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ORIGINAL RESEARCH

Effect of far cortical locking (FCL) on healing of long bone fractures of lower limb

[1]Dr. Dhruv Lashkare, [2]Dr. Harish Rao, [3]Dr. Tribhuwan Narayan Singh Gaur, [4]Dr. PV Siddhartha

[1-4]Department of Orthopedics, People's College of Medical Sciences and Research Centre, Bhanpur, Bhopal, India

Corresponding author
Dr. Dhruv Lashkare
Department of Orthopedics, People's College of Medical Sciences and Research Centre, Bhanpur, Bhopal, India

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ABSTRACT

Introduction: The present study was conducted to evaluate the effect of Far Cortical Locking (FCL) on healing of long bone fractures of Lower Limb. **Materials and Methods:** This Non-Randomized Prospective Interventional Study was carried out in People's College of Medical Sciences and Research Centre, Bhopal from November 2016 to April 2018 on 32 cases that were treated with Far Cortical Locking technique in various locations of the long bone fractures of the lower limb and giving consent for the study. Data was compiled using MS Excel and analyzed using SPSS. **Results:** Mean age of study participants was 40.3±14.7 years. Majority of patients were male. Mean duration since injury was 8.94±7.13 hours whereas Mean injury surgery interval was 3.31±1.17 days.Union clinical time was significantly higher in high grade injury as compared to low grade injury similarly union time radiological was significantly higher in high grade injury as compared to low grade injury. Weight bearing was equally distributed among different fracture configuration (p=0.443). Mean time for toe touching was 2.88±1.00 weeks whereas full weight bearing was possible after mean time of 18.59±1.94 weeks. **Conclusion:** The use of FCL screws in place of standard locking screws significantly reduced construct stiffness and provided controlled interfragmentary motion for promotion of fracture healing by callus formation. Similar fracture healing rates as reported by previous studies indicate improved fracture healing with FCL technology.However, a large randomized case control trial is needed to provide strength to present study finding.

Keywords: FCL, stiffness, long bone fracture, Bhopal

INTRODUCTION

The priority in fracture stabilization has shifted from rigid fixation & anatomical reduction aiming at primary fracture healing to biological fixation and elastic stabilization resulting in secondary fracture healing. The realization, that preservation of biology around the fracture is paramount in fracture healing and could be traded off for anatomical reduction and rigid fixation, led to evolution of newer techniques and frontiers in implantology.[1] The concept of biological fixation involves stabilization of fracture without violating the biology in the vicinity of the fracture site.

The mechanism of progression by which a fracture heals is affected by the stiffness of the construct. High stiffness of the Locked Plate Construct suppresses the inter-fragmentary motion, and improves fixation to a level insufficient for optimal promotion of secondary bone healing.[2] Recent case studies on Locked Plating have supported concerns of delayed union or non-union and insufficient callus formation.[3] The benefits of locked plating, including improved fixation strength in osteoporotic bone and the ability to provide a more biologically friendly fixation construct have led to the rapid adoption of this technology.[4] However, controversy persists with regard to whether locked plating constructs provide a proper mechanical environment to reliably promote secondary bone healing by callus formation.[4,5,6]Secondary bone healing is stimulated by inter fragmentary motion in the millimeter range and is enhanced by active or passive dynamization.[1] Conversely, secondary bone healing can be suppressed by rigid fixation aimed at preventing inter fragmentary motion. Locked plating constructs have been described as internal fixators, capable of providing relative stability while allowing controlled range of micromotion at the fracture zone conducive to secondary fracture healing.[7] However, locking constructs are several times stiffer than external fixators because of their close proximity to the bone. They are reported to be as stiff as conventional plating constructs designed to induce primary bone healing. Therefore, locked bridge plating constructs may be too stiff to promote callus formation reliably.[3,8] Till date, no in vivo study of fracture-healing has been published to document

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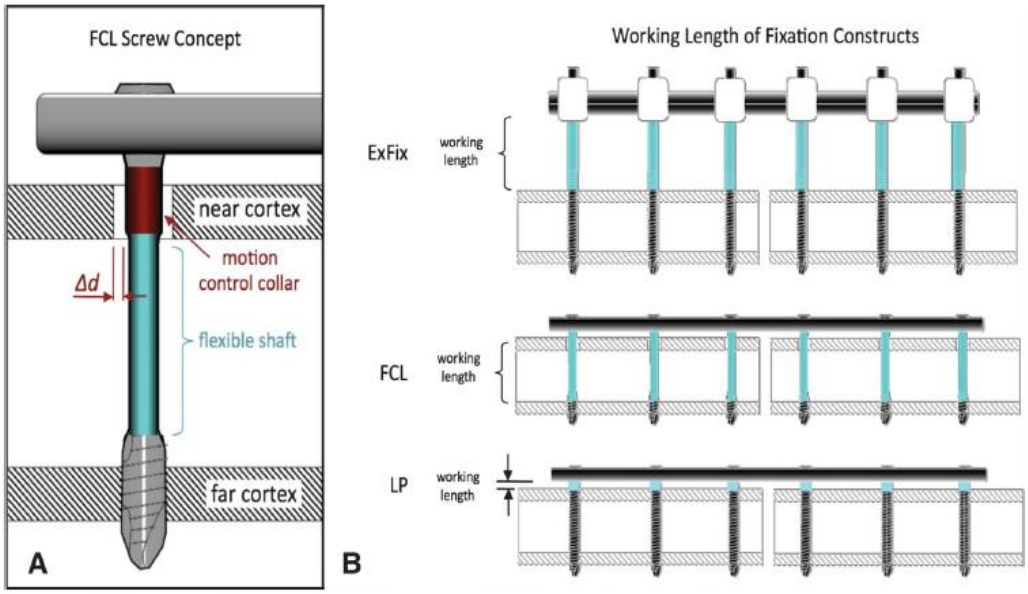
callus formation associated with locked plating constructs. To address this stiffness concern, a modified locked plating technology, termed as far cortical locking, capable of reducing the stiffness of a locked plating construct while retaining its strength, has been introduced recently. The far cortical locking screws decrease the stiffness of the plating construct by acting as elastic cantilever beams similar to half-pins of an external fixator.[9] A thorough internet search has revealed no Indian study evaluating the role of far cortical locking in healing of long bone fractures of Lower Limb. Hence present study was planned to evaluate the healing process of long bone fractures of Lower Limb fixed with Far Cortical Locking (FCL) technique.



Aim

To evaluate the effect of Far Cortical Locking (FCL) on healing of long bone fractures of Lower Limb.

MATERIALS AND METHODS

This Non Randomized Prospective Interventional Study was carried out in People's College of Medical Sciences and Research Centre, Bhopal from November 2016 to April 2018. The study consisted of a total of 32 cases that were treated with Far Cortical Locking technique in various locations of the long bone fractures of the lower limb. Diaphyseal/Metaphyseal fractures of Femur/Tibia in adults of either sex and Closed or Open (Grade I) Long Bone Fractures of Lower Limb up to 2 weeks old were included in the study. Patients in pediatric age Group in either sex; Pathological Fractures/Non-traumatic fractures; Co-morbid neurological conditions which preclude weight bearing; Mental retardation or difficulty in patient-doctor communication; any intra-articular fractures, fractures associated with bone loss, polytrauma, cases with poor condition or loss of soft tissue, infection and necrosis were excluded.

Research permission and ethical approval was obtained from Research Advisory Committee (RAC reference number-PCMS/OD/2016/3158) and Institutional Ethics Committee (IEC reference number-PCMS/OD/2016/3159 Code no. IEC-2016/43) of PCMS & RC, Bhopal, respectively. CTRI registration no. CTRI/2017/11/010568

Procedure

All cases received primary treatment in the emergency room and a thorough examination was done to find out the associated injuries. A detailed written and explained consent was obtained from the patients. Standard radiographs with antero-posterior and lateral views of the affected site were taken and the fracture was classified according to AO group classification and evaluated for the extent of comminution. The limb was immobilized in a plaster slab till definitive surgery was possible and appropriate antibiotic cover was provided with a combination wherever indicated. Patients having other bony or soft tissue injuries were treated accordingly. Patients were subjected to routine pre-anaesthetic investigations and additional investigations wherever indicated. Antero-posterior and lateral X-rays taken were evaluated to determine the length of the plate to be used was ascertained by taking length of the plate 3 times that of the fractured segment and in case of two part fractures, 8-10 times the length of the fracture.

Surgical Techniques

Surgery was performed under regional or general anaesthesia. All the interventions were done under all aseptic precautions in the major OT as per established surgical principles and appropriate antibiotic cover. Adequate reduction of the fracture was obtained by method of indirect/direct reduction and the plate position (medial/lateral) was determined accordingly. The plate was applied by MIPPO/open surgical

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technique using the bridge plating principles. Number of screws fixed was 50% of the holes in the plate for diaphyseal and 75% for holes in the cancellous bone. The procedure of screw fixation was in accordance with the surgical principles of locking plate.

Data collection procedure

Follow up visits were scheduled at 2, 6, 12 & 24 weeks. Clinical examination was done and x-rays were taken at all follow up visits to assess callus formation at the far and near cortex. Based on the clinical examination and x-ray findings, timing and extent of weight bearing was decided.

Statistical analysis

All the data analysis was done using IBM SPSS version 20 software. Frequency distribution and cross tabulation was used to prepare tables. Microsoft word 2010 was used to prepare graphs. The parametric Student 't' test were used to compare mean±SD. According to the characteristics of the subjects, they were compared using the Chi-square test value of less than 0.05 will be considered statistically significant.

OBSERVATIONS AND RESULTS

Table I: Distribution of study participants according to sociodemographic variables

Sociodemographic variables		No of patients (n=32)	Percent
Age (years)	18-25	7	21.88
	26-35	6	18.75
	36-45	8	25.0
	46-55	6	18.75
	>55	5	15.62
Gender	Female	6	18.8
	Male	26	81.3
Residence	Rural	15	46.9
	Urban	17	53.1

Mean age of study participants was 40.3±14.7 years. Most common age group in present study was 36-45 years [8 (25%)] followed by16-25 years [7 (21.88%)].Majority of patients were male [26 (81.3%)] followed by female [6 (18.8%)]. Maximum patients i.e. 53.1%were residents of urban areaand rest 46.9% were resident of rural area.

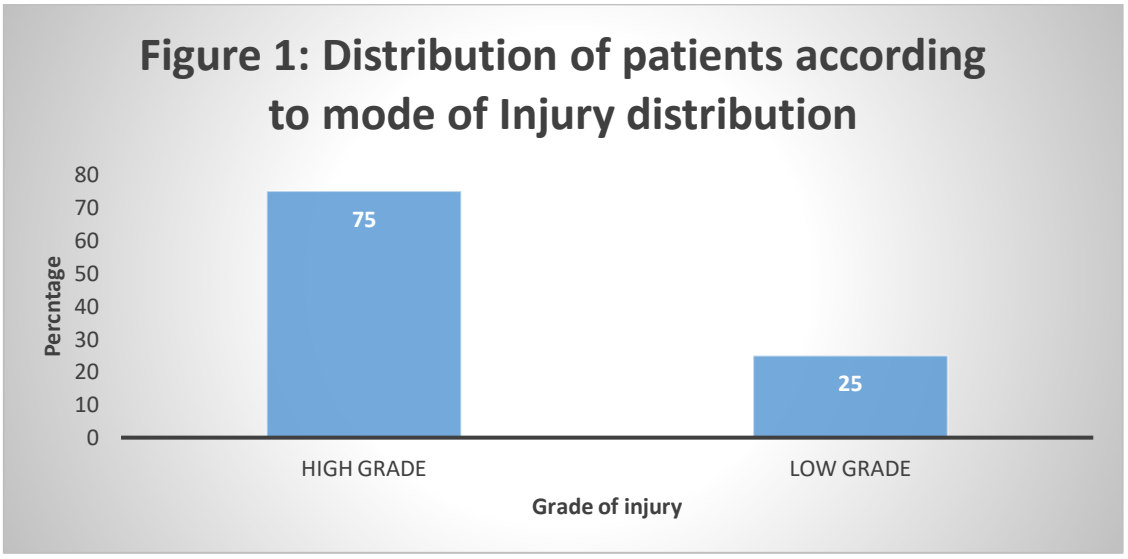

Figure 1: Distribution of patients according to grade of injury

Most common grade of injury was high [24 (75%)] followed by low grade [8 (25%)]. In present study, 75% patients presented with the history of road traffic accident and the rest 25% presented followed by fall.

Table II- Distribution according to injury surgery Interval

Surgery Interval (days)	No of patients	Percentage
1	1	3.1
2	6	18.8
3	16	50.0
5	9	28.1
Total	32	100.0

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Mean duration since injury was 8.94±7.13 hours whereas Mean injury surgery interval was 3.31±1.17 days.Maximum patients underwent surgery with injury surgical interval of 3 days [16 (50%)] followed by 5 days [(9 (28.1%)].

In present study, most common diagnosis was Proximal 1/3rdTibia Fracture (43.8%), followed by middle 1/3rd tibia fracture (21.9%), distal 1/3rd tibia fracture (18.8%) and the least were distal 1/3rd femur (9.4%) and middle 1/3rd Femur Fracture (6.3%). Maximum patients had closed fracture [23 (71.9%)] followed by open grade I [9 (28.1%)].

Table III: Association of Union Time with Grade of injury

Variable	Grade Of Injury	N	Mean	Std. Deviation	P value
Union Time clinical	High	24	6.33	1.21	0.01
	Low	8	4.0	0.78	
Union Time radiological	High	24	10.33	1.31	0.001
	Low	8	8.0	0.98	

Independent sample t test, union clinical time was significantly higher in high grade injury as compared to low grade injury similarly union time radiological was significantly higher in high grade injury as compared to low grade injury. The comparison was highly significant.

Table IV- Comparing Weight Bearing with Fracture Configuration

Fracture Configuration (AO)	Weight Bearing full (Weeks)								Total	P value
	16	17	18	19	20	21	22	23		
32A	1	0	0	0	0	0	0	0	1	0.443
32C	1	0	0	0	0	0	0	0	1	
33A	0	0	1	0	1	0	0	0	2	
33C	0	0	0	0	1	0	0	0	1	
41A	0	2	1	1	0	1	1	0	6	
41B	0	1	2	1	0	1	0	0	5	
41C	0	2	0	0	1	0	1	0	4	
42A	0	0	0	4	0	0	0	0	4	
42B	1	0	0	0	0	0	0	0	1	
42C	1	0	0	0	0	1	0	0	2	
43A	1	1	1	1	0	0	0	1	5	
Total	5	6	5	7	3	3	2	1	32	

Weight bearing was equally distributed among different fracture configuration (p=0.443). Comparing Level of fracture with weight bearing revealed that maximum patients with proximal 1/3rdtibia fracture have achieved full weight bearing followed by those who had distal 1/3rdTibia fracture.

Table V: Mean Weight bearing (weeks)

Weight bearing	Mean (weeks)	Std. Deviation
Toe touching	2.88	1.00
25%	4.84	1.05
50%	7.84	1.05
75%	12.84	1.05
Full	18.59	1.94

In present study, mean time for toe touching was 2.88±1.00 weeks, 25% of the weight bearing was possible at 4.84±1.05 weeks, 50% of the weight bearing was possible at 7.84±1.05 weeks, 75% of the weight bearing was possible at 12.84±1.05 weeks of time whereas full weight bearing was possible after mean time of 18.59±1.94 weeks.

Table VI: X ray findings in follow up

X Ray time (weeks)	Finding	No of patients	Percentage
2	No callus	32	100
6	1 cortex united	11	34.4
	2 cortices united	13	40.6
	3 cortices united	8	25.0
12	2 cortices united	11	34.4

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	3 cortices united	13	40.6
	All cortices united	8	25.0
24	All cortices united	32	100

X ray finding revealed that at the end of 2 weeks none of the patients (100%) have found to have callus, 6 month x ray analysis found that in most of the patients 2 cortices were united [13 (40.6%)], at the end of 12 months in most of the patients 3 cortices were united [13 (40.6%)] an at the end of 24 months X ray findings revealed that in all the patients all cortices were united [32 (100%)].

DISCUSSION

Far cortical locking (FCL) (screws lock into the plate and far cortex but allow movement at the near cortex of a diaphysis). This feature enables the so called 'controlled dynamisation' by flexion of the elastic shaft of the FCL screws.[5] With regard to FCL, the main principle here is to achieve fracture healing resembling the biomechanical properties of external fixators in an internal fixation method. FCL aims to reduce stiffness whilst maintaining strength of a construct.

In present study most common age group in present study was 36-45 years (25%) followed by18-25 years (21.88%) and maximum patients were male (81.3%) in agreement to present study findings Ries et al found that most of the FCL were done in female patients (19 out of 20) with a mean age of 77 years.[10]

In present study open fracture was found in 28.1% patients similar results were revealed by Ries et al who found 3 (15%) fractures which were open out of total 20.[10]

Far cortical locking (FCL) screws have been shown to promote callus by providing a biomechanical environment and healing response for locking plates similar to that provided by external fixators.[9] The mean callus formation time in present study was 5.75±1.50 which seems to be the main advantage provided by the FCL as the stiffness reduction provided by far cortical locking may be desirable for bridge plating osteosynthesis, which relies on secondary, not primary, bone healing.[11]Ries et al performed a similar study on 18 patients who underwent open reduction and internal fixation of periprosthetic distal femur fractures using FCL constructs and reported that bridging callus was identified separately for themedial, anterior and posterior fracture lines in sixteen of the eighteen patients by the 24 weekfollow up for a healing rate of 88.9%. In patients that healed, the average time to medial bridging callus formation was 10.7±6.7 weeks, 11.0±6.6 weeks for anterior fracture line and 13.4±7.5 weeks for the posterior fracture line. Ries et al also reported that pre-operative and 24 week post-operative radiographs showed that all the patients formed bridging medial, anterior and posterior callus and returned to baseline activity level.[10]

In present study we found that weight bearing, mode of injury and union time were comparable between different type of mechanism of injury and diagnosis. Results of Zhang J et al showed a delayed union (%) in 7.4%, 11.5%, 8.7% and 11.15 of the patients respectively.[12]

Low initial stiffness allows fracture-site motion in the early postoperative phase under reduced weight-bearing conditions.[13]In present study, mean time for toe touching was 2.88±1.00 weeks, 25% of the weight bearingwas possible at 4.84±1.05 weeks, 50% of the weight bearing was possible at 7.84±1.05 weeks, 75% of the weight bearing was possible at 12.84±1.05 weeks of time whereas full weight bearing was possible after mean time of 18.59±1.94 weeks. Ries et al reported that the average time to radiographic healing ranged from 10 – 24 weeks. The rate of non-union and need for a revision surgery varied from 0 – 22% and the rate of implantfailure was as high as 26%.[10]

In present study x-ray finding revealed that at the end of2 weeks none of the patients (100%) have found to have callus, 6 month x ray analysis found that in most of the patients 2 cortices were united (40.6%), at the end of 12 months in most of the patients 3 cortices were united (40.6%) an at the end of 24 months X ray findings revealed that in all the patients all cortices were united (100%)]. In agreement to present study Rice et al also reported that all 12 FCL patients achieved fracture union at the end of follow-up.[14]

In present study on comparing Level of fracture with weight bearing revealed that maximum patients with proximal tibia fracture has achieved full weight bearing followed by those who had distal Tibia fracture (p=0.017) Previous reports have shown that FCL screws have been shown toreduce the axial stiffness of: 1) metaphyseal femoral fractures fixed with locking plates by 80%;[6] 2) femoral diaphyseal fractures fixed with a standard locked plating system by 88%;[5]3) tibial diaphyseal fractures fixed with a locking plate in bridging mode by 84%.[9]Bottlang et al in 2009 studied compared locked plating constructs and far cortical locking constructs and concluded that FCL significantly reduces the axial stiffness of a locked plating construct. This gain in flexibility causes only a modest reduction in axial strength and increased torsional and bending strength.[5] in agreement to in present study we also found that FCL-treated fractures tended to be more complex, the similar fracture healing rates as reported by previous authors indicate improved fracture healing with FCL technology, but this possibility requires further investigation.

CONCLUSION

The use of FCL screws in place of standard locking screws significantly reduced construct stiffness and provided controlled interfragmentary motion for

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promotion of fracture healing by callus formation. Similar fracture healing rates as reported by previous studies indicate improved fracture healing with FCL technology. However a large randomized case control trial is needed to provide strength to present study finding.

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