screws.
3. Failure of the screws to lock in the implant, whereby the effect of the internal fixator was compromised.

4. Postoperative, uncontrolled full weight-bearing on the operated leg as the result of existing psychiatric illness (Fig. 4a-d).

### **Implant breakage**

Two implant breakages occurred 11 and 15 months post-operatively. Both patients withdrew from the follow-up examinations for various reasons. In both cases, a pseudarthrosis formed in the course of healing. A lack of callus consolidation of the fracture precipitated cyclical overloading of the implant which eventually caused the LISS to fail.

### **Rotational malalignment**

A correction osteotomy became necessary for a 33 C2 fracture after a malrotation had been identified on the radiograph. Exact alignment was achieved without difficulty at the revision operation. The proximal screws were re-sited and the implant stabilized again.

### **Infections**

Four patients required a total of seven debridements or revision operations following locally manifest infections. Three cases had initially been II° or III° open fractures. Four of the patients were polytraumatized with multiple fractures.

In two cases, the advanced infection could not be controlled by local revision or systemic antibiotics so that radical debridement was required.

In one 30-year-old female patient this led to amputation of the distal femur and implantation of a tumour prosthesis. Subsequent healing was uneventful.

### **Restricted movement:**

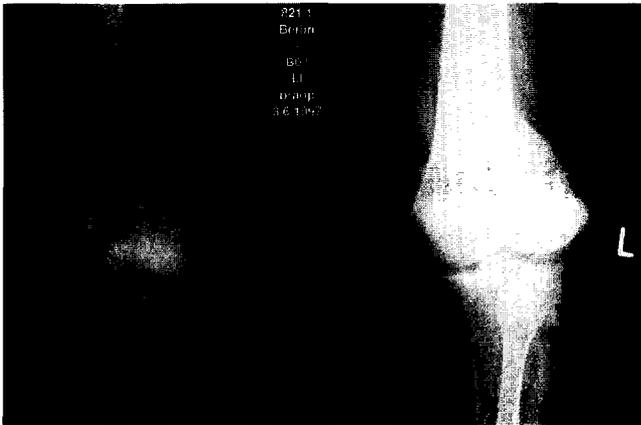
Three arthrolyses were necessary for complex intra-articular fractures. These were also cases of polytraumatized patients or patients with multiple fractures. One of the patients had already been treated unsuccessfully with another type of implant, in one other patient severe heterotopic ossifications occurred following a severe head trauma. The participating surgeons all noted that restricted movement could not be attributed to the implant in any of the cases.

### **Discussion**

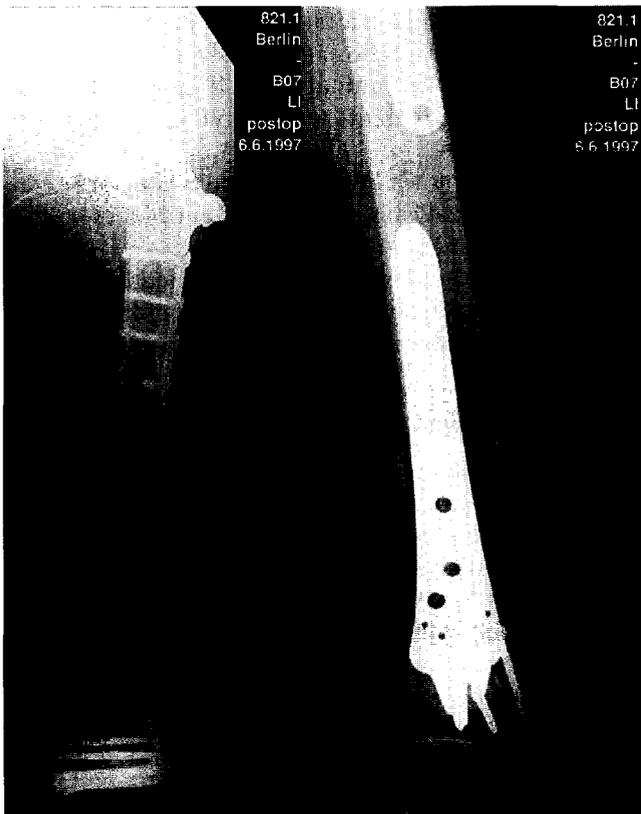
The results of treatment of distal femoral fractures with the new internal fixator "LISS-DF" arising from clinical studies are presented here. It has been shown that the LISS can be used in the treatment of all supra and intra-articular femoral fractures. The exception is the mon-condylar fracture which is more practically treated

using only screw osteosynthesis [3-5] (Fig. 5a-d). There was a high proportion of severe soft tissue injuries (29% open fractures) and a high proportion of complex, intra-articular fractures (20% 33 C3 fractures). By the end of the study, 96% of the fractures presenting had consolidated and treatment had been completed. The study showed clearly that when working with the LISS, primary cancellous bone grafting is not necessary. This is

comparable to the results of recent, retrospectively evaluated series using the retrograde intramedullary nail [6-8] and represents clear progress compared with the results of the 1980s [9-11]. Likewise, the number of complications following infection can be regarded as minimal and is comparable with the results reported in earlier publications for application of extramedullary operative procedures or markedly lower [12,13].



4a: pre-operative radiograph;



4b: postoperative radiograph.



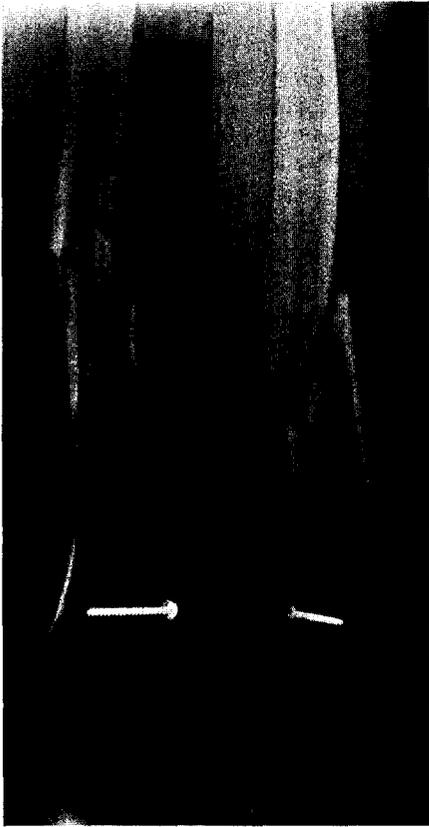
4c) Pull-out on day 6 post-operatively.



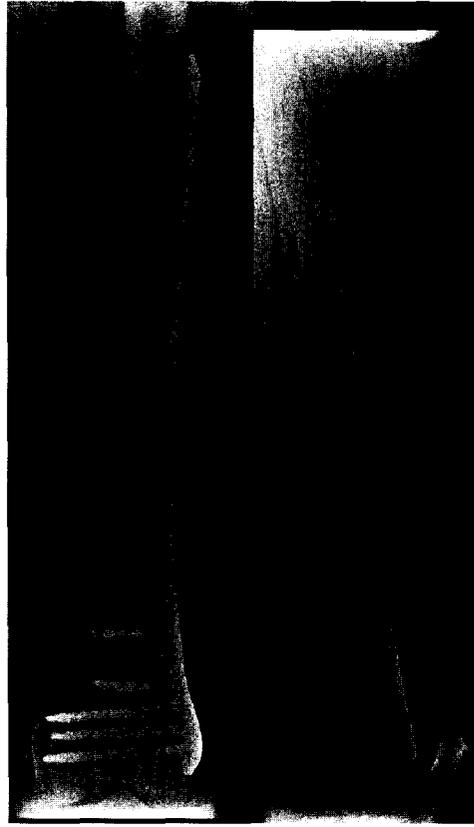
4d) fracture healing 7 months post-operatively.

#### Fig. 4a-d: Complications – Implant pull-out.

A 54-year-old female polytraumatized patient with a closed 33 C1 fracture. In the presence of an existing psychiatric illness, in the course of an uncontrolled psychotic attack 6 days after the operation, the operated limb was subjected to full loading which caused plate pull-out proximally. In retrospect, it can be stated that pull-out could also be attributed to the selection of too short a plate. The short 5-hole LISS only permitted the insertion of three fixation screws in the proximal fracture fragment. The experience gained in this study indicated that it would have been better to apply a longer implant in this case. After refixation with bicortical screws, the fracture healed uneventfully 7 months after the operation.



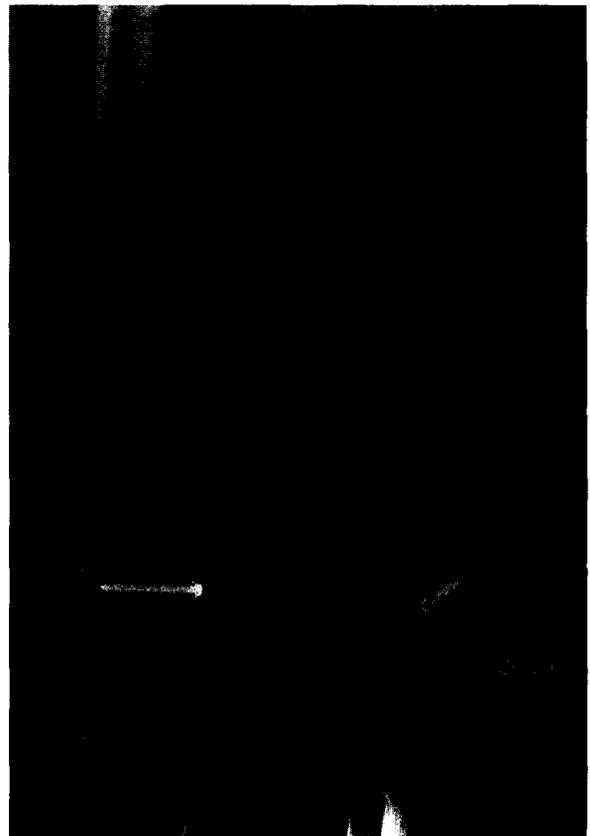
5a) preoperative radiograph;



5b) postoperative radiograph.



5c: 10 months postoperatively;



5d: status after plate removal.

Fig. 5a-d: 68-year-old female patient with isolated closed 32-B1 fracture. The fracture was treated after reduction using the distractor on the day of the accident with a 13-hole LISS by applying a fracture bridging technique.

Thorough analysis of the revision operations indicated that these could generally be justified by the complexity of the fracture or the severity of the soft tissue injuries with subsequent restriction of movement. There was no correlation with patient age. In isolated cases, deficiencies in operative technique were in evidence which occurred in relation to the greater demands of the new system on preoperative planning and indirect reduction techniques. Also, a lack of patient compliance, which is part of everyday life in the clinic, created a need for re-operation.

Almost all the surgeons participating in the study emphasized the suitability of the new system. One disadvantage at the beginning of the study was the lack of the radiolucent aiming device for the insertion of the implant and, above all, for exact placement of the screws.

## Conclusions

The study presented here demonstrates the suitability of the new system for application to distal femoral shaft fractures, distal intra-articular multifragmentary fractures of the femur and also to periprosthetic fractures. Fracture treatment was performed by way of a minimally invasive approach for all types of fracture, thus conserving as far as possible any intact soft tissue and fragment vascularity.

The essential intraoperative steps were temporary primary reduction, independent of the implant, and implant alignment on the femoral shaft. Special attention must be paid to this procedure since the majority of misplacements are recognized at this stage.

The results of this study show that the new system, given a good knowledge of operative technique and careful, preoperative planning, represents an excellent, safe procedure for the treatment of almost all types of fracture, including even periprosthetic fractures of the distal femur. Generally, primary cancellous bone grafting can be dispensed with.

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- BG Unfallklinik Tübingen
- Benjamin Franklin Klinikum Berlin
- Inselspital Bern
- Kantonsspital Basel
- Kantonsspital Fribourg
- Spital Davos
- Academisch Ziekenhuis Utrecht

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