Does rigidity related Mechanical Construct factors affect Union Time of distal Femur Fractures treated with Locking Plates?

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Abstract

Introduction: Distal femur fractures treated with lateral locking plates usually has poor callus formation with suboptimal healing. This has caused serious concerns regarding exact nature of healing and time of consolidation. Mechanical variables in plate fixation which affect rigidity of construct are controversial topics with regards to union. For most of the studies, primary endpoint of analysis was nonunion. No study has specific end point of union time. The main objective of this study is to test hypothesis that union time depends on rigidity related mechanical construct factors and to identify independent factors for union.

Patients and methods: It's a retrospective case control study. 32 distal femur fractures treated with locking plates between 2015 to 2017 were included. Patients with open fractures /steroid intake/ dialysis/DM/Smoking were excluded. Factors affecting construct like plate length/ empty holes/ total screw density (TSD)/ proximal screw density (PSD)/rigidity score/ presence or absence of screw crossing main fracture fragment were recorded and assessed for union time.

Results: out of 32 patients, 23 patients who met all inclusion criteria's with full follow up were analyzed. All the fractures united with index surgery. Two sample T test with CI and Regression analysis showed that union time was significantly affected by PSD and Rigidity score. 18 patients had rigidity score of 1 with mean union time of 19.78 weeks (SD 7.06) while 4 patients with rigidity score of 2 had mean union Time of 35 weeks (SD 8.67); [T value=-3.64, P value=0.001,DF=20]. Eighteen patients with PSD <0.6 had mean union time of 19.78 weeks (SD 7.06) while 5 patients with PSD >0.6 had mean union time of 35.20 weeks (SD 8.67); [T value=-4.13, P value=0.0013, DF=21]. Type of fracture A/C was not associated with time of union [T value=-1.48, P value=0.077, DF21]. Age, plate length, plate holes, empty holes, TSD are not significantly related with union time.

Conclusion: In treatment of distal femur fractures with locking plates, union time depends on rigidity of construct and PSD. Rigidity score > 2 & PSD > 0.6 leads to delayed union. We could evaluate predictors of union relative to construct stiffness. This has relevance while analyzing the literature and attempting to compare results of different studies. To prevent delayed union, less rigid construct can be achieved with PSD < 0.6.

Keywords: Distal femur fracture, Fracture union, Locking Plate, Construct Stiffness, Rigidity score

Introduction

Distal femur fractures account for less than 1% of all fractures and 3-6% of all femur fractures with bimodal distribution [1]. Fixation of distal femur fractures with bridge plating technique using anatomically pre contoured locking plates is based on relative stability principle with secondary bone healing [2]. Initial studies reported promising results with nonunion rates in range of 0-14%. However with more common use of it, reports with non union rate reaching as high as 18-22% has been published [3]. Suboptimal healing with decreased callus formation has raised concern regarding exact nature of healing and factors affecting healing. Surgeon controlled variables related to mechanical construct factors may contribute to union time. Many recent studies, biomechanical and clinical attribute non union to use of stainless steel implants, working length and screw density. In spite of these reports, relation between rigidity due to construct related factors and union time is still a concern to surgeons. The main objective of this study is to test hypothesis that union time depends on rigidity

related mechanical construct factors and to identify independent factors for union.

Patients & Methods

This is a retrospective case - control study of distal femur fractures (AO type 33A & 33C) treated with locking plates at our institute Level 1 Trauma Care centre during 2015 to 2017. The minimum age for inclusion was 18 years with follow up till fracture union. Intraarticular and periprosthetic fractures were also included provided they were fixed with locking plates. We excluded open fractures, patients with diabetes, chronic kidney disease. Patients with steroid dependency, smoking and incomplete follow up were also excluded. Union was defined as bridging of 3 cortices out of 4 and disappearance of fracture lines on x-ray for a patient who was able to bear full weight. Nonunion was defined as a need for secondary procedure to improve poor bone healing. As it is a retrospective study, criteria of exposure or surgery were not pre-established and there were no restriction on number of locking screw, plate length, cortical screw or working length. Main outcome measure was union time. Each patient's records were reviewed for union time and construct variables including 1)Plate length[number of holes in shaft section of plate 2) Total filled screws 3) Number of screws used proximal to fracture 4) empty holes 5)Total Screw Density[TSD] defined as ratio of total number of screw used to total number of screw holes available in plate.6) Proximal screw density[PSD] defined as the ratio of the total number of screw

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Figure 1: Distal femur fracture fixed with Locking plate with TSD - 0.63/ PSD - 0.53/ Union time 12 weeks

TSD – 0.65/PSD – 0.6/ Union time 48

used proximal of fracture to total number of screw holes in shaft of plate. 7) Presence of screw crossing main fracture plane. 8) Rigidity score for each construct [range- 0 for low to maximum 3 for high rigidity] Rigidity score was calculated for each construct by giving points for each of following

- 1]1 point if screw crossing main fracture line
- 2]0 point if PSD < 0.25
- 3] 1point if 0.25 < PSD > 0.6
- 4] 2 point if PSD > 0.6

Additional variables like age/AO classification and associated injuries like Hoffa's and periprosthetic fractures were also recorded. No co morbidity variables were assessed as study population was similar in this respect. Two sample T test was used to test relation of union time with Rigidity score1, 2&3; TSD; PSD and type of fracture A or C.



Figure 3: Locking plate with TSD - 0.5/ PSD -0.38/Union time 12 weeks



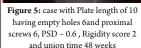
fixation with locking plate of 10 hole plate, empty holes 8 and proximal screws 4, PSD - 0.4, Rigidity score of 1 and Union time 12 weeks

Multivariate analysis done using logistic regression to calculate confounding factors to identify independent factors for union with 95% confidence interval CI.

Results

A total 32 distal femur fractures treated with locking plates were included in our study. Nine patients were excluded according to exclusion criteria. 23 patients were eligible for study analysis. There was no case of nonunion. All the fractures united with index procedure. There was significant association between the union rate and the rigidity score along with PSD. Two sample T test & CI done for PSD group >0.6 Vs group 0.25 to 0.6 showed 95% upper bound for difference of -8.9909. T value was -4.13 & P value 0.001 with degree of freedom 21. As we did not find evidence for variance being unequal, we chose to use pooled standard deviation which was 7.3934. Since P value is less than commonly chosen a-level; we reject H0 Null hypothesis at 0.05 level of significance. Similarly, two sample T test & CI used for testing relation between Rigidity score and union time. Two sample T test for score 1 Vs score 2. H0: μ 1= μ 2 H1: μ 1< μ 2. 95% upper bound for difference was -8.0020. T value was -3.64 and P value 0.001 with degree of freedom 20. Pooled Standard deviation was 7.5733. As P value was less than commonly chosen a-level, we reject H0 Null hypothesis at 0.05 level of significance. Two sample T test & CI test for union time with Fracture type A Vs Type C showed 95% upper bound for difference 0.95182 with T value -1.48 & P value of 0.077 at degree of freedom 21. H0 was accepted at 0.05 level of significance i.e. no difference between union rate for different fracture types. Other mechanical variables were not independently significant.







amputation limb fixed with Locking plate. Though PSD was 0.55 use of screw across main fracture fragment resulted in Rigidity score of 2 and union time 40 weeks

These factors were plate length (P value 0.096/Odds ratio 17842.44); Empty holes (P value 0.899); Total filled screw (P value 0.408); Total number of proximal screws (P value 0.952); TSD (P value 0.775)

Discussion

The increase in rates of nonunion for distal femur fractures treated with locking plates could be in part secondary to increased use of this technique. But additional contributing factors related with construct rigidity may be also responsible for delayed union or healing concerns and are still not clinically evaluated. The variables like plate length, empty holes, TSD, PSD can make construct stiff or rigid. This can impair healing and these factors are still controversial [4, 5]. We have selected these variables as biomechanical factors of construct rigidity based on literature review. These factors are1) Plate length [number of holes in shaft section of plate] 2) Total filled screws 3) Number of screws used proximal to fracture 4) empty holes 5) Total Screw Density [TSD] defined as ratio of total number of screw used to total number of screw holes available in plate. 6) Proximal screw density [PSD] defined as the ratio of the total number of screw used proximal of fracture to total number of screw holes in shaft of plate. 7) Presence of screw crossing main fracture plane. 8) Rigidity score for each construct [range 0 for low to maximum 3 for high rigidity]. Henderson et al [6] in 2011 in his retrospective study of 86 distal femur fractures did not find bridge span length of plate associated with union rate. But he inferred that leaving the hole adjacent to fracture without screw resulted in significantantly more unions than non unions. E.K.Rodriguez et al in 2016 concluded that stainless steel constructs resulted in more cases of nonunion than titanium with statistical significance. But no other mechanical variable was independently significant for nonunion. Contrary to this, W.H.Harvin et al in retrospective study in 2017 inferred that bridging construct with all locking screws was 2.9 times more likely to incur a nonunion. Henschel at al [7] compared 4 methods of dynamisation of locking plates for amount and type of fracture motion. Construct stiffness was more in bridge plating and locked plates as compared to Far Cortical

Locking plates or Active plates. Interfragmentory shear motion was found highest with bridge plating and less with FCL/Active plates. But for most of the studies, primary endpoint of analysis was nonunion. No study has specific end point of union time. The studies which reported nonunion, neither mentioned union time of united fractures nor did they study variables for union in united fractures. Recent biomechanical studies advocates FCL or Active plates and puts question mark on current practice of bridge plating [8, 9, 10]. Our intuitive technical tricks like tapping of locking screws, use of cortical screw does not have statistical support in current literature. Very few studies are focused on construct factors related to union time. Hence we undertook this study with primary objective to find independent factors of rigidity with regard to union time. Out of all construct variables which were assessed, PSD and Rigidity score were significantly affected time of union. Rest all variables like plate length, empty holes, TSD did not have significant relation with regards to union time (P value >0.05). When PSD is >0.6, union time was significantly long as compared to PSD <0.6, irrespective of TSD. (Fig 1, 2, 3) All the three representative X-rays had TSD almost similar but case with PSD - 0.38 had union time less. Similarly cases with rigidity score 2 had long union time as compared to score 1 (Fig. 4, 5). Although both X-rays had similar plate length, empty holes; Rigidity score was different and so was union time. Rigidity score also gets increased if screw through major fracture line is used which increases rigidity score and delays the union (Fig 6). We had one case with rigidity score 3 and union time for that was 9 months. But there are 2 inherent limitations of our study. Being retrospective case control study, we have limited number of patients and variable patient demography. But we tried to reduce variability by excluding co morbidities along with using single implant and material (Stainless Steel) so that we can assess only construct related variables In spite of these limitations, we could evaluate predictors of union relative to construct stiffness. This has relevance while analyzing the literature and attempting to compare results of different studies. This clinical study can give guideline to achieve PSD < 0.6 so that delayed unions can be avoided in distal femur fractures.

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