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Dr. Amit Dhond
Professor, Department of Orthopedics, D.Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, Maharashtra, India

Dr. Parth Agarwal
Assistant Professor, Department of Orthopaedics, D.Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, Maharashtra, India

Dr. Pratik Dhabalia
PG Resident, Department of Orthopaedics, D.Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, Maharashtra, India

Dr. Abhineet Chand
PG Resident, Department of Orthopaedics, D.Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, Maharashtra, India

Corresponding Author:
Dr. Amit Dhond
Professor, Department of Orthopedics, D.Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, Maharashtra, India

A study on the management of non-union of fracture distal femur with locking plates

Dr. Amit Dhond, Dr. Parth Agarwal, Dr. Pratik Dhabalia and Dr. Abhineet Chand

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Abstract
Background: US FDA defines non-union as fracture bone that has not completely healed in 9 months since injury and which has not shown any signs of healing over 3 consecutive months on serial x-rays. The operative treatment depends on the type of non-union. There are one-step or two-step procedures according to the principles of the 'diamond concept'. This involves the improvement of the mechanical situation (in most cases with a re osteosynthesis) and vascularization, local application of osteoconductive carriers e.g. tricalcium phosphate, vial cells from autologous bone and osteoinductive substances like bone morphogenic proteins (BMP-2 or BMP-7).
Aim: To study the principles and method of fixation of non-union of distal femur with lock plates.
Material and Methods: It was a prospective study including patients with non-union of distal femur admitted and examined according to protocol after obtaining informed consent from the patient and permission from the institutional ethics committee. 40 cases satisfying the inclusion criteria admitted in tertiary healthcare centre of Navi Mumbai since May 2018 to March 2020 with minimum 1 year of follow up were included in the study.
Results: Patients were also evaluated as per non-union scores. The average non-union score was 19 (range 11 to 27). All of the non-unions united, at an average of 19 weeks. The average arc of knee motion improved from 85° preoperatively to 114° postoperatively. The average Neer's score improved from an average of 60.4 points (range 16 to 44 points) preoperatively to 89 points post operatively. The knee society score (Part 1) improved from an average of 51.87 points (range 36 to 68) preoperatively to 81.725 points (range 74 to 93) post-operatively.
Conclusion: The operative technique respecting the biology and biomechanical principles has shown the influence of success of treating these fractures with locking plates.

Keywords: non-union fracture, distal femur, locking plates

Introduction
Distal femoral fractures are a common orthopedic problem in all age groups of patients with an incidence of about 37 per 100,000-person years [1]. Distal femoral fractures since a long time has been considered difficult to treat using traditional implants due to high failure rate and secondary varus collapse [2]. Distal femoral fractures in young age group are most commonly due to high energy trauma while in older age group it is mostly associated with low energy trauma along with osteoporosis. Treatment of these fractures can be successfully done with variety of plates [3, 4, 5] and retrograde intramedullary nails [6, 7]. Early studies of treating distal femoral fractures with locked plates reported excellent out come with non-union rates of 0-14% (mostly less than 6%) [4, 8, 9]. However, the analysis of recent data shows non-union rates as high as 17-21% [8,10,11].
Presently, US FDA defines non-union as fracture bone that has not completely healed in 9 months since injury and which has not shown any signs of healing over 3 consecutive months on serial x-rays [12].
A proper radiological evaluation with plain x-rays of the affected part in AP, lateral and both oblique views (45 degrees internal and external views) aids in the diagnosis and planning of management. CT scan is more accurate modality than plain x-rays in diagnosing the non-union [13].

Infection should be ruled out in all cases of femoral non-union. Hence proper blood work-up is must which should include complete blood count, ESR and CRP. Deep tissue culture at the time of secondary surgery is the gold standard for diagnosis of infection [14].

The operative treatment depends on the type of non-union. There are one-step or two-step procedures according to the principles of the 'diamond concept'. This involves the improvement of the mechanical situation (in most cases with a re osteosynthesis) and vascularization, local application of osteoconductive carriers e.g. tricalcium phosphate, vial cells from autologous bone and osteoinductive substances like bone morphogenic proteins (BMP-2 or BMP-7). Hypertrophic and atrophic non-unions without large defect gaps or signs of infection can be treated with a one-step procedure.

For treating infected non-union or non-unions with large defect gaps, Masquelet technique is recommended. In our study we advocated to plate osteosynthesis for stabilization of the fracture with administration of bone graft from iliac crest with either a one stage or two staged procedure.

Aims and Objectives

1. To study the principles and method of fixation of non-union of distal femur with lock plates.
2. To evaluate the results obtained by treatment of non-union femur by lock plates in terms of:
   - Bone Union.
   - Functional Outcome
3. To study complications associated and its management.

Material and Methods

Study site: Tertiary Healthcare centre, Navi Mumbai

Study Population: Cases satisfying the inclusion criteria admitted in tertiary healthcare centre of Navi Mumbai since May 2018 to March 2020 with minimum 1 year of follow up.

Study design: It was a prospective study including patients with non-union of distal femur admitted and examined according to protocol after obtaining informed consent from the patient and permission from the institutional ethics committee. The fractures were classified as per AO trauma classification and non-union scores were assessed for each.

Sample Size: 70 (40 patients followed up, 30 patients lost follow up)

Inclusion Criteria

- Skeletally mature patients
- Patients presenting with non-union of distal femoral fractures with or without osteoporotic changes
- Patients who gave the consent to be a part of this study

Exclusion Criteria

- Comorbid patients or patients unfit for surgery
- Patients with previous deformity of femur
- Patients who did not consent to the study

Pre-operative assessment

- History and clinical examination
- Radiological investigations:
- X-ray-whole Thigh with ipsilateral Hip joint and knee (antero- posterior and lateral views)
- CT (when needed)
- General investigations:
- Complete hemograms
- 25-hydroxy vitamin D.
- Liver profile, renal profile
- Viral markers for HBV, HCV, HIV
- BT, CT, PT, INR.
- Chest roentgenogram
- Status of soft tissues and neurovascular structures was considered
- Status of the bones and type of non-union was considered

Pre-operative antibiotics: In all cases prophylactic antibiotic was given 30 minutes before the commencement of surgery.

Instruments Required: Distal femoral lock plates, mallet, allied instrumentation of Distal femoral lock plate assembly, bone lever, corticotome, osteotome, periosteal elevator, power drill, C-arm and some other general orthopaedic and general surgery instruments.

Intraoperative protocol: All ORIF was performed with the patient in supine position after induction of general or regional anaesthesia. The lower extremity and the iliac crest were prepared and draped in a sterile fashion. A lateral approach or parapatellar approach was taken to the distal femur. Dissection was performed to reach the site of the non-union followed by removal of previous implant. A medial approach was taken in selected patients for application of medial buttress plate. Samples were taken for Culture and sensitivity and site was debrided of any fibrous tissue. C arm imaging was utilized to assist with reduction and implant positioning. Bone for grafting was harvested from iliac crest was packed into non-union site followed by closure of the wound in layers.

Post-operative protocol: Rehabilitation of the quadriceps muscle with isometric exercises was begun immediately after the operation. Forty-eight hours after the operation, continuous passive motion was started as tolerated. Progressive weight-bearing was started at eight weeks. At twelve to sixteen weeks, the patient was allowed to bear weight as tolerated if there was radiographic evidence of healing (no radiolucent line seen at the non-union site and evidence that the bone defect was being replaced by new bone. Patient were discharged on oral antibiotics for a period of 6 weeks post operatively. The patients were followed up to achievement of bony union i.e. at 2 weeks, 6 weeks and 12 weeks and then every 2 months till 1 years.

Parameters for evaluation

- Non-Union scores
- NEER's Scoring system
- Knee society score

Pre-operative radiograph comparison was done with serial radiographs post-operatively on subsequent follow up or visit to hospital.

Statistical analysis methods: The initial data thus obtained were captured into the customized study proforma and then transferred to Microsoft Excel (version office 365). The data forage, fracture union time and assessment scores are expressed as means with standard deviation and 95% confidence intervals (C.I.), whereas discrete and ranking data for gender, age groups, fracture union time and post-operative complications are presented as numbers with percentages.

Since there is no study hypothesis and all results are presented as descriptive.

Financial inputs and funding: All the material used for collecting the data and other expenses related to the study was borne by investigator. The study was neither funded by any pharmaceutical company nor institution.

Ethical considerations: After approval by ethics committee, the study was initiated at our institution. A voluntary informed consent in writing was obtained from the patient/legal guardian prior to enrolment in the study program. The patients were to undergo investigations and procedures as laid down under the protocol for the management of condition. There was no additional burden on the institution for carrying out the present study. No company/ institution have funded this project.

Conflict of Interest: The authors declare that they have no conflict of interests.

Observations and Results

The study comprises of 70 patients out of which 40 were assessed and 30 patients lost follow up. Among the 40 patients who followed up, 26 (65%) were male and 14 (35%) were female. The mean age of patients presenting to us at the detection of non-union was 48.875 years.

We observed an almost symmetrical distribution of 17 cases (42.5%) in the age group from 16-49 years, the youngest case was 22 years and the oldest patient being 74 years old.

Right limb (55%) was involved in marginally a greater number of patients than the left limb (45%). Road traffic accidents were noted to be the main cause of primary fractures (70%) and the rest being fall from height (30%).

70% of patients in our study sustained trauma post road traffic accident; 20 were of and under 50 years of age and 8 patients more than 50 years of age. 30% of patients suffered fall from height; 1 was under 50 years of age and 7 were more than 50 years.

Patients were also evaluated as per non-unionscores. The average non-union score was 19 (range 11 to 27). 6 patients (15%) who were smokers were counselled to quit smoking, 2 patients (5%) in our series had diabetes, and 3 (7.5%) patients who were morbidly obese were advised dietary restriction and weight reduction and 5 (12.5%) were hypertensive (well controlled).

Fractures were classified using the AO system; they included 33-A1 (2), 33-A2 (3), 33-A3 (15), 33-B1 (1), 33-B2 (1), 33-B3 (1), 33- C1 (1), 33-C2 (14) and 33-C3 (2).

The preoperative arc of knee motion was <90° in twenty-two patients, and it averaged 85° (range 0° to 90°) in the series as a whole. There were 5 patients with intra medullary nail in situ, 1 with an external fixator on, 1 treated conservatively beforehand and others were treated with plate fixation before. There were 2 patients with non-union of Hoffa fragment that were success fully treated with revision fixation. Majority of revision fixation were carried out from lateral approach with bone graft taken from ipsilateral iliaccrest.

Dual plating was done in 4 patients; an antero lateral and lateral plate in 3 and lateral and medial plate fixation in one of our patients. Free fibular vascularised graft was used for reconstruction of the medial column in one of our patients. In 8 (33.3%) of our patients masquelet technique of fixation was resorted to, all of which underwent to stable union.

Regarding complications, 4 of our patients complained of pain at the region of donor site of bone graft (iliaccrest) post operatively till 3 months which then resolved on its own. 2 patients developed wound infections at the locking plate insertion site following initial ORIF, both with MRSA; both patients underwent a single irrigation and debridement with appropriate antibiotics as per culture report and placement of antibiotic cement beads which were removed before stitches were removed. All cultures obtained from the non-union site at the time of surgery were negative. In our series of 40 patients, there were no cases varus/valgus alignment of more than 5 degrees.

In 3 cases, there was persistent limping due to limb length discrepancy with shortening of about 1 cm due to inadequate restoration of length and incomplete restoration of the knee ROM with limited flexion range to about 90°.

No cases had iatrogenic neurovascular complications; no cases were complicated by DVT or compartment syndrome; no cases developed reflex sympathetic dystrophy; and all cases went all to stable union at the fracture site.

All of the non-unions united, at an average of 19 weeks (range 12 to 20 weeks). Union was defined as the presence of bridging callus of three of the four cortices and disappearance of the fracture line on the plain radiographs for a patient who was able to bear full weight, with the area of comminution bone graft completely incorporated, amalgamated, and remodelled with the proximal and distal ends of the comminuted fractures.

The average arc of knee motion improved from 85° (range 0° to 90°) preoperatively to 114° (range, 80° to 135°) postoperatively. In three patients, the arc of knee motion was still <90° after the operation because of joint contracture in two and degenerative arthritis of the knee in one.

The minimum follow-up period was for 1 year. The average Neer's score improved from an average of 60.4 points (range 16 to 44 points)preoperatively to 89 points post operatively (range 72 to 96) thereby indicating satisfactory outcome of surgery in total. 7 patients scored in range of 70 to 85; rest 33 patients scored above 85.

The knee society score (Part 1) improved from an average of 51.87 points (range 36 to 68) preoperatively to 81.725 points (range 74 to 93) post-operatively thereby indicating excellent outcome of surgery in total.14 patients scored in the range of 70 to 79 while remaining 26 patients scored above 80.

The knee society function score improved from an average of 46.625 points (range 15 to 45 points) preoperatively to 84.125 points (range 70 to 90 points) post-operatively thereby indicating excellent outcome of the surgery in total. 5 patients scored in the range of 70 to 79 while remaining 35 patients scored above 80 points.

Discussion

The management of distal femoral non-union is a challenging task with the aim of restoration of length, axis and rotation of affected extremity with a congruous knee joint. In this prospective study (n = 40) subjects of distal femoral non-union were treated surgically with revision fixation and bone grafting and were evaluated for functional and radiological outcome after fixation with locking compression plate (LCP) with appropriate scores preoperatively and post operatively.

A proper implant selection is important in treating these high energy trauma fractures and should be able to provide both; high stability as well as flexibility to favour osteosynthesis at the site of non-union. An implant satisfying the above criteria is LCP which has an added advantage of angular stability apart from the above mentioned. Moreover, LCP is a single

length (plate screw construct) fixation where the pull-out strength is proportionally equivalent to the sum of all screw plate bone interface in contrast to a single screw axial pull-out strength in non-locking plates [15]. Biomechanically, it is based on the principle of splinting rather than compression thereby providing favourable environment for dynamic osteosynthesis and callus formation by avoidance of stress shielding. The distal femur locking plate has its origin from LISS, which was introduced in mid to late 1990's [16]. The difference in two implants lies in the fact that LISS has a locking jig which guides the placement of locking screws. The holes on Distal femoral locking compression plates are oval which has an added advantage of placement of either locking or compression screws which allows more accurate plate positioning as it is able to be closely compressed to bone.

Use of longer plate construct is one of surgeon's controlled factors for achieving union at fracture site. In all our cases we paid attention to factors under the control of surgeon viz plate length, screw density of plate, material of implant (titanium implant was used) and cortical reduction all aimed towards obtaining positive results and avoiding failure. Titanium has been noted to have superior biocompatibility with an elasticity modulus more similar to bone than stainless steel [17].

In our study we found out relatively higher number of people (n= 17) in the age group of 16 - 49 years, majority of them being males and sustaining trauma due to road traffic accident which was consistent with the findings of another study done by Martinet *et al*. [18] who reviewed, between 1980 and 1989, reports on 2,165 fractures of the distal part of the femur (1,051 women and 1,114 men) which were collected by AO documentation and were analysed. Lee *et al*. [19] in a similar study found the average age 42 years ranging from 18 to 82 years. These results suggest that distal femoral fractures around knee joint are common in young adult group as they are involved in outdoor activities.

In our study we found relatively higher number of males (65%) as compared to females which is again consistent with findings of other related studies [20]. The higher male to female ratio in our study may be due to larger percentage of males being involved in outdoor activities.

Right limb (55%) was involved in marginally a greater number of patients than the left limb (45%). This may be probably due to the right limb being dominant in majority of population.

The cause of fractures was road traffic accident in n = 28 patients (70%) and fall from height in the remaining n = 12 (30%) patients. Similar pattern of observations was reported in earlier studies [20], which suggest that with modernization high energy trauma accidents have increased.

Radiological union was defined as presence of bridging callus across three cortices. The average time to union was 19 weeks (range 12 to 20 weeks). Ryan *et al*. [21] in their comparative study reported average time for union with locking plating as 6 months (range 3 - 14 months) versus 7 months (range 3 - 15 months) in external fixation group.

The average arc of knee motion improved from 85° preoperatively to 114° postoperatively. In three patients, the arc of knee motion was still <90° after the operation because of joint contracture in two and severe degenerative arthritis of the knee in one. Stannard *et al*. [22] Lee *et al*. [19] and Cole *et al*. [5] in their studies reported average range of motion 127o (range 90 - 145 o), 105o (range 0 - 135o) and 122 o respectively.

Regarding complications, apart from post-operative pain at donor site which resolved on its own and infection addressed with debridement, antibiotic cement bead placement and appropriate antibiotics as per culture sensitivity report; there was a case of comminuted supracondylar fracture Muller type C3, which was primarily operated , went into Non-Union and was operated elsewhere with bone graft augmentation (which eventually failed); was then re-operated upon at our centre (revision fixation with LCP was done with bone grafting) which went onto good functional outcome. On analysing it retrospectively we believe the cause for implant failure was shorter plate length and severe metaphyseal comminution which lead to gap non-union. The case was planned for exchange plating with a longer plate with bone grafting.

In this study, it has been observed that the operative technique respecting the biology and biomechanical principles have shown the influence of success of treating these fractures with locking plates. In consideration to biomechanical principles, the aim should be on using long plates, to apply bicortical screws, to leave two to three screw holes empty around the fracture gap in order not to create a too rigid construct.

Table 1: Profile of patients enrolled

	No.	% (n=40)
Age group		
▪ 20-40 yrs.	15	37.5
▪ 41-60 yrs.	14	35.0
▪ 61-80 yrs.	11	27.5
Gender		
▪ Male	26	65.0
▪ Female	14	35.0
Mode of Injury		
▪ RTA	28	70.0
▪ Fall	12	30.0
Side affected		
▪ Left side	18	45.0
▪ Right side	22	55.0
Union time		
▪ <18 wks.	14	35.0
▪ 18-24 wks.	19	47.5
▪ >24 wks.	7	17.5

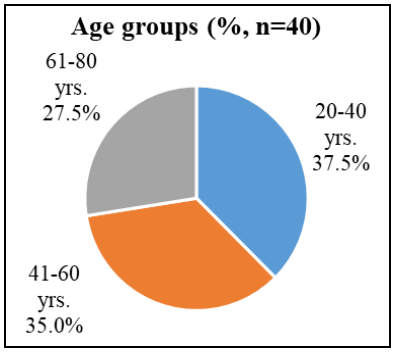


Fig 1: Age group of patients

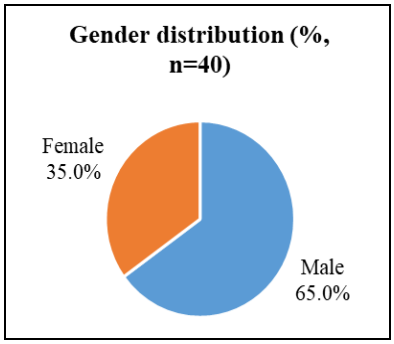


Fig 2: Gender distribution

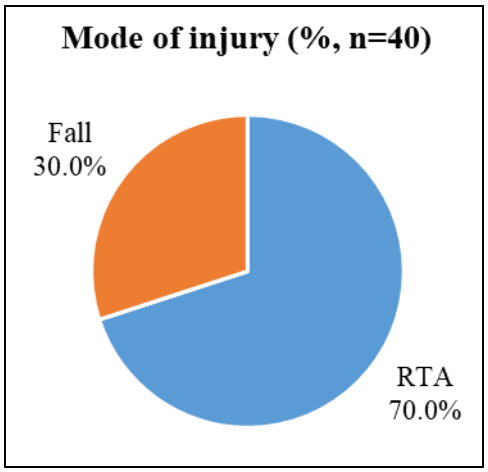


Fig 3: Mode of injury

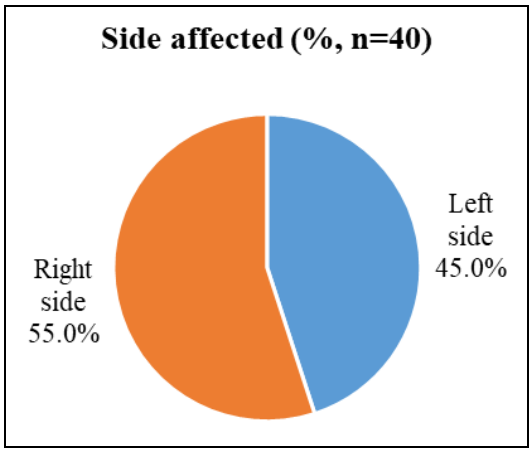


Fig 4: Side affected in injury

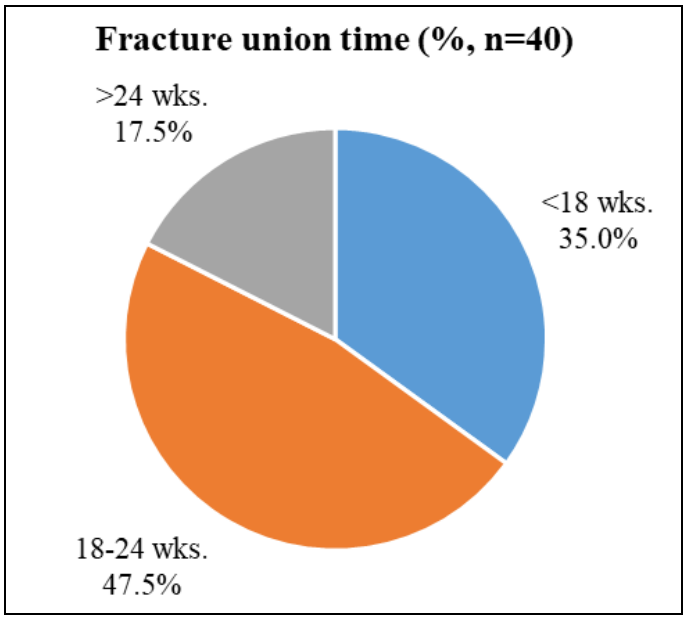


Fig 5: Fracture union time

Table 2: Age scores and union time

	Mean	Median	S.D.	95% C.I. for mean	Min.	Max.	Mann-Whitney 'U' test*	
							Z	p
Age (yrs.)	48.88	49.5	15.78	(44 to 54)	22	75	-	-
UnionTime (wks.)	19.68	19.0	4.30	(18 to 21)	13	29	-	-
KSS part 1								
▪ Pre-op	51.88	52.0	5.88	(50 to 54)	43	66	5.513	<0.0001
▪ Post-op	81.73	82.0	5.18	(80 to 83)	70	90		
KSS Function								
▪ Pre-op	46.63	45.0	10.65	(43 to 50)	25	65	5.535	<0.0001
▪ Post-op	84.00	85.0	5.91	(82 to 86)	70	95		
Neer's Score								
▪ Pre-op	60.40	61.0	4.36	(59 to 62)	53	69	5.514	<0.0001
▪ Post-op	89.00	89.0	3.30	(88 to 90)	81	96		
Knee Score								
▪ Pre-op	0	-	-	-	-	-	-	-
▪ Post-op	0	-	-	-	-	-		
* Pre-op Vs Post-op								

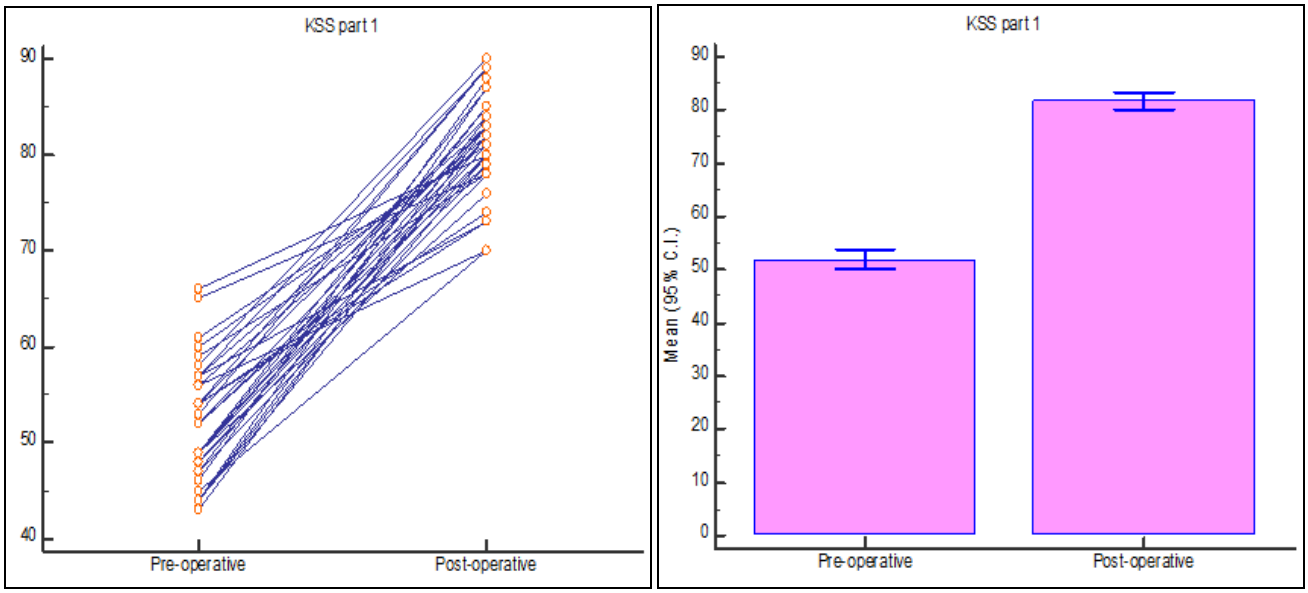


Fig 6: Mean scores for KSS part 1 before and after surgery

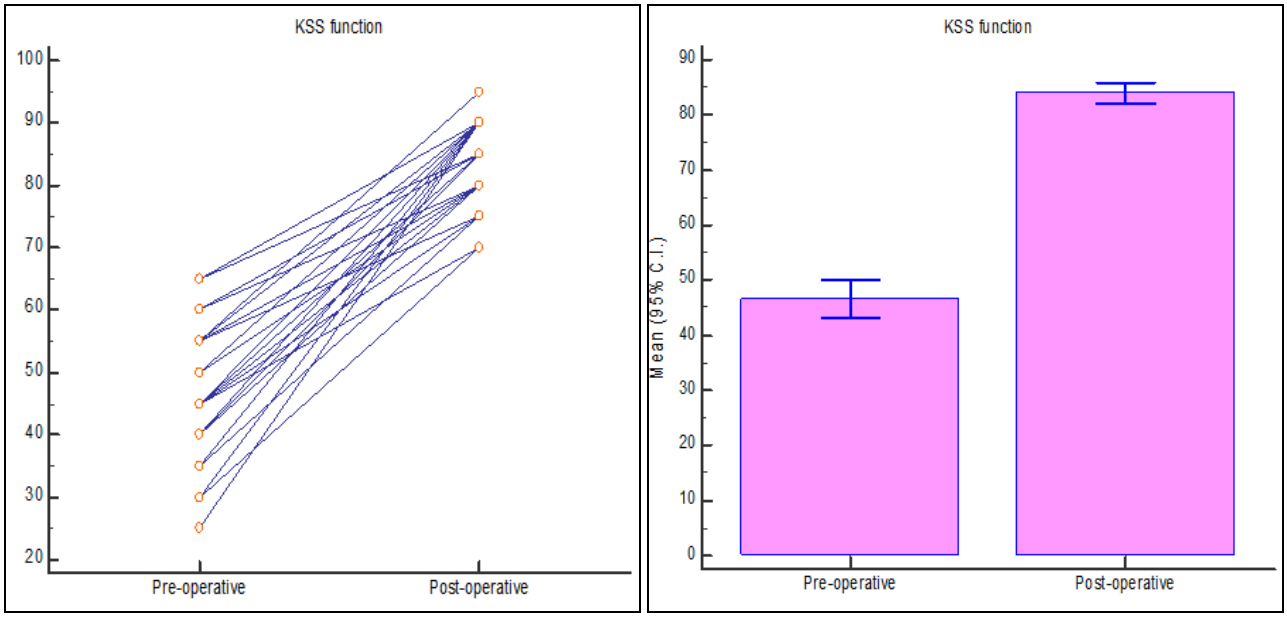


Fig 7: Mean scores for KSS function before and after surgery

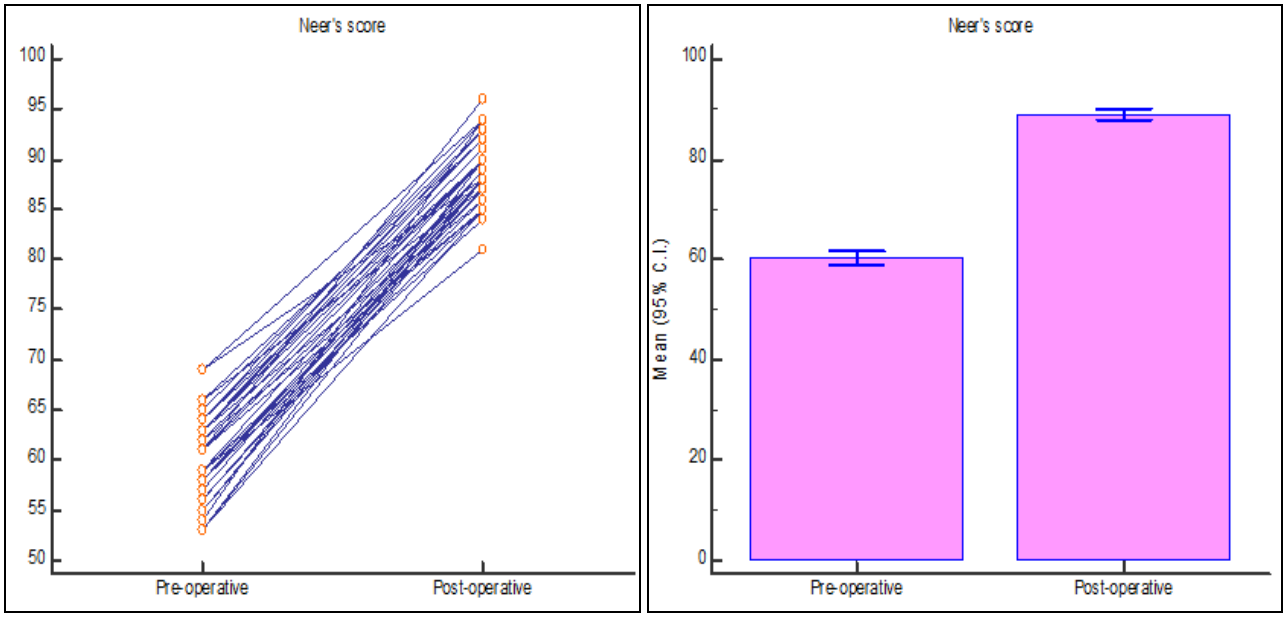


Fig 8: Mean scores for Neer's score before and after surgery

Table 3: Complication of surgery

	No.	% (n=40)
Complication		
• Infection	2	5.0
• Non union	2	5.0
• Implant failure	2	5.0
• Knee Stiffness	9	22.5

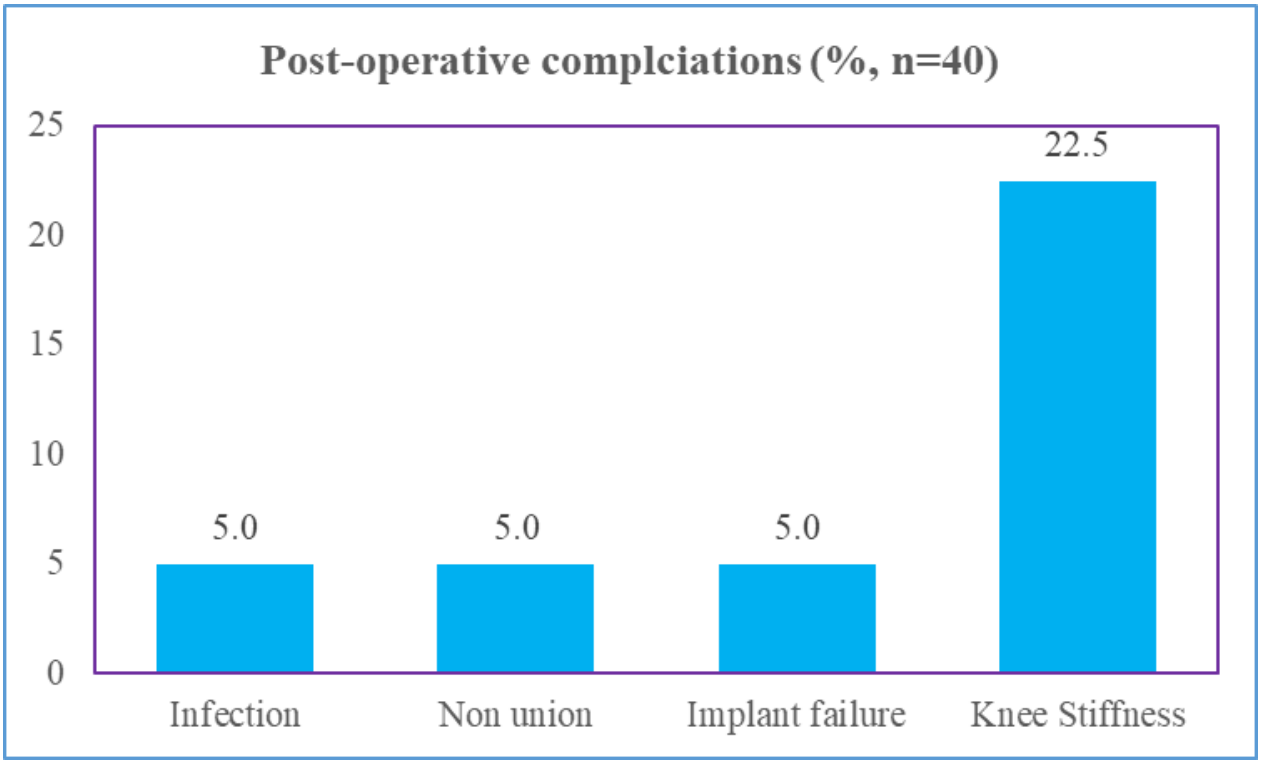


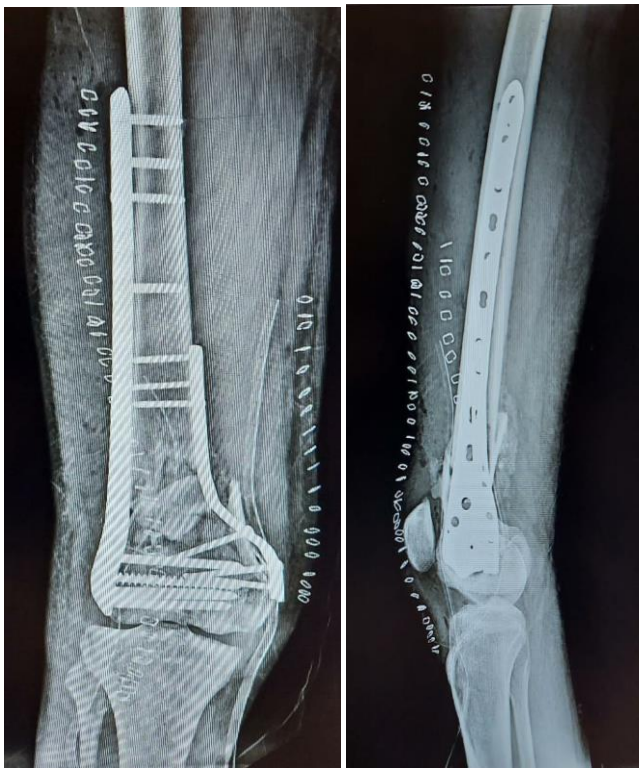
Fig 9: Complications of surgery (%, n=40)

Appendix

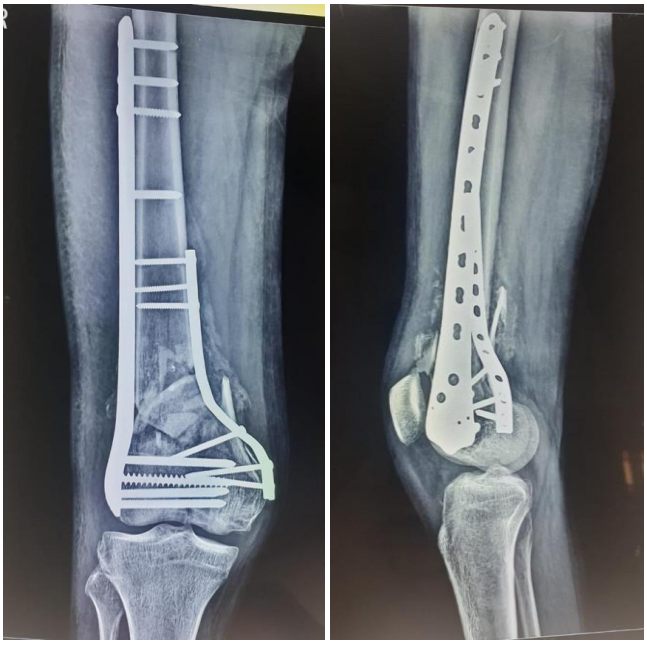
I Xrays:

Xray 1 – 64-year-old male, Post traumatic case of right sided distal femur fracture. Patient had alleged history of Road traffic accident and was neglected.

1A– Pre-operative xrays



1B – immediate Post-Operative xrays: Patient was managed with Open reduction internal fixation with dual plating.



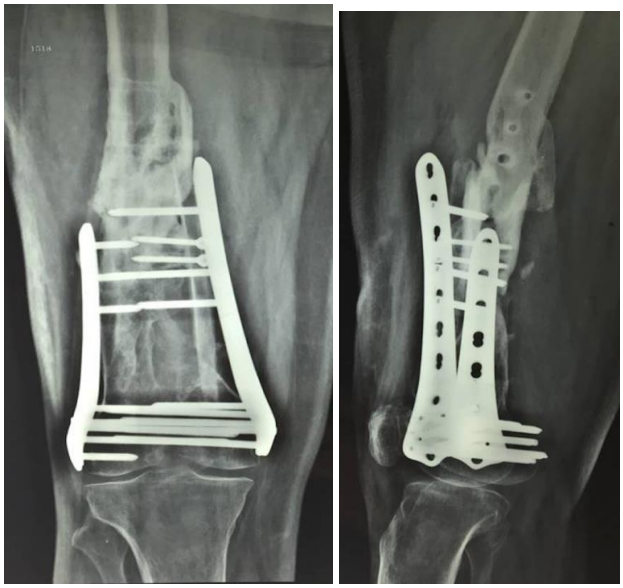
1C – Post operative xrays– follow up 1 month

1D – Postoperative xrays – follow up 6 month

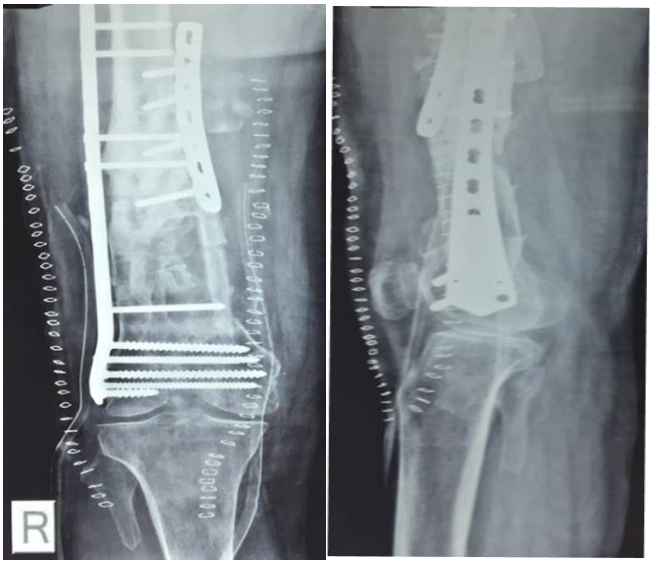
Xray 2 – Implant Failure with Instability (Stress Views)
2B – Pre-Operative xrays

2B – Post-Operativexrays: ORIF with implant removal with Medial and lateral plating with Bone grafting

Xray 3– Medial and lateral plating with bone grafting



3A – Pre-Operative xrays



3B – Post-Operative xrays

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