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Micromotion in the fracture healing of closed distal metaphyseal tibial fractures: A multicentre prospective study

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ABSTRACT

The dynamic locking screw (DLS) in association with minimally invasive plate osteosynthesis (MIPO) in a bridging construct for simple metadiaphyseal long bone fractures enables modulation of the rigidity of the system and facilitates the development of early and triplanar bone callus.

Twenty patients affected by distal tibial fracture were treated with MIPO bridging technique and DLS at the proximal side of the fracture. Time of consolidation, quality of the reduction, complications and American Orthopaedic Foot and Ankle Society (AOFAS) score were monitored and the results compared with those from a control group treated with only standard screws on both fracture sides. Student *t*-test for independent samples was used for the comparison of means between the two groups. Chi-square test was used for the comparison of proportions. A multiple logistic regression model was constructed to assess the possible confounding effects. Performance was considered significant for $p < 0.05$. The mean healing time was 17.6 ± 2.8 weeks in the group treated with standard screws and 13.5 ± 1.8 weeks in the group treated with DLS ($t = 5.5$, $p < 0.0001$). The DLS was associated with early healing and triplanar bone callus.

Introduction

The stiffness of a fixation construct is a principal determinant of fracture-site motion and, therefore, affects the mechanism and progression of fracture healing [1–3]. Traditionally, conventional compression plates have been used to promote primary bone healing by delivering absolute stability at the fracture site [4]. With the development of locking nails, distal tibial fractures were treated by indirect reduction in a closed approach. The goal of this intramedullary splinting procedure was correct axial and rotational alignment and secondary bone healing with callus formation. Malunion with axial and rotational malalignment and knee pain are known disadvantages of this approach [5–7].

The introduction of locking plates improved the fixation strength of plate constructs, which expanded their indications to bridge plating for diaphyseal comminuted fractures [8–10] and periarticular fractures as an alternative to intramedullary nails and non-locking buttress plates [11]. Furthermore, locking plates enable the use of biological fixation techniques that emphasise preservation of blood supply and functional reduction over anatomic reduction and interfragmentary compression. However, in the absence of anatomic reduction and interfragmentary compression, locked plating constructs rely on secondary bone healing [12,13], induced by interfragmentary motion in the millimetre range [1,14,15] and can be enhanced by passive or active dynamisation [16,17].

Development of bridge plating constructs for comminuted fractures where anatomic reduction is not absolutely required promotes the development of minimally invasive plate osteosynthesis (MIPO). The plate is tunnelled extraperiostally through a small skin incision and then fixed with screws; this approach reduces soft tissue damage and respects bone biology.

The inherent stiffness of locked constructs is increasingly recognised as a potential cause of deficient healing that has been observed in simple fracture patterns stabilised with periarticular locking plates [18,19]. The near cortex adjacent to the plate is particularly predisposed to deficient healing because interfragmentary motion of locked plating constructs is asymmetric and minimal at the near cortex [19]. This seems to be particularly true when bridge plating techniques are performed for simple fracture

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patterns and periarticular fracture [11]. The amount of motion required to promote bone healing is still not well established for these types of injuries and the delays in bone healing and rehabilitation time are disappointing.

The interfragmentary strain hypothesis predicts that fracture healing will occur only if the interfragmentary motion divided by the fracture gap width is less than the fracture strain of bone (2%) [1,20,21]. Krettek et al., in a series of 99 open tibial shaft fractures, demonstrated that lag screws applied to further stabilise the fracture in combination with external fixation, significantly reduce fracture consolidation [22]; in contrast, there are good union rates for shaft fractures that are stabilised with external fixators alone [23]. Horn et al. [24] reviewed a total of 41 patients affected by fracture of the distal tibia and showed that interfragmentary screws might help to control and limit interfragmentary movement when simple fracture patterns were observed. Moreover, according to the interfragmentary strain hypothesis, the likelihood of union will increase for a given interfragmentary movement if the fracture gap increases. There is now clear evidence that the opposite is true [15,21,23] and that the strain patterns within an osteotomy or fracture gap are heterogeneous [25]; moreover, the fracture gap in a transverse osteotomy should not exceed 2 mm [1,21]. Fracture fixation should therefore follow certain principles: if secondary fracture healing is the goal of fixing simple fracture patterns, movement of the fragments along the axes is beneficial for the formation of soft callus [17], but both the gap and the amplitude of movement should be kept small (amplitude: 0.2–1 mm; fracture gap $<$ 2 mm) [1]. Higher strain amplitudes may be tolerated only for different fracture patterns (spiral fracture, multiple fragments). The formation of hard callus is compromised by vigorous mechanical stimulation [26].

Several approaches have been proposed to decrease the stiffness of locked plating constructs [18,27].

Working length (i.e., the distance between the screws less proximal and distal to the fracture), the kind of fixation of the screws in the bone, the implant itself and the distance of the plate to the bone influence the flexibility of an osteosynthesis. Another method to increase stiffness and reduce flexibility in a fracture zone is the moderate use of interfragmentary screws to block certain fragments towards each other or to limit interfragmentary movement [24].

The methods analysed are quite effective, but most of them primarily decrease the bending stiffness of the locked plate constructs. In these cases, interfragmentary motion results from the bending of the plate, which leads mainly to a rise of the motion at the far cortical side, while the interfragmentary movement at the near cortical side is hardly affected. In the context of these concerns, new implants were developed.

Bottlang et al. [28] developed the concept of far cortical locking (FCL). Unlike standard locked screws, in which the screw achieves threaded purchase in both the near and far cortex, the FCL screw has a smooth shaft with threads at the tip that achieve purchase in only the far cortex. The smooth shaft of this screw decreases the stiffness of the plating construct by acting as an elastic cantilever beam. Bending of these flexible screw shafts can occur with axial loading of the implant construct. Greater callus was seen with FCL implants compared with standard locked implants in a sheep tibial osteotomy study [29]. However, both the previous studies were limited to the evaluation of FCL function in diaphyseal bridge plating constructs in which plates were applied with FCL screws that were symmetrically placed on both sides of fractures. A later study investigated the use of FCL for periarticular fracture; in this type of lesion, FCL can be applied only to the diaphyseal side of the fracture [11].

Döbele et al. [19] reported on the use of the dynamic locking screw (DLS), which is an innovative concept to primarily reduce the axial stiffness of locked plate osteosynthesis, while the bending stiffness is less manipulated. In addition, the interfragmentary movement increases on the near cortical side. The DLS enables a fracture motion similar to a dynamic intramedullary nail system.

The present study analysed the influence of the DLS on simple distal metadiaphyseal long bone fractures when MIPO and bridging configuration technique were adopted. The objective of this study was to show that DLS may enable an expansion of the indications for MIPO bridge plate technique to more simple fracture patterns, which up to now were treated with intramedullary nailing or compression plate technique and associated with a delay in the healing process when treated with bridging plate technique.

Patients and methods

A prospective, multicentre, randomised study was conducted to evaluate the outcome of 40 patients affected by distal tibial fracture without joint affection who were treated with minimally invasive bridging plate technique. Patients with Volkmann's fracture were included and treated with one additional free screw. Twenty patients had only locking screws (LS) on both fracture sides and twenty patients had DLS on the proximal side of the fracture and standard LS on the distal side. Patients were enrolled between 2011 and mid-2013 in three different Orthopaedic Clinics and were treated by six expert surgeons. A distinct shared protocol was followed for treatment. Written consent to analyse the data of the patient charts for scientific purposes was obtained from every patient.

Operative management

Time of consolidation, quality of the reduction, complications and American Orthopaedic Foot and Ankle Society (AOFAS) score in the DLS group were monitored and compared with the results from a control group treated with only homogeneous locking compression plate (LCP) and standard screws. A total of 17 males and 23 females with a mean age of 43.5 $\pm$ 16.8 years were included in the study. Fractures were identified according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) Classification. Open fractures were excluded from the study. Tscherne classification for soft tissue damage was used for closed fractures.

Complex pilon fractures (AO43C3) were excluded because these require a different treatment approach and surgical technique. There were two patients with additional Volkmann's fracture in the group of extrarticular fractures: in these patients, the Volkmann fragment could be addressed easily with anterior-to-posterior screws that were independent of the plate.

Patients with polytrauma, metabolic bone disease or nickel sensitivity (DLS consists of a chromium cobalt [CrCo] alloy) were excluded from the study. Trans-skeletal traction or temporary external fixator was adopted as first procedure to avoid soft tissue and neurovascular disease. Definite surgery was conducted after sufficient detumescence of the soft tissues. Six surgeons were finally involved in the treatment. If the fibula had to be reduced for length reconstruction, it was addressed first; then the tibial fracture was reduced under fluoroscopy.

The use of 3.5–4.5 Medial Distal Tibial LCP with MIPO technique was chosen for all the fracture patterns. Surgery was performed in supine position on a radiolucent table. Perioperative antibiotic and anti-thromboembolic prophylaxis were adopted. Adjuvant pharmacologic or physical therapy was not adopted.

The plate was inserted extraperiostally through a small incision over the medial malleolus, sparing the saphenous vein and nerve. The positioning was controlled under fluoroscopy. Fractures were then indirectly reduced by manual traction or with the help of AO distractor. Occasionally, reduction was achieved by using a reduction screw through the plate, to bring the distal fragment against the plate before insertion of two or three angle stable screws. In simple fractures (AO42-A1 and 43-A1), a pointed reduction forceps was inserted percutaneously to achieve direct reduction. Fixation of the plate was always conducted through a small incision with a 5.0 mm mono or bicortical screw. A soft cast splint was applied until mobilisation for comfort and to prevent equine position of the foot.

Depending on anatomic features, 3.7 or 5.0 DLS were used (only two 3.7 DLS were used in the study). The DLS was applied on only the proximal side of the fracture and always in a bicortical and parallel configuration. Standard LS were never used at the same side as DLS.

Follow-up took place at 4, 8, 12, 24 and 48 weeks after surgery, with a clinical and radiological examination by the expert surgeon who treated the fracture, a control expert surgeon and an expert radiologist; 3D CT scan was planned 3 months after surgery. Visual analogue scale (VAS) and AOFAS scores were used for clinical evaluation.

Classic definitions of pseudoarthrosis were strictly observed. Healing within 6 months was defined as normal, within 6–9 months as delayed and longer than 9 months as pseudoarthrosis. The fracture was considered healed when a visible callus bridging of one cortex was present on both lateral and posterior–anterior X-ray and the patient was fully weight-bearing without pain. Partial weight with crutches and brace (maximum 15–20 kg) was allowed on the fourth day postoperatively; it could then be increased gradually depending on the radiological and clinical findings.

Statistics

A form that reported sex, age, type of trauma, waiting period before surgery, complications and healing time was filled for each

Table 1
Overview of the analysed patients treated with LS screws (Group 0) and their fractures pattern. RTA = road traffic accident.

No.	Gender	AO type	Age	Mode of injury	Injury treatment interval (days)	No. of LS	Plate	Union time (weeks)	Complications
1	F	42-B2.2	38	RTA	7	3	DMT 4.5	18	N
2	F	42-A1.1	45	RTA	2	3	DMT 4.5	24	Non-union
3	F	42-A1.2	75	Fall	3	3	DMT 4.5	20	N
4	F	42-A2.3	58	Fall	5	3	DMT 4.5	18	N
5	M	42-A3.3	42	Fall	6	3	DMT 4.5	20	N
6	F	42-A3.2	32	RTA	4	3	DMT 4.5	18	N
7	F	43-B1.3	18	RTA	2	4	DMT 4.5	17	Ankle stiffness
8	M	43-B2.1	32	RTA	3	3	DMT 4.5	16	N
9	F	42-C3.1	48	RTA	10	3	DMT 4.5	14	N
10	F	42-C2.3	30	RTA	7	3	DMT 4.5	15	N
11	F	42-B2.1	42	Fall	6	3	DMT 4.5	19	N
12	M	43-A2.1	28	RTA	3	4	DMT 4.5	20	Superficial infection
13	F	42-C2.1	72	Fall	8	3	DMT 4.5	14	N
14	F	42-B2.1	18	RTA	5	3	DMT 4.5	17	N
15	M	42-C1.1	28	RTA	5	3	DMT 4.5	18	N
16	F	43-B1.1	32	Fall	4	3	DMT 4.5	16	Valgus angulation $<5^\circ$
17	M	42-A1.1	27	RTA	5	3	DMT 4.5	22	N
18	F	42-C2.1	72	Fall	12	3	DMT 4.5	12	N
19	F	42-A1.1	58	Fall	5	3	DMT 4.5	18	N
20	F	42-C1.1	62	Fall	7	3	DMT 4.5	17	N
Mean			42.85		5.35	3.1		17.65	

Table 2
Overview of the analysed patients treated with DLS screws (Group 1) and their fractures pattern. RTA = road traffic accident. V = additional Volkmann's fracture.

No.	Gender	AO type	Age	Mode of injury	Injury treatment (interval (days)	No. of DLS	Plate	Union time (weeks)	Complications
1	M	42-B1.2	47	Fall	10	3	DMT 4.5	12	N
2	F	42-A1.1	53	Fall	2	3	DMT 4.5	16	N
3	F	42-A2.3	35	RTA	4	3	DMT 4.5	18	Varus angulation $<5^\circ$
4	F	42-A2.1	48	RTA	4	4	DMT 4.5	12	Superficial infection
5	F	42-A1.3	47	Fall	7	3	DMT 4.5	14	N
6	F	42-A2.2	32	RTA	5	3	DMT 4.5	12	N
7	M	43-B1.2	55	Fall	5	3	DMT 4.5	14	N
8	M	43-B1.1	32	RTA	10	3	DMT 4.5	15	N
9	F	43-A3.3	58	Fall	5	3	DMT 4.5	12	Valgus angulation$<5^\circ$
10	F	43-B3.3	70	Fall	2	4	DMT 4.5	14	N
11	F	43-A3.3	52	Fall	6	5	DMT 3.5	16	N
12	M	43-A1.1	38	RTA	3	4	DMT 3.5	14	Sudeck syndrome
13	M	42-B2.3 (V)	17	RTA	2	3	DMT 4.5	12	N
14	M	42-B1.3	18	RTA	4	3	DMT 4.5	14	N
15	M	42-A1.1	28	Fall	7	3	DMT 4.5	12	N
16	M	43-B3.1	32	Fall	2	4	DMT 4.5	13	N
17	M	42-A1.1	27	RTA	8	3	DMT 4.5	12	N
18	M	42-C3.1	72	Fall	10	3	DMT 4.5	12	Valgus angulation$<5^\circ$
19	M	43-B1.1	58	Fall	7	3	DMT 4.5	15	N
20	M	42-A1.1	62	Fall	5	3	DMT 4.5	12	N
Mean			44.1		5.4	3.3		13.55	

patient and entered into a database (FileMaker software PRO11; STATA software MP11). The Student *t*-test for independent samples was used to compare means between the two groups. The chi-square test was used for the comparison of proportions. A multiple logistic regression model was constructed to assess the possible confounding effects. Performance was considered significant for $p < 0.05$. Correlation coefficients were determined for estimating correlations between healing time and type of reduction (MIPO with LS vs MIPO with a hybrid construct [DLS and LS]).

Results

A total of 40 patients were analysed in the study; no patients were lost at the follow-up. The main time until surgery was 5.45 days. The mean operative time was 115 min, depending on the type of fracture and the surgeon's experience of the MIPO technique.

Depending on the soft tissue conditions, mobilisation with partial weight-bearing started a mean of 4 days after surgery. Medial Distal Tibial LCPs were used in all 40 patients, of whom only 2 received a 3.5 plate and the remaining 38 patients had a 4.5 plate; the study group had a mean number of 3.3 DLSs, always located on the proximal side of the fracture, while the control group had a mean of 3.1 LS.

Based on our clinical and radiological definition of fracture healing, a total of 10 patients were classified as healed at 12 months; the longest healing time was 22 months, which was observed in only 1 patient. The group treated with DLS had a mean healing time of 13.55 ($\pm$1.8) weeks compared with 17.65 ($\pm$2.8) weeks in the LS group ($t = 5.5$; $p < 0.0001$). Tables 1 and 2 give an overview of the patients, fracture patterns, implant device properties, time of healing and complications.

Simple fracture patterns (42-A, 43-A) showed a quicker healing process in the DLS group (13.8 weeks) compared with the LS group (19.5 weeks) ($p < 0.0001$) (Fig. 1).

Mean AOFAS score was 89.65 in the DLS group and 85.50 in the LS group. There was one case of non-union in the LS group in a female patient with a simple pattern fracture (42-A1.1) and a history of heavy smoking and alcohol abuse. She refused additional treatment. There were three cases of varus/valgus angulation (<5°), one superficial infection and one algodystrophy in the DLS group (Table 2). There was one varus angulation (<5°), one superficial infection and one ankle stiffness in the LS group

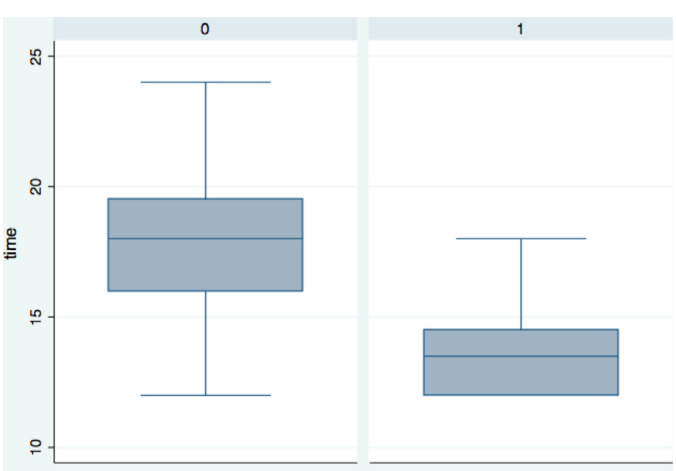

Fig. 1. Mean healing time was 17.6 ± 2.8 weeks in the group treated with standard screws (LS) and 13.5 ± 1.8 weeks in the group treated with DLS ($t = 5.5$, $p < 0.0001$).

Fig. 2. Implants were removed from two patients: 3.7 and 5.0 DLS at removal surgery; no screw breakage was observed at implant removal.

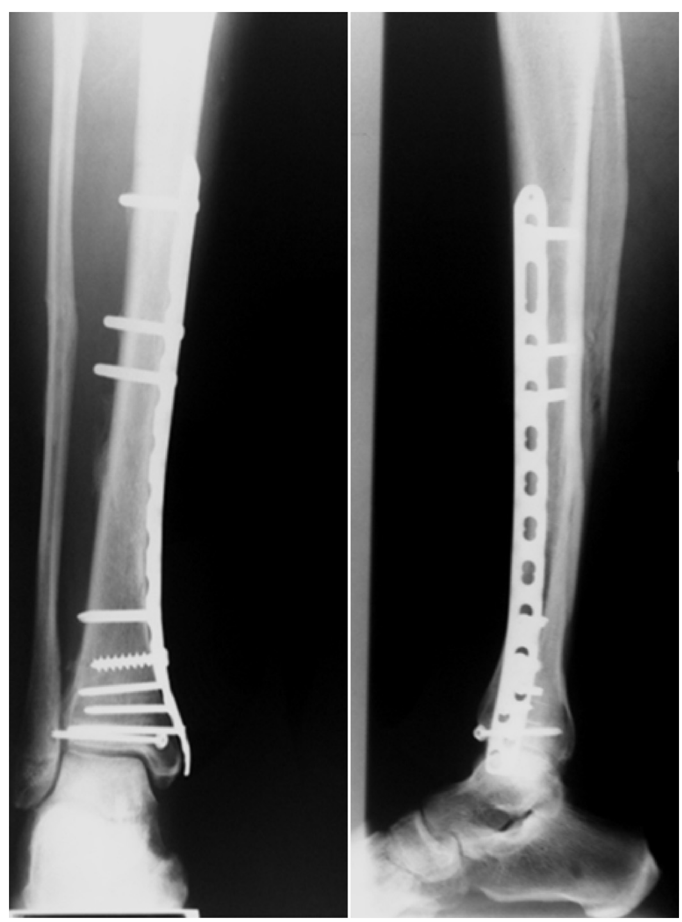

Fig. 3. X-ray at 3 months after surgery (DLS screws on the proximal side of the fracture).

(Table 1). The incidence of complications was not statistically different in the two groups (chi-square = 0.14; $p = 0.7$). No deep infection was observed. Two implants were removed in the study (Fig. 2); these were removed from thin patients in whom plates pressed against the wound causing cosmetic complaint. A medical device safety alert has recently been released about evidence of breakage at the bottom of the pin of the DLS. The breakages are recognised during planned implant removal of the whole construct after successful healing. When using this device, the surgeon must consider the potential risk that the breakage of a DLS may cause in terms of malunion or non-union, which would require additional medical intervention [30]. In the implant removal procedures in the current study, there was no evidence of breakage at the bottom of the pin.

Comparison of the plain radiographs and CT scan

All instrumental investigations were checked by the expert surgeon who treated the fracture, a control expert surgeon and an expert radiologist. A comparison of the X-rays of those patients treated with LS showed that there was a regular, but not always distinct, pattern. In over half of the cases, there was a strong callus formation on the cortex away from the plate, whereas there was very little or no callus formation on the cortex adjacent to the plate. All patients in the DLS group showed a regular callus pattern; and there were no differences in callus distribution between the two cortices (Figs. 3 and 4). Osteopenia was observed in three cases in the LS group at the near cortex; in one of these cases, a pseudoarthrosis later developed. Weight-bearing was addressed for each patient at 12 weeks; CT scan at this timepoint showed triplanar and symmetric bone callus in all cases in the DLS group (Fig. 5).

Discussion

The present study describes the efficacy of DLS confined to the proximal diaphyseal fracture side in conjunction with MIPO technique for simple distal metadiaphyseal tibial fractures. The results support the hypothesis that DLS can reduce the stiffness of a locking construct and induce parallel interfragmentary motion while retaining construct strength.

Abandoning the doctrines of conventional plate techniques (exact anatomical reduction and rigid fixation) the objective of fracture management with locking plates is no longer primary bone healing. Performed in bridging technique, locking plate fixation relies on indirect bone healing; therefore, the presence of interfragmentary movement is essential. Nevertheless, due to the rigid plate-screw connection, locking plates cause less bone stress and may suppress interfragmentary movement to an inadequate range for optimal indirect bone healing. The elastic oscillation of

Fig. 4. X-ray at 12 months after surgery (DLS screws on the proximal side of the fracture).

Fig. 5. 3D CT scan in a patient with DLS at 3 months shows triplanar symmetrical bone callus.

the plate leads to asymmetrical interfragmentary motion, which occurs predominantly at the far cortex side.

In an analysis of 32 patients with diaphyseal and distal tibial fracture treated with LCP in bridging configuration and MIPO technique, Hasenboehler et al. [5] found a consolidation in 3 months in only 10 cases. A total of 13 patients had recovered after 6 months, 4 patients needed 9 months and 3 patients required a revision. Although the number of patients in this series is too small to draw definitive conclusions, the authors considered that a bridging plate technique in simple fracture patterns is disadvantageous due to prolonged time to full weight-bearing. A compression osteosynthesis with percutaneous interfragmentary lag screws and a neutralisation plate should be performed for simple fracture patterns (AOA1-3). There are difficulties associated with interfragmentary screw positioning when using a minimally invasive approach, however, and the fracture bruise has to be cleaned to obtain anatomic reduction and it could be associated with delay in bone healing.

The stiffness of a fixation construct is the principal determinant of fracture site motion and primarily affects the mechanism and progression by which a fracture heals. On the basis of theoretical and clinically emerging concerns, several strategies to decrease the stiffness of locked plating constructs have been investigated. The stiffness of a locked plate construct can be modified by varying the length of the bridged part of the plate, the number and position of the screws and the plate–bone distance. In this manner, a reduction in stiffness involves primarily a reduction in the bending stiffness, and this causes a greater bending of the plate. A selective decrease of axial stiffness is not provided. The unequal distribution of micromovement at the fracture site therefore persists, primarily at the expense of the near cortex.

Horn et al. [24] retrospectively analysed callus index at full weight-bearing in a total of 41 patients treated with LCP Medial Distal Tibia Plate for distal metadiaphyseal fractures of the tibia. Bridge plating with interfragmentary movement was the strategy for such osteosynthesis. Interfragmentary screws were used to limit interfragmentary movement in certain cases and they noticed that fracture healing tended to be faster in patients with interfragmentary lag screws compared with in those who had only bridge plating. Interestingly, the study authors observed a very asymmetrical callus distribution in those patients who had a prolonged fracture healing phase. Much more callus was observed on the cortex opposite the plate compared with adjacent to the plate, where osteopenia was observed in some cases. The authors concluded that the plate used and its fixation technique in bridge plating (three to four screws in the proximal part of the plate, bridge plating and fixation with four to five screws in the distal part) does not always provide sufficient stability with increased flexibility in the frontal and sagittal layer. This may explain an asymmetrical distribution of interfragmentary movement, with little or no movement on the cortex adjacent to the plate and intense interfragmentary movement on the cortex opposite the plate. This is demonstrated by the asymmetrical callus distribution in the frontal layer.

Some authors have tried to reduce the stiffness of locked plate constructs by modifying the screw design while trying to preserve construct strength. Bottlang et al. [28,29] investigated a novel strategy, termed far cortical locking (FCL), which has been designed to reduce the stiffness of locked plating constructs while retaining construct strength. In FCL, locking screws with a reduced midshaft diameter provide unicortical fixation in the far cortex of the diaphysis without being rigidly fixed in the near cortex underlying the plate. The middle part of the screw shaft decreases the stiffness of the plating construct by acting as an elastic cantilever beam, similar to a half-pin of an external fixator. Bottlang et al. tested the hypothesis that FCL can significantly reduce the stiffness of a locked plating construct while retaining its strength. Locked plating constructs and FCL constructs were tested in a diaphyseal bridge plating configuration under axial compression, torsion and bending. The results supported the hypothesis that FCL can significantly reduce the stiffness of a locked plating construct while retaining its strength. Reduction in stiffness was most pronounced under axial loading. A limitation of this concept is that a certain length of the FCL screw is necessary to obtain the desired reduction in stiffness, and therefore its use depends on the geometry of the bone.

Doornink et al. [11] conducted a biomechanical study to evaluate periarticular locking plates when applied to stabilised distal femur fractures in 22 paired human femurs. One femur of each pair was stabilised in a standard locked plating approach (LP group). In contralateral femurs, FCL screws were used in place of standard locking screws for diaphyseal fixation (FCL group). Each specimen was then subjected to three tests under quasi-physiological loading. The authors reported an 81% reduction in stiffness with FCL fixation in the proximal segment of a periarticular locked plating construct. This result is similar to the 88% reduction in stiffness previously reported for diaphyseal plating construct in which three FCL screws were applied on each side of a diaphyseal plating [28]. The small difference between the use of FCL on both sides of the fractures justifies positioning of the FCL only on the diaphyseal side to avoid excessive movement near to an articular site. Results of this study are limited to a particular physiological loading mode that represents the stance phase of level walking in a simplified and controlled manner [31,32]. It is important to understand that the ability of FCL screws to reduce construct stiffness and to induce controlled interfragmentary motion relies on establishing a specific motion envelope in the near cortex. This is assured by placing the screw shaft concentrically in the near cortex drill hole. In absence of a concentric placement of the screw shaft, FCL functionality may be diminished or lost. FCL screws provide a simple and effective approach to reduce the stiffness of periarticular locking constructs without requiring additional procedures. Future studies are required to determine the effect of periarticular FCL plating constructs on fracture healing.

Döbele et al. [19] reported on the use of another DLS that was designed to reduce the stiffness of locked plate constructs. This DLS is a cobalt–chromium–molybdenum alloy composed of two parts: an outer sleeve with threads that engage the bone and an inner pin with threads that lock to the plate. The inner pin is designed to enable movement within the outer sleeve, while the plate–screw interface and bone–screw interface remain constant (Fig. 6). Döbele et al. conducted a mechanical study to compare the DLS with a standard LS and showed that the DLS reduced axial stiffness by 16%. The bending stiffness of the construct remained almost within the same level. The interfragmentary motion at the near cortical side (adjacent to the plate) was significantly greater with the DLS (423 μm) compared with the standard LS (282 μm).

The DLS may enable expansion of the indications for bridging plate technique to both periarticular and more simple fracture patterns, which were limited until now to treatment with intramedullary nailing or compression plate technique. The DLS merges the advantages of a nail osteosynthesis with the advantages of a plate osteosynthesis.

The aim of the current study was to transfer the theoretical data of the previous papers into clinical practice. The results of this study show that the combined use of DLS with locking plates in MIPO technique and bridging configuration leads to significantly earlier bone healing and ability for full weight-bearing compared with LS in patients with metadiaphyseal tibial fractures (13.5 ± 1.8 weeks for DLS compared with 17.6 ± 2.8 weeks for LS); fracture gap < 2 mm remains an unavoidable issue to grant fracture healing.

The current study also compared healing time of simple fracture patterns (42-A, 43-A) in the two groups: healing time in the DLS group was significantly less than in the LS group. This result concurs with data from other studies and confirms the need to modulate construct stiffness to provide indirect modulation of interfragmentary movement, particularly when comminution is not the main character of the lesion. Simple fracture patterns appear to require a precise and not yet well defined amount of interfragmentary movement.

In the current study, DLS was applied only at the diaphyseal side of the fracture and not at the metaphyseal side. A parallel configuration of the screws is required for fracture healing with this implant procedure and this is possible only at the diaphyseal side. Positioning DLS at the metaphyseal side could be associated with articular impingement at the syndesmosis and with excessive micromovement that would not be tolerable for the periarticular fracture healing process.

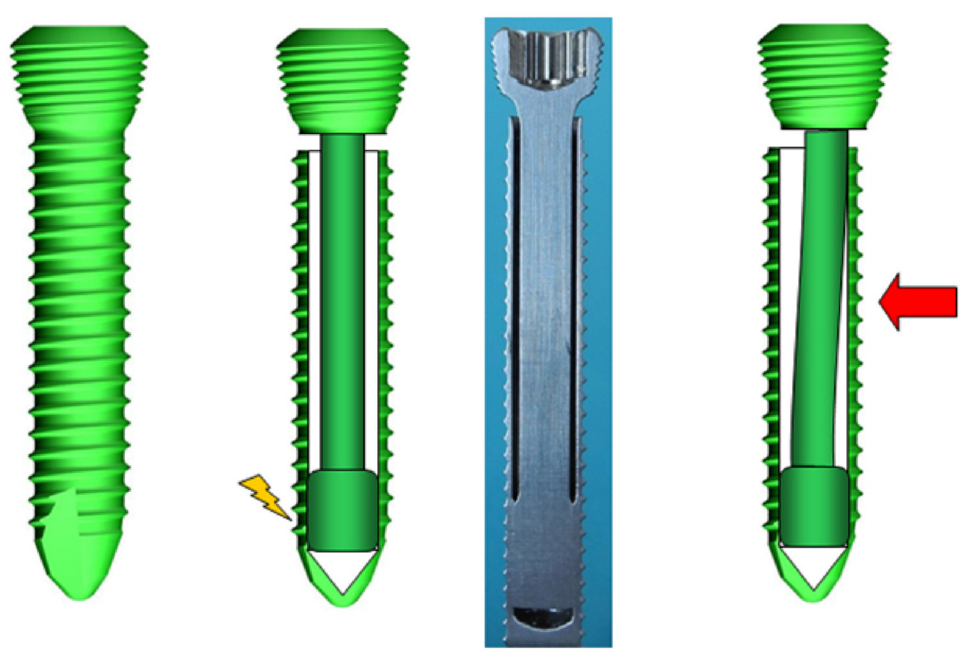

Fig. 6. DLS consists of chromium–cobalt–molybdenum alloy; a standard locking head with an outer-sleeve with treads that engage the bone and an inner pin with threads that lock to the plate. The inner pin is designed to enable movement within the outer sleeve, while the plate–screw interface and bone–screw interface remain constant. Micromovements (0.2 mm for 3.7 mm screws and 0.35 mm for 5.0 mm screws) are allowed and these modulate the rigidity of the LCP system, which stimulates bone healing.

Previous biomechanical studies on FCL showed little difference in stiffness reduction for periarticular fractures when a hybrid construct (FCL screws for diaphyseal fixation and conventional LS for metaphyseal fixation) was applied instead of an LCP construct with FCL on both sides [11].

In the current study, triplanar symmetrical distribution of bone callus could be observed on the control CT scan at weight-bearing in the DLS group; this could be explained by an earlier callus remodelling process with functional properties similar to physiological bone tissue biomechanics.

Although a medical device safety alert was released recently about evidence of breakage at the bottom of the pin of the DLS, there was no such complication during removal of two implants in the current study. The breakages are recognised during planned implant removal of the whole construct after successful healing. The difficulties of removing LCP with standard LS have been reported, and different technical tricks to avoid screw breakage have been described [33]. When using both DLS and LS, surgeons must consider the potential risk that the breakage of a screw may cause in terms of malunion or non-union, which would require additional surgical procedures [30].

The findings in this small prospective study cannot necessarily be generalised: interindividual differences in fracture healing and weight load have a stronger effect on the results than in large collectives. Furthermore, the amount of callus was not quantified through a callus index, and callus pattern was observed only empirically on CT scan and X-ray. The study also did not investigate the effects when DLS was positioned distally to the fracture side.

DLS with MIPO bridging technique enables *in vivo* micromotion by reducing construct stiffness. The DLS system delivers nearly parallel fracture site motion and, therefore, greater formation of circumferential callus of higher mechanical strength. This boost in biological bone healing offers a faster, more stable healing process compared with highly rigid fixation, particularly for simple pattern metadiaphyseal tibial fracture, which is often still associated with a delay in the time of consolidation.

Conclusion

This study compared the time until clinical and radiological healing of periarticular fractures of the distal tibia when treated with LCP with or without combination of DLS.

In this study, the use of DLS on the proximal fracture site reduced the time of bony consolidation and promoted an earlier and triplanar bone callus with a homogenous pattern that could represent a faster remodelling of the fracture site. This is particularly interesting for simple fracture patterns that until now were associated with a delay in the healing process when fixed with LCP construct. The study was limited by the small patient numbers. Large, prospective, long-term clinical trials are required to confirm the findings.

Conflict of interest

Authors certify that they have no affiliations with, or involvement in, any organisation or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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