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Early results with the new internal fixator systems LCP and LISS : A prospective study

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The Locking Compression Plate (LCP) and the Less Invasive Stabilisation System (LISS) are new implants with angular stability developed by the AO/ASIF. They offer an alternative for internal fixation in complex intra-articular fractures and high-energy diaphyseal fractures of the long bones.

The new system was used in a prospective study to treat 113 patients (76 women, 37 men; average age : 53.1 years) with 122 injuries (multifragment shaft fractures or complex intra-articular, delayed/ non-union, malunion) from October 2002. Of these, 13 affected the humerus, 20 the radius, 2 the ulna, 21 the femur, 42 the tibia, 10 the fibula, 2 the acetabulum and 12 the calcaneus. Because of severe concomitant injuries, 18 fractures were first treated with an external fixator and definitively stabilised more than two weeks after the injury. Thirty-one patients were operated on after failure of other implants and non-union.

Clinical and radiographic findings as well as complications were followed prospectively over a mean period of 20 months (range : 13 to 30). One patient was lost to follow-up. A total of 112 patients underwent a standardised follow-up examination.

The outcome correlated with the severity of the fracture, anatomic reduction, adequate positioning of the plate and concomitant injuries. Despite the large number of open and comminuted fractures, no serious complications such as deep infections, vascular lesions, deep venous thrombosis or non-unions were noted.

We found the new internal fixator system to be a safe and reliable procedure. It offers numerous fixation possibilities and has proven its value in complex frac-

ture situations and in revision operations. A good knowledge of biomechanics is essential as well as precise preoperative planning.

Keywords : fracture ; plate fixation ; Locking Compression Plate (LCP) ; Less Invasive Stabilisation System (LISS) ; internal fixator.

ABBREVIATIONS

LISS = Less Invasive Stabilisation System LCP = Locking Compression Plate AO/ASIF = Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation ORIF = Open Reduction Internal Fixation

LISS DF = Less Invasive Stabilisation System Distal Femur

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LISS PT = Less Invasive Stabilisation System Proximal Tibia

MIPPO = Minimally Invasive Plate Percutaneous Osteosynthesis

INTRODUCTION

The Locking Compression Plate system combines the facilities of conventional plate osteosynthesis with those of the internal fixator systems. It combines the two treatment methods (i.e., the compression plating and locked internal fixation methods) into one implant (9, 29). In order to achieve this combination, a new plate hole design permits the use of both standard screws and locking head screws, which achieve fixed-angle stability.

The aim of the present study was to investigate the results of an initial application of the LCP and LISS across a wide range of indications and to make conclusions relevant for routine clinical application.

PATIENTS AND METHODS

From October 2002 until April 2005, 112 patients with 121 injuries were treated with the new LCP/LISS system at the Department of Orthopaedic Surgery 12 de Octubre University Hospital in Madrid as part of a prospective and non randomised study.

Since this documentation series involved the first ever broad-based application of LCP/LISS implants in routine clinical practice, the operations and the follow-up assessment were performed exclusively by experienced surgeons.

The inclusion criteria included all fracture types treated with an LCP/LISS. There were no restrictions in terms of fracture severity or localisation. Reasons for treatment included : acute trauma, secondary treatment of an acute fracture (time from accident to operation longer than two weeks), pathological fracture, delayed union of an existing fracture (no healing 6 months after injury) or non-union (no healing 12 months after injury), refracture of an initial fracture that had already been treated by ORIF with some other implant, and revision operation to deal with infection or malunion of an existing fracture. The study design did not affect the surgeon's choice of treatment or implant.

The demographic and clinical data were recorded pre- and postoperatively and at the follow-up assessment

during a mean period of 20 months (range : 13 to 30) after the operation. All complications occurring in the period between the operation and the final appointment were recorded.

The study design did not require any additional radiographic or clinical investigations. No uniform postoperative regimen was stipulated as obligatory for the treating surgeons.

At final follow-up, the following investigations were performed :

- Radiological documentation of the course of healing. Evaluation of the radiographs was performed by each surgeon. Fracture union was determined by the appearance of bridging callus on both anteroposterior and lateral radiographic views. Complete healing was defined as radiologically complete bone regeneration at the fracture site and a pain-free patient with full weight-bearing on the injured limb. Delayed union was defined as absence of healing 6 months after the operation. Non-union was defined as absence of healing 12 months after the operation.
- 2) Evaluation of any possible loss of reduction that might have occurred by comparing the postoperative radiographs and those taken at the time of final assessment by the treating surgeon.
- Assessment and analysis of any complications observed and the necessary revision operations with regard to their cause, the role of the implant and operative technique.

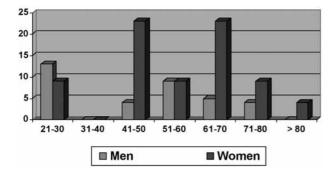
The final follow-up assessment, which took place on average 20 months (range : 13 to 30) postoperatively, terminated the study procedure.

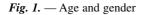
The study included treatment of a total of 121 injuries in 112 patients, 76 female and 36 male, aged 21 to 85 years (mean = 53.1 years) (fig 1). Nine patients had several different fractures.

The severity of the soft tissue injuries was recorded. Eighty-five fractures were closed. According to the Tscherne classification, 45 (52.9%) fractures were grade I, 30 (35.3%) grade II and 10 (11.8%) grade III. Five fractures were open. According to the Gustilo and Anderson classification, three open fractures were type I, one was type II and one was type IIIB (fig 2).

In this study, injuries of the tibia (n = 41), femur (n = 21) and radius (n = 20) predominated (fig 3).

Injury location was only analysed for long bone injuries and revealed a predominance of isolated distal injuries (n = 57) over isolated proximal (n = 39) or isolated shaft injuries (n = 2). The proportion of injuries involving an adjacent joint amounted to 79.3% (n = 96).





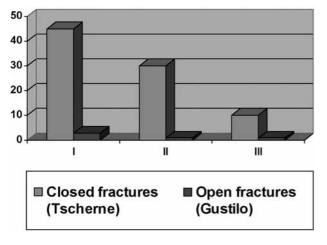


Fig. 2. — Acute fractures

The proportion of "special indications", e.g. acetabular injuries and calcaneus injuries ("other") was 11.6% (n = 14) (fig 4).

Analysis of the indications for applying the LCP/LISS system in this patient sample revealed a very mixed spectrum. The most frequent cause of injury requiring operation was clearly acute trauma and secondary treatment of an acute fracture (time interval between accident and operation longer than two weeks), which occurred in 90 patients. Another relatively large group (n = 27) consisted of patients whose fractures did not heal (delayed union or non-union). Four patients required a revision operation to treat malunion of an existing fracture.

The time interval between the accident and treatment with the LCP/LISS was on average 12.3 days (range : 2 to 38). For the patients with delayed union or non-union, the interval between the primary injury and treatment

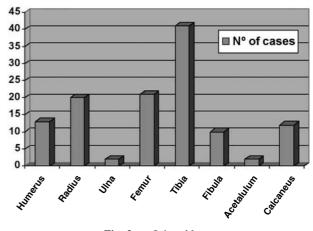
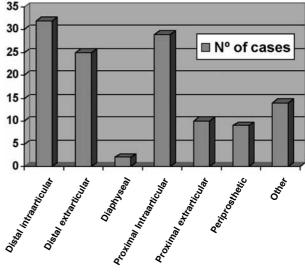
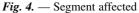


Fig. 3. — Injured bone





with the LCP/LISS ranged between 120 and 1440 days (average : 452.5 days).

The surgeon found bone quality to be good in 27 cases (24.10%) and fair in 4 cases (3.57%), and found obvious osteoporosis in 81 cases (72.32%).

A total of 121 LCP/LISS implants were used to treat 112 injuries. In 9 cases the LCP/LISS implants were combined with conventional plates (e.g. LC-DCP).

Analysis showed that the 3.5 mm LCP implants were implanted most frequently (n = 54), followed by the LISS DF (n = 21) and the 2.4/2.7 mm LCP (n = 20) (table I).

Analysable data on reduction technique or stabilisation procedure were recorded. Direct reduction was

LC-plates N° of cases % 3.5 mm LCP : small fragment 54 44.6 4.5/5.0 mm LCP : large fragment 15 12.4 2.4/2.7 mm LCP : distal radius 20 16.5 LISS DF 21 17.3 LISS PT 11 9.1

Table I. — Types of LC-plates used for 121 injuries

Table II. - Complications

Complications	N° of cases
– Delayed or non-union	2
– Loosening of the implant + loss of reduction	1
 Implant breakage 	1
 Superficial infection 	2
 Wound dehiscence 	2
 Implant-related pain 	9

performed in 92 cases and indirect reduction in 29. Bridging technique was employed in 58 cases, combination technique (compression and bridging) also in 58 cases and compression technique alone in 5 cases.

The 121 injuries were treated operatively by a total of nine different surgeons.

The data were statistically analysed using software (SPSS; Statistical Package for the Social Sciences, Chicago, IL) for Windows (Microsoft, Redmond, WA).

RESULTS

Of the 113 patients treated, one patient was lost to follow-up before the fracture had healed.

During a mean period of 20 months (range : 13 to 30) follow-up assessment was attended by 112 patients with 121 injuries (follow-up rate : 99.1%).

For 90 fractures there was uneventful and complete fracture healing without secondary loss of reduction in 88 cases and delayed union or nonunion in 2 cases; in one patient, revision operation was required to deal with non-union with implant failure. This patient underwent removal of the broken plate and intramedullary nailing with an 11-mm CTN (cannulated tibial nail, Synthes), with proximal and distal locking, in combination with autologous cancellous bone graft (fig 5).

Table III. — Seventeen reoperations in 14 patients

Reoperations	N° of cases
 Reoperation after plate breakage Bone grafting and change of implant 	1
after non-union	1
 Debridement after infection 	2
 Implant removal 	13

Of the 27 patients who received an LCP/LISS to treat delayed union or non-union, uneventful healing was observed in 26 patients; loosening of the implant and loss of reduction occurred in one patient, who refused revision operation (fig 6). All patients with corrective osteotomy went on to uneventful healing.

During the course of the study, 17 complications (adverse events) were documented in 12 patients. One patient experienced four adverse events and in one patient, three such events occurred (table II). These complications required a total of 17 revision operations in 14 patients (table III).

Wound dehiscence and superficial infection occurred in two patients. In the first patient, the plate on the tibia was exposed. Culture revealed the presence of *Staphylococcus aureus*. The patient was prescribed linezolid. The wound was extensively debrided and a soleus rotation flap was used to cover the wound (fig 7). In the second patient culture revealed the presence of *Staphylococcus aureus* and *Enterobacter Cloacae*. The patient was prescribed linezolid. The wound was debrided and managed by local dressing changes to achieve healing by granulation.

DISCUSSION

The present study documented the results of our first applications of the LCP/LISS system to a heterogeneous patient population and across a very mixed spectrum of indications.

The 17 complications of varying severity as documented during the study (in 12 of 112 cases followed up; sometimes several complications per case) correspond to a complication rate of 10.7%. None of these complications were judged to be purely implant related.

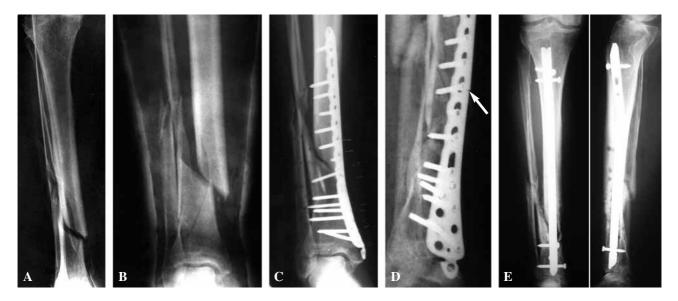


Fig. 5. — Radiographs of a 69-year-old man who was a pedestrian hit by a car. A) Anterior-posterior radiograph showing the distal tibial fracture (AO 43-A3). B) Primary treatment with closed reduction under general anaesthesia and immobilisation in an above-theknee cast. Anterior-posterior radiograph demonstrating secondary displacement one month later. C) The patient underwent open reduction and internal fixation with a 3.5-mm LCP distal tibia 10-hole plate. Indirect reduction with a no touch technique was not possible. Fixation of the fracture with bridging technique, no compression was applied. Anterior-posterior radiograph one month after surgery. D) Nine months after injury, the patient was admitted with a broken plate and delayed union. E) He was treated successfully with removal of the broken plate and intramedullary nailing with an 11-mm CTN (cannulated tibial nail, Synthes), with proximal and distal locking, in combination with autogenous cancellous bone graft. Anterior-posterior and lateral radiographs.

The LCP/LISS system with its various types of screw offers a very wide range of possible applications but involves the risk that errors may occur during preoperative planning as well as intraoperatively.

The LCP with combination holes allows three principles of application (11, 30) : LCP in a conventional plating technique (compression technique, principle of absolute stability), LCP in a MIPPO technique bridging the fracture zone (bridging technique or internal fixator, principle of relative stability), and LCP in a combination of both methods (compression and bridging, combination technique) using one plate.

There are different indications to use the LCP for different techniques and biomechanical principles (*30*) :

1. Compression technique : Simple fractures in the diaphysis and metaphysis (if precise "anatomical" reduction is necessary for the functional outcome), articular fractures, delayed or nonunion and closing-wedge osteotomies.

- 2. Bridging technique : Multifragmentary fractures in the diaphysis and metaphysis, simple fractures in the diaphysis and metaphysis (if a non precise reduction is sufficient for the functional outcome), opening-wedge osteotomies, periprosthetic fractures, secondary fractures after intramedullary nailing, delayed change from external fixator to definitive internal fixation and tumour surgery.
- 3. Combination technique : Articular fracture with multifragment fracture extension into the diaphysis and segmental fracture with two different fracture patterns (one simple and one multifragment).

The great variety of possible application modes demands a good understanding of biomechanics on the part of the surgeon and precise preoperative planning.

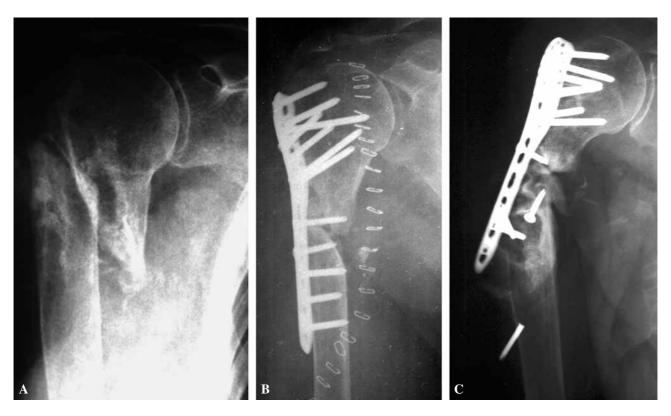


Fig. 6. — Radiographs of a 72-year-old woman who presented with a fracture of the humerus after a fall. A) Primary treatment was immobilisation in a brace. Anterior-posterior radiograph demonstrating non-union. B) The patient underwent fixation of her fracture with an LCP in combination with autogenous cancellous bone graft. C) The patient presented loosening of the implant and loss of reduction. She refused a revision operation.

Internal fixators provide several biological and technical advantages in comparison to existing fixation methods (29). The internal fixator method can be applied through an open but less invasive or a MIPPO (minimally invasive percutaneous plate osteosynthesis) approach. An indirect closed reduction is necessary when using the implant (e.g., LISS, LCP) in the internal fixator method bridging the fracture zone (30).

The infection rate (2/112, or 1.8% of the fractures) was low for this heterogeneous sample with several open fractures and many revision operations in patients that had already been operated on before. There are numerous explanations for this :

1. The good "biology" of the implant : the insertion of locking head screws dispenses with the need for compression between the plate and the bone, which means that there is little or no impairment of the periosteal blood supply beneath the plate and, thus, the bone necrosis observed beneath conventional plates is prevented. Preservation of the viability of the bone fragments is the key to unimpaired fracture healing. The biological fracture management provides environmental conditions that allow the natural healing process to occur as quickly and undisturbed as possible. The new biological plating technique imitates the concept of intramedullary fixation (*12*).

2. Numerous cases (n = 19) were performed with minimally invasive percutaneous plate osteosynthesis (MIPPO). This technique gives priority to biology over mechanics (31). The fracture zone was not exposed and the periosteal blood supply to the fragments was not further damaged at surgery.



D

Madrid. A) Anterior-posterior radiograph showing the right tibial pilon fracture (AO 43-A3). B) Anterior-posterior and lateral radiographs showing primary treatment with an external fixator. C) Two weeks later, the patient underwent minimally invasive LCP osteosynthesis on his right tibia and two fibular LCP's. D) Anterior-posterior postoperative radiograph. E) Six weeks after surgery, this patient presented wound dehiscence and superficial infection. The tibial plate was exposed. Culture revealed the presence of *Staphylococcus aureus*. The patient was prescribed linezolid. The wound was extensively debrided and a soleus rotation flap was used to cover the wound. No further treatment was required.

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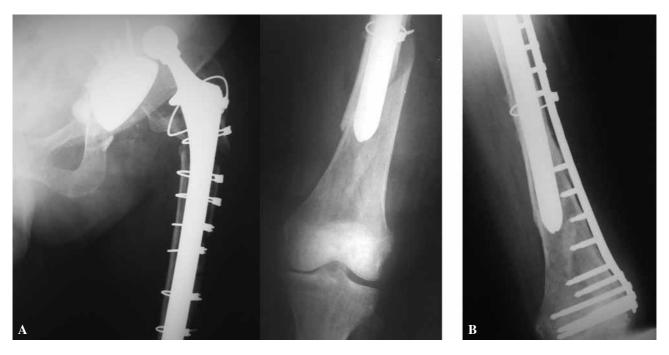


Fig. 8. — Radiographs of a 78-year-old woman who presented after a fall. She sustained a dislocation of her total hip arthroplasty and a supracondylar periprosthetic fracture. She underwent fixation of the femur with LISS and cup revision with a double mobility cup (SERF, France). A) Anterior-posterior radiographs showing dislocation of the hip prosthesis and supracondylar periprosthetic fracture. B) Anterior-posterior radiograph 6 months after surgery showing healing of the fracture.

Based on the open indirect "biological" technique of osteosynthesis, MIPPO first requires reduction and contention of the fracture using such aids as external fixation, AO distractor, and percutaneous reduction clamps before the plate can be applied (2, 3).

The main clinical benefits for using the LCP/LISS are in the following situations :

- Epi-/metaphyseal fractures (short articular block, limited bone mass for purchase) (15, 17, 19, 21, 25).
- Complex proximal tibia fractures without the need for additional medial stabilisation (5, 8, 9, 14, 22-24).
- Periprosthetic fractures of the femur (fig 8) (1, 16, 18, 32).
- Unstable fracture fragments that might be at risk of tilting in a conventional procedure (e.g. distal radius fractures).
- Fractures with severe soft tissue damage.
- Patients with diminished bone quality (6).

- No or reduced need for primary cancellous bone grafting (10).
- As an alternative method to intramedullary nailing (narrow medullary canal, preexisting bone deformity, fractures in adolescents, polytrauma).
- Corrective interventions.
- Revision operations after failure of other implants.
- Wider range of indications (20).

In two cases described here, treatment was unsuccessful due to implant breakage or loosening. In each case, non-union and early weight bearing, and choice of an inappropriate plate and/or fixation technique were identified as the reasons for plate failure rather than the features of the LCP system itself (4, 26).

The superficial peroneal nerve is at significant risk during percutaneous screw placement in holes 11 through 13 of the 13–hole proximal tibia LISS plate. Use of a larger incision and careful dissection down to the plate in this region may minimise the risk of damage to the nerve. In our series there was no postoperative nerve palsy (7).

There is little information available on removal of these implants. Frequent stripping of the locking screws has been found when removal was attempted (*13*). No problem has been encountered by our group.

Early experience with the new fixed-angle screw-plate system has confirmed the value of its application in routine clinical practice (28). The high primary stability in combination with newly developed minimal-invasive techniques (MIPPO) provide a basis for a functional aftertreatment and a rapid bony consolidation with a low complication rate (27).

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