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Research Article

External Fixation Versus Volar Locking Plate for Unstable Intraarticular Distal Radius Fractures: A Prospective Comparative Study of the Functional Outcomes

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Abbreviations

AP	Antero-posterior
BPKIHS	B.P. Koirala Institute of Health Sciences
CRPP	Closed Reduction and Percutaneous Pinning
CRPS	Complex regional pain syndrome
CONSORT	Consolidated standards of reporting trials
DASH	Disabilities of the Arm, Shoulder and Hand
DNVD	Distal neurovascular deficit
ER	Emergency room
K wire	Kirschner wire
OPD	Out patient department
ORIF	Open reducion and internal fixation
PG	Post-graduate
POP	Plaster of paris
RCT	Randomized controlled trial
ROM	Range of motion
RTA	Road traffic accident
SD	Standard deviation
SPSS	Statistical Package for Social Sciences

UV Ulnar Variance

VAS Visual analog scale

VLP Volar Locking Plate

Introduction

Distal radius fracture is the most commonly encountered fracture of the upper extremity(1,2) accounting for approximately one sixth of all fractures seen in emergency departments.(3,4,5) While many of these fractures are simple metaphyseal fractures that can be managed through closed reduction and immobilization, approximately 50% involve the articular surface or distal radioulnar joint, necessitating more intensive treatment. The history of fractures of the distal radius reflects the evolution of the understanding of many conditions in orthopedic trauma. The credit for recognition of the true nature of the injury is shared between Petit, Pouteau, and Colles, prior to whose writings it was believed that the injury was a carpal or distal radioulnar joint dislocation. Petit first suggested in the early 18th century that these injuries might be fractures rather than dislocations but it was Pouteau (6) who first recognized that injuries to the wrist from a fall on to the outstretched hand were usually fractures of the distal radius with “outward” or dorsal displacement. He recognized “inward” or volar displacement but attributed it to ulnar fracture. His meticulous observations demonstrate the knowledge that can be accrued from clinical examination. Pouteau could not defend his opinion from the scepticism of his colleagues as this article was published post humously. Added to this, little attention was paid to his views outside France. In 1847 Malgaigne (7) defined the injury further and stated that most fractures of the distal radius were caused by a fall on the palm of the hand and fewer by a fall on the back of the hand.

The concept of a variety of types of distal radius fractures was developed by John Rhea Barton (8) from Philadelphia, who in 1838 described “a subluxation of the wrist consequent to a fracture through the articular surface of the carpal extremity of the radius.” He described dorsal displacement of the wrist and the partial articular fracture.

Internal fixation of distal radius fractures has long been dominated by percutaneous pinning, which was first suggested for distal radius fracture treatment by Lambotte in 1907 with the use of one radial styloid pin.(9)

This was followed by reports of many other techniques of multiple pinning in the middle to late 20th century.(9) Plating was first popularized by Ellis.(10) In 1965. Since then, the development of initially dorsal plating and then volar locked plating has extended its indications.

In management, the primary goal is to restore the anatomical integrity and function of the joint.(11) Simple stable fracture patterns are best treated with a period of immobilization.(1,12) Many studies have associated as little as 1 mm of incongruity of the articular surface with worse outcomes, so the desire for anatomic restoration of the distal radial joint often is the rational for operative treatment. However, there is no established treatment method for unstable fractures.(1,2,12) There are numerous surgical options for the management of distal radial fractures, which include the use of percutaneous K-wire fixation, external fixation and open reduction internal fixation with volar and dorsal plates, both locking and non – locking.(12,13) Two commonly used methods of fixation are open reduction with internal fixation using plates and percutaneous pin fixation.(1,13) It is widely accepted that restoration of anatomical alignment and preservation of the articular surface facilitates to achieve early and sustained function without pain.(1,13)

External fixation, with or without percutaneous pinning, is a commonly used modality for treating fractures of distal radius and has been shown to be effective for maintaining radial length in the setting of the deforming force of the brachioradialis muscle. They are also easy to apply, can be adjusted in the office, require minimal exposure and thus avoid operative complications and leave no internal hardware to be dealt with. Disadvantages include an amiability to visualize and manually reduce intra-articular fracture fragments, inability to visualize concomitant ligamentous damage, and reduced early mobilization of the radio carpal joint. While external fixation utilizes ligamentotaxis to maintain reduction of displaced fracture fragments and is very useful for several types of fractures, it may not provide adequate reduction for severely comminuted or displaced intra-articular fractures, though the subject is highly controversial.

Internal fixation provides direct visualization and manipulation of fracture fragments, allows early active movement; however, it requires use of tourniquet and maximal soft-tissue dissection and it also requires need of another surgery for removal of plate. Volar plates are also biomechanically superior, with an implant stiffness that will support the physiological load placed on the wrist joint.(13) Studies have reported tendon problems despite carefully performed internal fixation.(1,12)

There is still a dearth of prospective comparative study in this area. The aim of this trial is to investigate upon the better method of treatment of distal radius fracture that provides patients with functionally, clinically, and radiologically superior results between volar plate and external fixation. There is no consensus in the literature regarding treatment of displaced distal radius fracture in adults. So we aim to compare external

fixation and volar plating for the treatment of distal radius fracture in terms of functional outcome, fracture union, stiffness and deformity.

Few studies in our setting have been done to evaluate the relative merits and demerits of external fixation and ORIF (Open Reduction and Internal Fixation) with volar plate. Hence, we aim to compare between these two techniques.

Aims and Objectives

Primary objective:

- To compare functional outcome among the two groups with the Green and O'Brien scoring system modified by Cooney.

Secondary objectives:

- To compare intraoperative parameters- Blood loss, Duration of surgery, image exposure required (number of shots).
- To compare intraoperative parameters- Blood loss, Duration of surgery
- To compare the rate of complications:
    - Surgery/ Fracture related: Infections, time for Union/ Deformity
    - Implant related: symptomatic hardware, implant failure
    - Post-operative pain and stiffness

Research Hypothesis

There is no significant difference in functional outcome between the two techniques of ORIF with plating and External fixation for intra articular distal end radius fractures.

Materials and Methods

Research Design: Prospective comparative study

Setting: The study was conducted in the Department of Orthopedics, B.P. Koirala Institute of Health Sciences, Dharan

Duration: December 2019 to November 2020 (12 months)

Whether study involved humans/ animals or both: Humans only

Sampling technique: Total population enumeration will be employed (all cases diagnosed with intra articular distal end radius fracture fulfilling the inclusion criteria will be taken as sample).

Sample Size:

Based on a study done by Rajeev Shukla et al M±SD of flexion (range of motion) in between group open reduction and internal fixation and External fixator were reported as (80.33±11.25) and (75.54±17.7) respectively. Considering the difference in mean δ=22.94 and pooled standard deviation σ=14.47 and, significance level α=5%, power β=80%, Zα=1.96 and Zβ =0.84

$n= 2 (Z \alpha + Z\beta) 2 \sigma 2/ \delta 2$

$= 2(1.96 + 0.84)2 (14.472 / (22.94)2$

$=143.37$

$=143$

Sample size is calculated to be 143 in each group with total sample size of 286. But based on previous medical record total number of eligible patients coming to BPKIHS Emergency and Orthopaedics OPD is 50. So corrected sample size formula considered for finite population

N: calculated sample size/1 + calculated sample size/estimated population (CDC Atlanta who, epi info 2007 software)

The sample size is 21 in each group.

- However all cases coming to BPKIHS who can be included in the study will be taken. The patient will be followed up at 2nd week, 6th week, 12th week and 24th week respectively. The withdrawal reasons are applicable and lost to follow up will be considered.

Inclusion criteria:

- All patients aged > 18 years with traumatic isolated and recent (up to 1 week) intra-articular distal end radius fractures.

Exclusion Criteria:

Patients with any of the following features were excluded from the study:

a. A preexisting joint or carpal bone disease which interferes with rehabilitation

b. Open fractures Gustilo grade ii and above

c. Fracture avulsion and dislocation

d. Patient not fit for surgery

e. Not willing to provide consent

Ethical clearance:

Ethical approval was taken from the Institutional Review Committee and PG Program committee of BPKIHS prior to the conduction of the study.

Randomization and allocation concealment:

- Random allocation was done using Excel random number generation technique into two groups.
- A big brown envelope was made and numbered to achieve concealment of randomization recruitment. It was kept with sisters in OT.
- A subject enrollment form was filled and eligible patients were offered detailed printed information about the proposed study.
- Patients agreeing to take part in study were requested to sign the consent form.
- After signing the consent, a sealed numbered envelope was opened by sister just prior to anesthetizing patient and the patient was recruited to either ORIF with volar locking plate group or CRPP with k wire fixation group.

- Pro formas were filled for each case and follow up data were entered in subsequent visits.

Methods

Enrollment of patients;

- Patients with final diagnosis of Intra-articular distal end radius fracture presented to BPKIHS Orthopedics Outpatients Clinic and Emergency were enrolled in the study.
- A detailed history regarding demographic profile, mode of injury, associated injuries, co-morbidities were recorded in preset pro forma.
- A through general physical and systemic examination was carried out to look for underlying exclusion criteria.
- X-ray wrist in standard AP and Lateral view was taken.
- A prior informed and written consent was taken from each patient after explaining about the surgery, complications and possible outcomes as per their respective group.
- Prophylactic IV antibiotic as 2nd generation Cephalosporin with Aminoglycoside (Inj. Cefuroxime + Inj. Amikacin) was administered to both the groups, for similar duration, dose, frequency as per standard practice.
- Surgeries were performed under general or regional block. Patient were set up in the supine position on the operating table with the required upper limb supported on a side table.

Group A

- In volar plating group, anterior approach (Henry/ Chung) incision was used after painting and draping. Meticulous soft tissue dissection was done.
- Locking volar plate(of adequate length) was used to fix the fracture ; with the guidance of image as per requirement
- The FCR sheath was opened and tendon retracted to radial side to expose ulnar corner of distal radius.

- Underneath FCR lies FPL which is retracted ulnarly revealing pronator quadratus (PQ)
- The PQ muscle is elevated from its radial origin and reflected ulnarly to expose distal radius.
- During operation, the fracture reduction will be visualized via an image intensifier.
- Fractures may be stabilized with additional k wires.
- Number of image shots required were noted.
- Below elbow posterior slab was applied.
- Intra-operative blood loss and operative time were noted.
- Post-operative check X-ray was taken on next day.
- Dressing was opened after 48 hrs and physiotherapy was started as soon as per feasibility. Post-operative fever and post-operative pain were noted and looked for superficial infection.
- Patient was discharged on second post op day.

Group B

- In External fixation group also, patient will be treated in similar set up and criteria.
- After adequate traction and initial reduction, painting and draping will be done.
- During the procedure, two 2.5mm Schanz pins in the second metacarpal and two 3.5mm pins in the radius proximal to the fracture will be used.
- The pins will be interconnected and tightened with solid connecting rod and link joints.
- Longitudional traction was along the forearm to help reduce fracture and correct radial length and displacement through ligamentotaxis.
- Sterile beta dine dressing of pin tract will be done.
- May require extra k wire to control posterior tilt when EF alone failed to restore the dorsal or frontal angulations of the articular surface.
- Post-operative check X-ray will be taken on next day.

- Dressing will be opened after 48hrs and physiotherapy will be started soon as possible. Post-operative fever and post-operative pain will be noted and observed for superficial infection.
- Patient will be discharged after few days depending upon the condition of the patient.

Follow Up:

- In both groups, patients were followed up on 14th post-operative day and suture were removed for ORIF group and pin site inspection was done for External fixator group. Wound infection, wrist ROM, pain, intra-articular step-off if any were also noted. Similarly, during 6 weeks and 3 months follow-up, wound infection, wrist ROM, intra-articular stepping, pin site infection, grip strength, functional activity, Varus/Valgus tilt and hardware impingement if any were noted.
- Patients were followed every 6 week to assess status of union by X-ray and functional outcome was evaluated using Green and O' Brien scoring system modified by cooney.

Outcomes evaluation (instrument/scale used are attached in annexure)

- The functional outcome was assessed using Green and O' Brien score modified by Cooney
- Intensity of pain was evaluated using the Visual Analog Scale (VAS) score
- The range of motion (wrist flexion-extension, wrist ulnar and radial deviation) was measured in degrees by using a goniometer.
- The complications were evaluated in terms of: tourniquet palsy, infection, haematoma formation, compartment syndrome, nonunion/ delayed union/ malunion/deformity, implant failure, complex regional pain syndrome, stiffness, postoperative carpal tunnel syndrome.

Data Management:

The data obtained from the pro forma were collected, checked and entered in SPSS data sheet version 17.

Statistical Analysis:

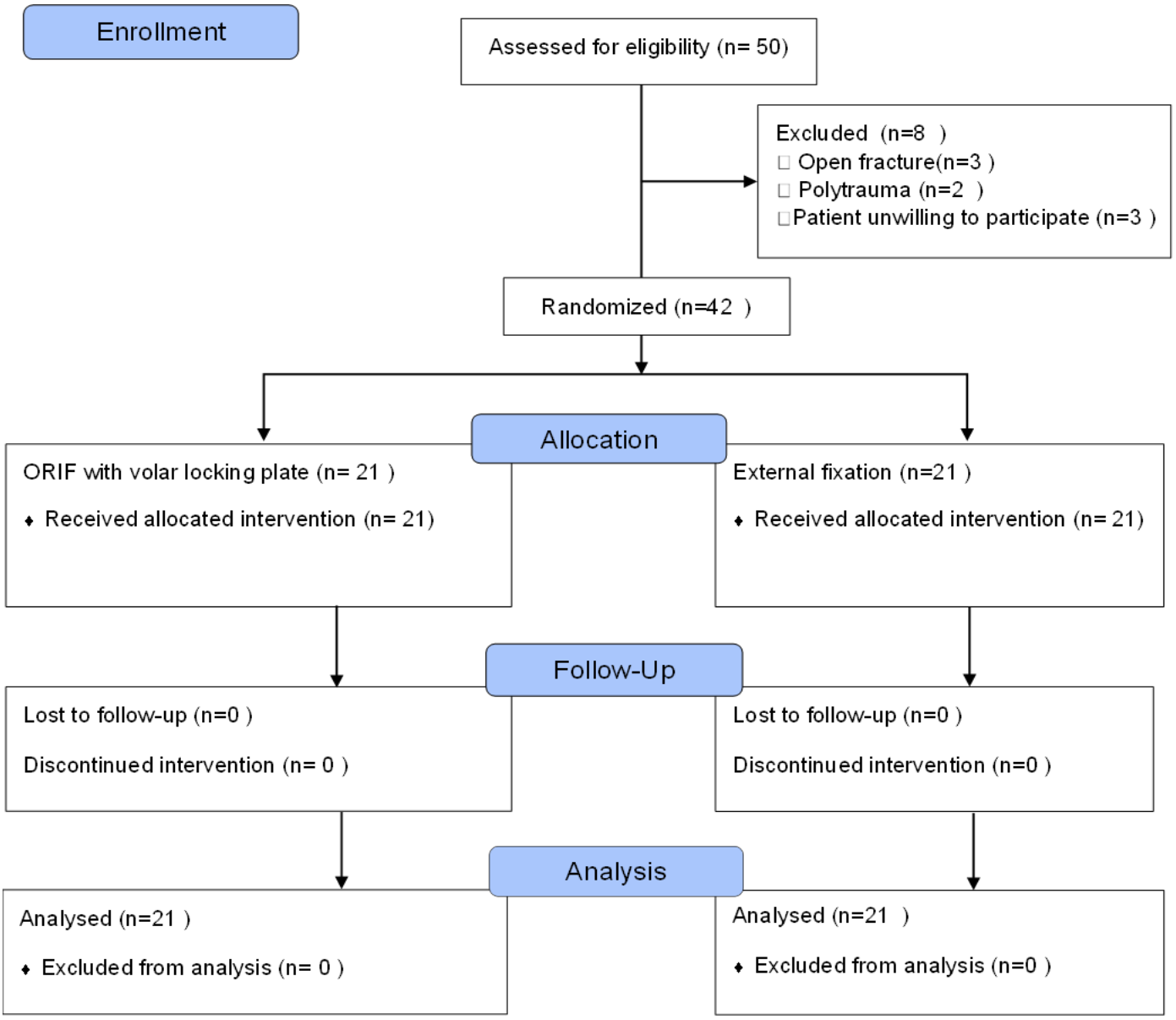
Random allocation of the patients was done on the basis of computer based random numbers. Proportion, measure of central tendency and dispersion of continuous variables like age, sex, involved limb, mode of injury, interval between injury and surgery were tested by appropriate parametric and non-parametric statistical techniques (e.g. Independent Sample T-test or Mann-Whitney U test). Chi-square test and Fisher's exact test were used for categorical data like socio-demographical variables with graphs. The outcomes at various follow up intervals were compared between two groups and both magnitude and significance of difference were measured using appropriate tests. The results were compared with other relevant studies in the literature and consensus view presented comparing outcomes and complication rates between the two groups.

Observations and Results

The patients were enrolled from December 2019 to November 2020. Initially 50 patients were assessed for eligibility for our study. There were 8 patients not meeting the inclusion criteria (2 had polytrauma and 3 had Gustilo Grade II or III open fractures) and 3 patients were unwilling to participate in the study, and they were excluded.

A total of 42 patients were randomized into two groups; ORIF with volar locking plate group and External fixation group, each group consisting of 21 patients. At final follow up (6 months post-operatively), all patients were analyzed (21 in each group).

CONSORT Flow Diagram



Excluded (n=8) Open fracture(n=3) polytrauma (n=2)

patient unwilling to participate (n=3)

Figure 1: CONSORT flow diagram of our study

		Group		Total	P-value	Remarks
		External fixation	ORIF			
Sex	Male	8((38.1 %)	9(42.9 %)	17	0.553	Not significant
	Female	13(61.9 %)	12(57.1%)	25		
Total		21	21	42		

Table 1: Sex distribution (n=42)

In our study, 9(42.9%) patients were male and 12 (57.1%) were female in the ORIF with volar locking plate group and 8 (38.1%) were male and 13 (61.9%) were female in the external fixation group.

The difference in sex distribution was not statistically significant between the two groups (Chi Square test, p-value 0.553).

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Age in years (Mean ± S.D.)	42.76 ± 14.237	37.76 ± 14.124	0.911	Not significant

Table 2: Mean age distribution in years

The mean age distribution was comparable between the two groups: it was 37.76years (S.D. 14.124years) in the ORIF with volar locking plate group and 42.76years (S.D 14.237 years) in the external fixation group.

The difference in mean age distribution was not statistically significant between the two groups (p-value 0.911).

Table 3: Socio demographic characteristics of study population

The following table demonstrates the distribution of population in different age and gender:

Categories		No of patients	Percentage (%)
Age groups(in years)	<20	2	9.5
	21-40	9	42.9
	41-60	6	28.6
	>60	4	19.0
Gender	Male	17	40.47
	Female	25	59.52

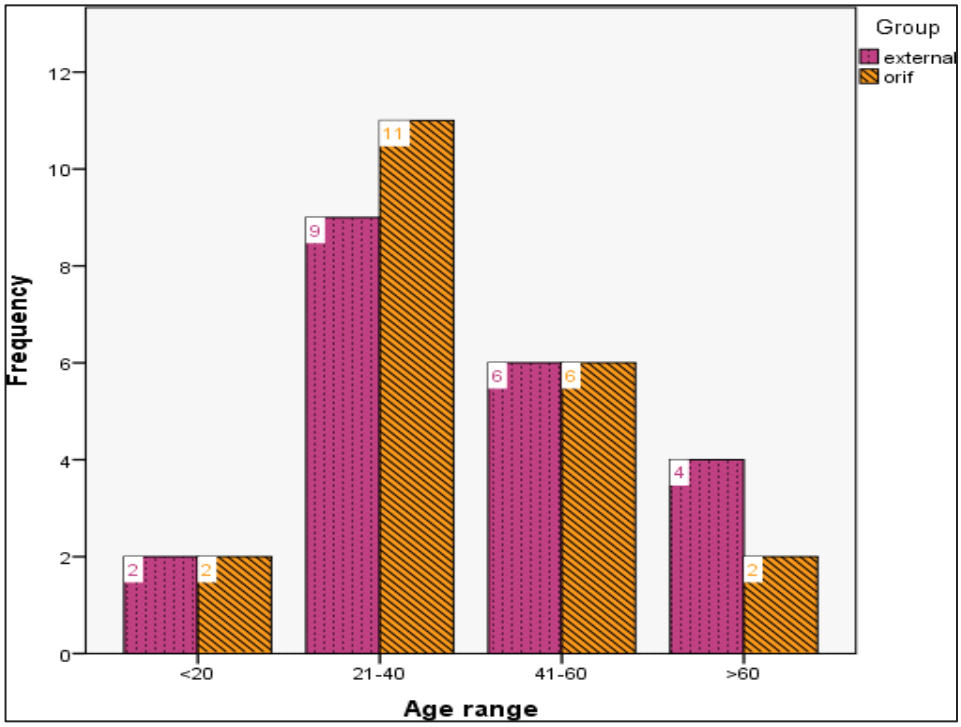


Figure 1: Bar diagram showing age range

An observation that intra-articular distal end radius fracture was commoner in young age group 21-40 yrs (42.9%) and female sex was seen 25 (59.52%).

		Group		Total	P- value	Remarks
		External fixation	ORIF			
Side	Right	9 (42.9%)	9(42.9 %)	18	0.755	Not significant
	Left	12(57.1%)	12 (57.1 %)	24		
Total		21	21	42		

Table 4: Side distribution

In ORIF with volar locking plate group the right side (the dominant side) was injured in 9 (42.9%) patients and the left side (non-dominant side) in 12(57.1%) patients. In external fixation group the right side (the dominant side) was injured in 9 (42.9%) patients and the left side (non-dominant side) in 12 (57.1%) patients.

The difference in side distribution was not statistically significant between the two groups (Chi Square test, p-value 0.755).

		Group		Total	P-value	Remarks
		External fixation(%)	ORIF			
Mode of injury	RTA	12(57.1) %)	9(42.9 %)	20	0. 314	Not significant
	Physical assault	0	3(14.3%)	2		
	Fall from height	6(28.6 %)	4(19.0 %)	14		
	Fall on ground	3(14.3 %)	5(23.8%)	8		
Total		21	21	42		

Table 5: Mode of injury

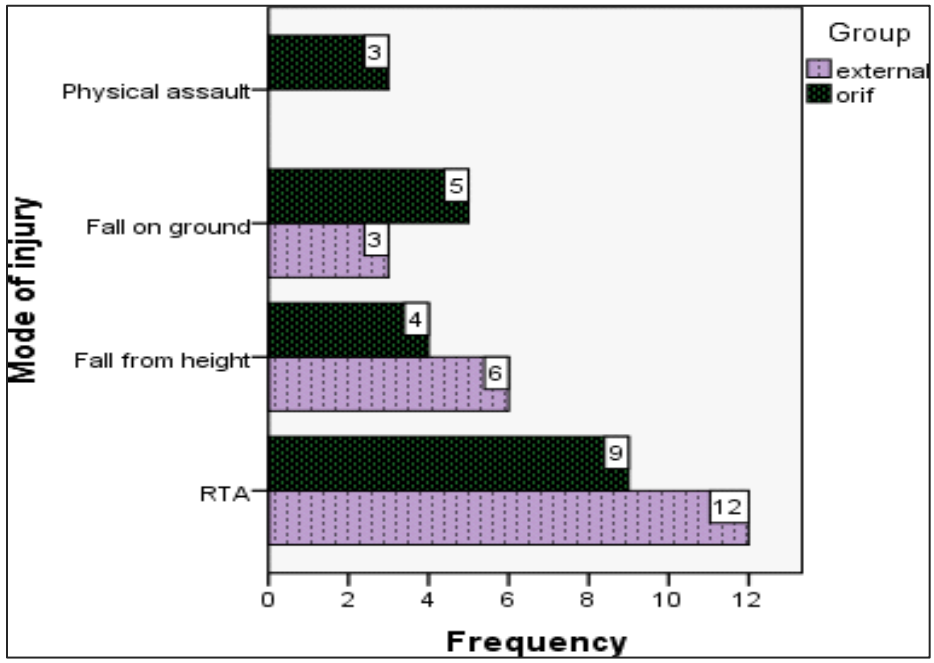


Figure 2: Bar diagram showing mode of injury

In 20 patients, RTA was the cause of the injury; in plate group 9(42.9 %) and in external fixation group 12(57.1 %). 22 patients presented with fall injury either from height; 4 (19%) in plate and 6 (28.6%) in external fixation group or on level ground;

5 (23.8 %) in plate and 3 (14.3%) in external fixation group. 3(14.3%) patients presented with physical assault in plate group.

However, the difference in the modes of injury was not statistically significant between the two groups (p-value 0.314).

Types of fracture	External Fixation	ORIF	p-value*	Remarks
Open	5 (23.8%)	1 (4.8%)	<0.001	significant
Closed	16 (76.2%)	20 (95.2%)		

Table 6: Comparison of types of fractures

In external fixation group 16 (76.2%) patients presented with closed fracture and 5(23.8%) patient presented with open fracture(GGI). In ORIF with volar plate group 20(95.2%) patient presented with closed fracture and 1% (4.8%) with open fracture(GGI).The difference between the two groups is statistically significant(p value<0.001).

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Presentation to hospital in days (Mean ± S.D.)	1.43± 0.676	1.33 ± 0.577	0.264	Not significant

Table 7: Presentation to hospital in days

The mean duration of presentation to hospital in the ORIF with volar locking plate group was 1.33 ± 0.577 days and in the external fixation group was 1.43 ± 0.676 days.

The difference in mean duration of presentation to hospital was not statistically significant between the two groups (p-value 0.264).

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Injury to surgery time in days (Mean ± S.D.)	2.57 ± 0.746	2.62 ± 0.740	0.611	Not significant

Table 8: Injury to surgery time in days

The mean duration from injury to surgery in the ORIF with volar locking plate group was 2.62 ± 0.740 days and in the external fixation group was 2.57 ± 0.746 days.

The difference in mean duration from injury to surgery was not statistically significant between the two groups (p-value 0.611).

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Duration of surgery in minutes (Mean ± S.D.)	39.52 ± 3.842	55.48 ± 3.842	<0.001	Significant

Table 9: Duration of surgery in minutes

The average duration of surgery in ORIF with volar locking plate was 55.48± 3.842 minutes and 39.52 ± 3.842 in the external fixation group and their difference was statistically significant (p-value< 0.001). This study shows that external fixation is the faster method of fixing intra-articular distal end radius fracture.

Variable	Group		P-value	Remarks
	ORIF	External fixation		
Duration of hospital stay in days (Mean ± S.D.)	4.24± 0.436	4.14± 0.359	1.0	Not significant

Table 10: Duration of hospital stay in days

The mean duration of hospital stay in ORIF with volar locking plate group was 4.24 ± 0.436 days and in the external fixation group was 4.14± 0.359 days.

The difference in mean duration of hospital stay was not statistically significant between the two groups (p-value 1.0).

Variable	Group		P-value	Remarks
	External fixation	ORIF		
No of shots (Mean ± S.D.)	3.43 ±0.507	6.05 ± 0.740	0.257	Not Significant

Table 11: No of shots (Image exposure)

The mean no of shots in ORIF with volar locking plate group was 6.05 ± 0.740 and in the external fixation group was 3.43 ± 0.507 .

The difference in mean in no of shots were statistically not significant between the two groups (p-value 0.257). Significant amount of radiation exposed should alert the concerned personnel inside OT, to use maximally the protective accessories like lead apron.

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Blood loss in ml (Mean ± S.D.)	32.86 ± 6.036	140.48 ± 40.679	<0.001	Significant

Table 12: Blood loss

The mean blood loss in ORIF with volar locking plate group was 140.48 ml (SD 40.679ml) while it was 32.86ml (SD 6.036ml) in external fixation group. The values are statistically significant between the two groups (p value <0.001). But the requirement of blood transfusion in the post-operative period among the two groups were not significant thus, despite statistically significant it merely has any clinical significance.

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Immediate post-operative pain (VAS score) (Mean ± S.D.)	3.45± 1.335	5.68 ± 1.086	<0.001	Significant

Table 13: Immediate post-operative pain (VAS score)

The average VAS score for pain in the immediate post-operative period was 5.68 ±

1.086 in the ORIF with volar locking plate group and 3.45 ± 1.335 in the external fixation group.

The difference between the values was statistically significant (p-value <0.001. This is obvious to have more pain in plating group due to significant soft tissue dissection.

		Group		Total	P-value	Remarks
		External fixation (%)	ORIF(%)			
Wound status at 2 weeks follow up	Healthy	20 (95.2 %)	19 (90.5 %)	39	0.148	Not significant
	Infected	1 (4.8 %)	2(9.5 %)	3		
Total		21	21	42		

Table 14: Wound status at 2 weeks follow up

Only two (9.5%) patients had postoperative wound infection in the ORIF with volar locking plate group. 1(4.8%) patient had infected surgical wounds (i.e. pin tract infection) in the external fixation group and 2 patients (9.5%) had infected surgical wound in ORIF with volar plate group .The remaining 39 patients had healthy surgical wounds at 2 weeks follow up.

The difference in wound status at 2 weeks follow up was not statistically significant between the two groups (Fisher's exact test, p-value 0.148).

	Wrist flexion-extension in degrees (i.e., arc of motion) (Mean ±SD)		P-value	Remarks
	Plating (n=21)	External fixation (n=21)		
6 weeks	115.86 ± 9.96	116.08 ± 12.24	0.948	Not significant
12 weeks	133.69 ± 11.79	134.34 ± 11.7	0.852	
24 weeks	147.39 ± 11.95	144.56 ± 8.9	0.368	

Table 15: Wrist flexion-extension in degrees

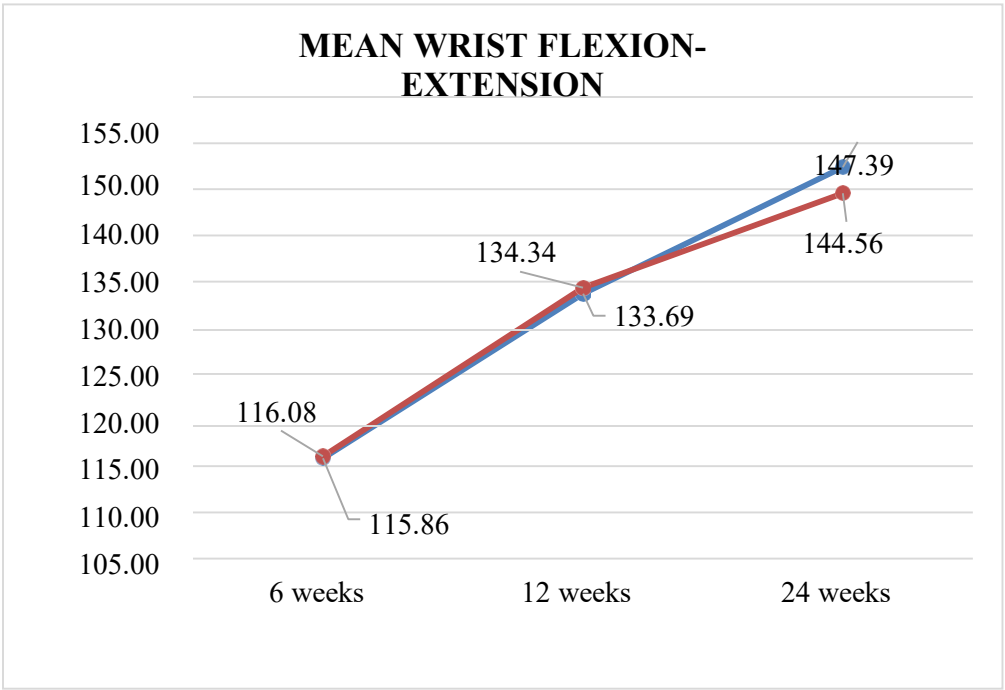


Figure 3: Line diagram showing wrist flexion-extension arc in degrees

There was progressive increase in wrist flexion-extension arc during patient follow up. Though initially, at 6 weeks, ROM was similar between the two groups (115.86 ± 9.96 degrees for ORIF with volar locking plate and 116.08 ± 12.24 degrees for external fixation group), at 6 months, the ORIF with volar locking plate group showed better ROM (147.39 ± 11.95 degrees) than the external fixation group (144.56 ± 8.9 degrees). However, their differences were not statistically significant (Independent sample T-test, p-value > 0.05).

Follow up	**Forearm supination-pronation in degrees (i.e., arc of motion) (Mean ±SD)**		**P-value**	**Remarks**
	Plating (n=21)	**External fixation (n=21)**		
6 weeks	126.73 ± 11.54	129.13 ± 9.84	0.454	Not significant
12 weeks	143.69 ± 9.19	143.47 ± 6.47	0.927	
24 weeks	158.04 ± 5.16	156.3 ± 5.26	0.264	

Table16: Forearm supination-pronation in degrees

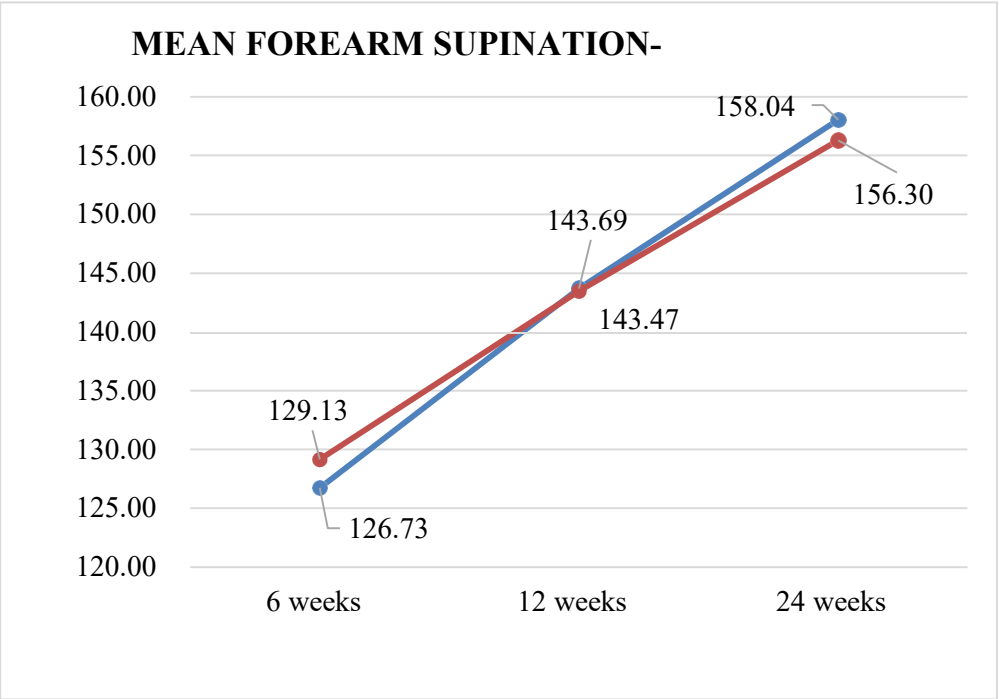


Figure 4: Line diagram showing forearm supination-pronation arc in degrees

There was progressive increase in forearm supination-pronation arc during patient follow up. Though initially, at 6 weeks, ROM of ORIF with volar locking plate group (126.73 ± 11.54 degrees) was less than the external fixation group (129.13 ± 9.84 degrees) at 6 months, the plate group showed better ROM (158.04 ± 5.16 degrees) than the external fixation group (156.3 ± 5.26 degrees). However, their differences were not statistically significant (Independent sample T-test, p-value > 0.05).

Follow up	Radial inclination in degrees (Mean ±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
Immediate post-operative	19.29 ±3.663	17.81 ±2.804	<0.001	significant
6 weeks	16.81 ± 3.919	16.71 ± 1.648	0.295	Not significant
12 weeks	16.81 ± 3.919	16.71 ± 1.648	0.295	
24 weeks	16.81 ± 3.919	16.71 ± 1.648	0.295	

Table 17: Comparison of radial inclination in degrees

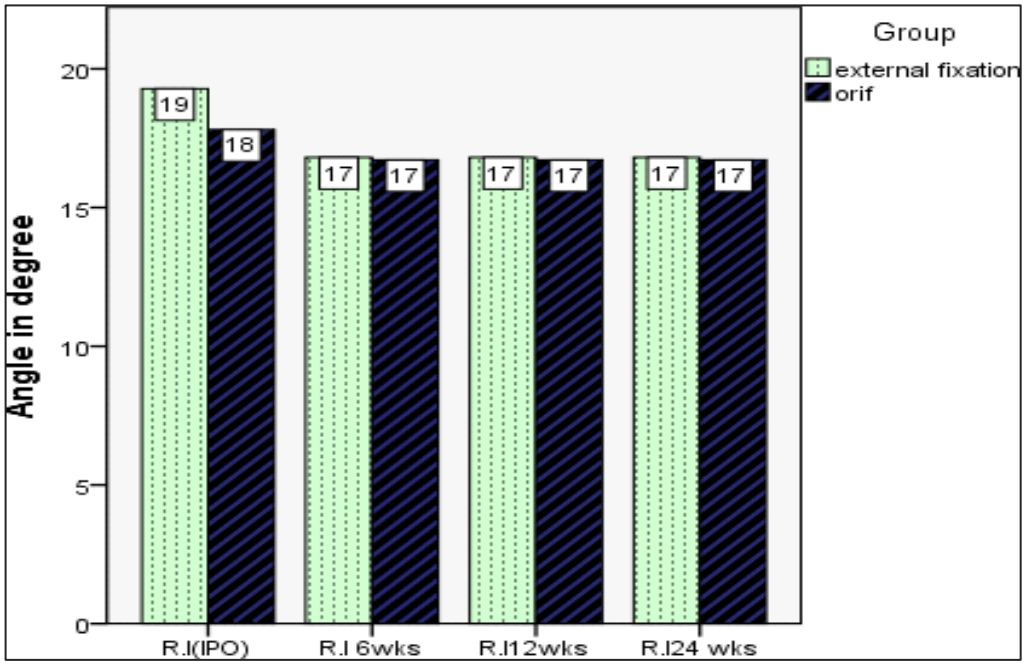


Figure 5: Bar diagram comparing Radial inclination (in degrees) measured immediate postoperatively, 6,12 and 24 weeks

Immediate post-operative radial inclination was found to be significantly higher in the group external fixation. At 6 weeks follow up both the groups demonstrated loss of radial inclination however a significant ($p<0.001$) was noticed in the group external fixation as compared to ORIF in immediate post- operative period. There was no further loss of radial inclination in either groups at subsequent follow ups and no significant difference was noticed in radial inclination at subsequent 6, 12 and 24 weeks follow ups.

Follow up	Radial length in mm (Mean ±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
Immediate post-operative	12.67 ± 1.713	12.10 ± 1.814	0.940	Not significant
6 weeks	10.95 ± 2.037	11.71 ± 1.521	0.731	
12 weeks	10.95 ± 2.037	11.71 ± 1.521	0.731	
24 weeks	10.95 ± 2.037	11.71 ± 1.521	0.731	

Table18: Comparison of radial length

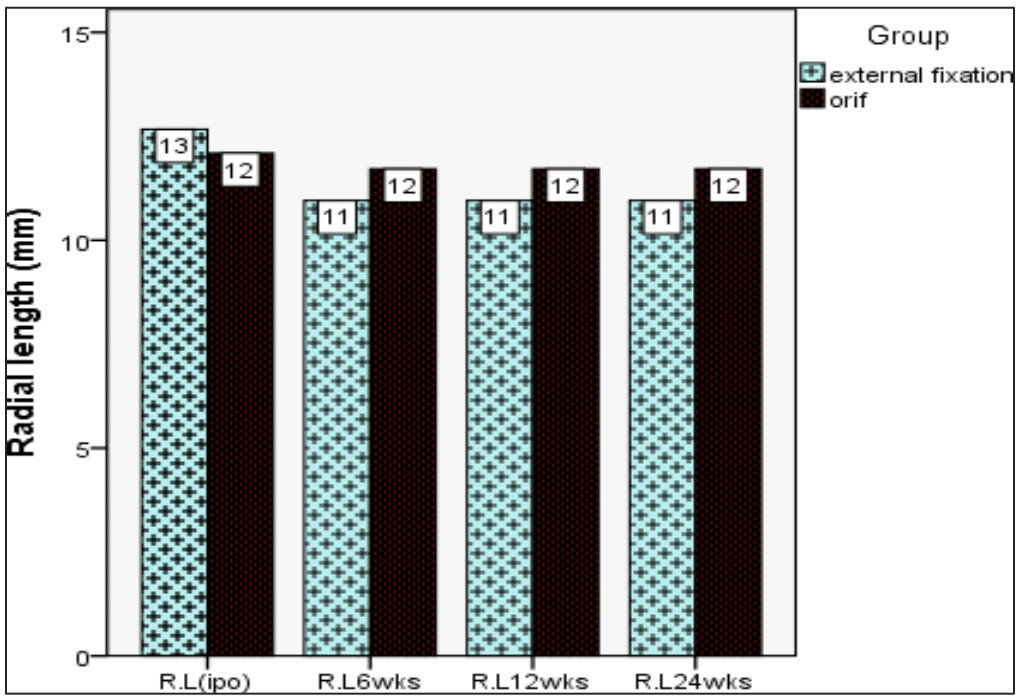


Figure 6: Bar diagram comparing Radial length (in mm) measured immediate postoperatively, 6,12 and 24 weeks

Immediate post-operative radial length was found to be comparable in both external fixation group and ORIF group (p value 0.940). At 6 weeks follow up both the groups demonstrated loss of radial length .There was no significant further loss of radial length in either groups at subsequent follow ups at 6,12 and 24 weeks respectively.

Follow up	**Articular step off in degrees (Mean ±SD)**		P-value	Remarks
	External fixation (n=21)	**ORIF (n=21)**		
Immediate post-operative	1.20±0.422	1.17±0.408	0.189	Not significant
6 weeks	1.38 ± 0.506	1.17 ± 0.408	0.131	
12 weeks	0.57 ± 0.811	0.76± 0.700	0.268	
24 weeks	0.86 ± 0.793	0.33 ± 0.577	0.131	

Table19: Comparison of articular step off in degrees

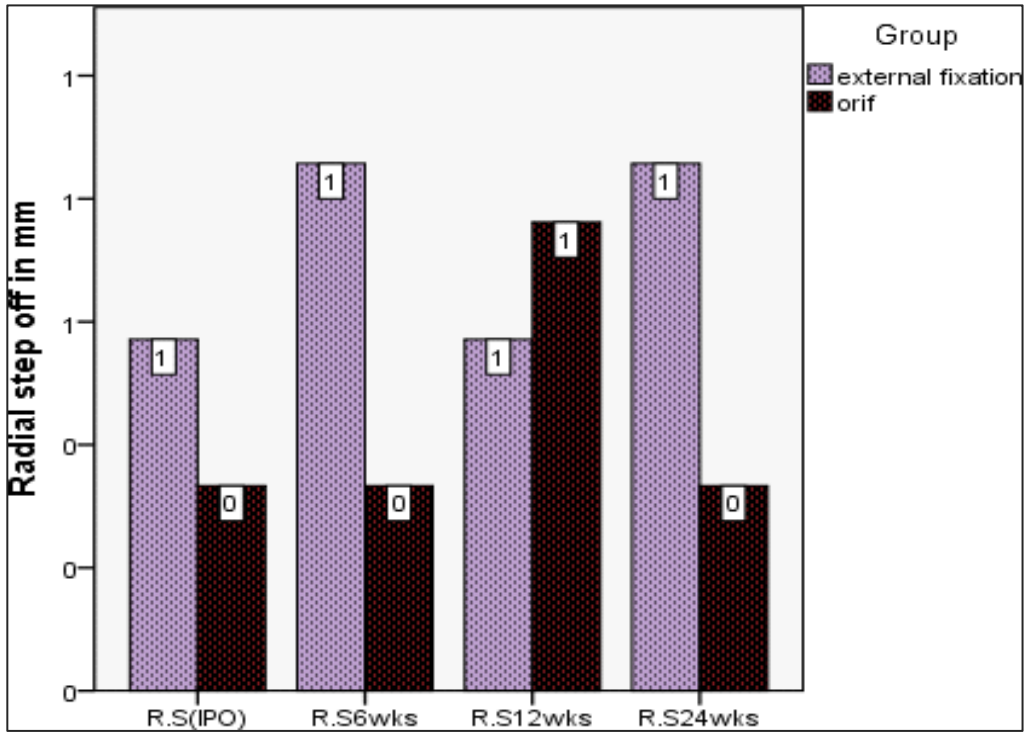


Figure7: Bar diagram comparing Articular step-off (in degrees) measured immediate postoperatively, 6,12 and 24 weeks

Immediate post- operative articular step off was found to be greater in external fixation group but statistically not significant. At 6 weeks follow up articular step off increased in external fixation group and static in ORIF group. On further subsequent visit 12 and 24 wks there was no further increase in articular step off in both the groups.

Follow up	Ulnar variance in degrees (Mean ±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
Immediate post-operative	-1.74±1.821	-1.63±1.707	0.705	Not significant
6 weeks	-0.35 ± 1.967	-1.53 ± 1.645	0.305	
12 weeks	-0.56 ± 1.999	-1.28± 1.742	0.728	
24 weeks	-0.63 ± 2.062	-1.28± 1.742	0.617	

Table 20: Comparison of ulnar variance in degrees

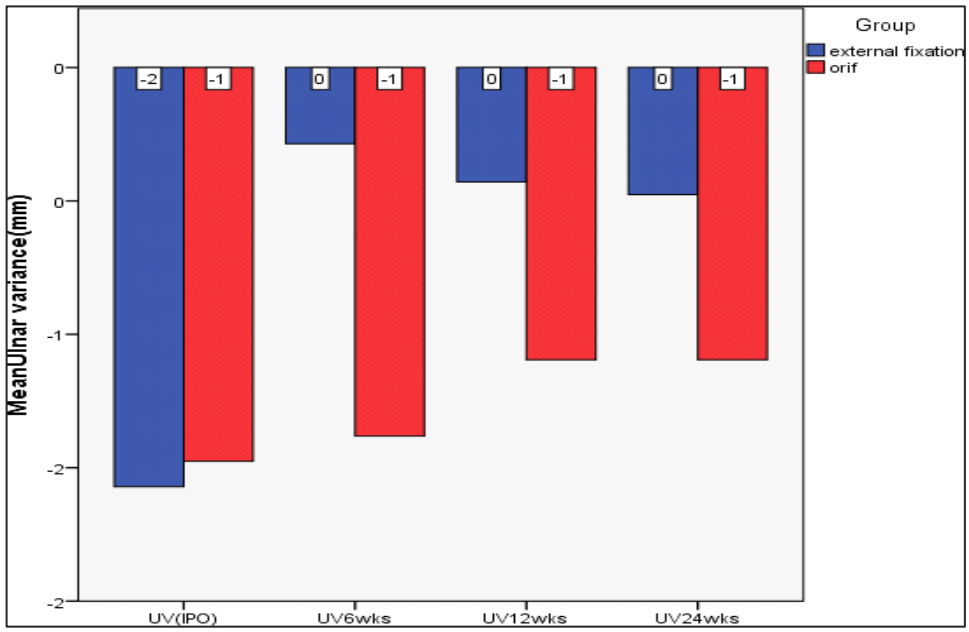


Figure 8: Bar diagram comparing Ulnar variance (in degrees) measured immediate postoperatively, 6,12 and 24 weeks

Immediate post operative ulnar variance was comparable in the two groups. At 6 weeks follow up both the groups demonstrated change in ulnar variance however a significantly greater change of ulnar variance was noticed in the external fixation group while change of ulnar variance in the plating group was not significant(p:0.705). There was no further change in either groups at subsequent follow ups and difference in ulnar variance was found to be comparable in between two groups at 6,12 and 24 weeks.

Follow up	Wrist dorsiflexion in degrees (Mean ±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
6 weeks	20.38 ± 7.437	34.29 ± 7.410	<0.001	significant
12 weeks	41.86 ± 10.129	47.52± 10.505	0.295	Not significant
24 weeks	56.14 ± 15.589	61.43± 10.656	0.562	

Table 21: Comparison of wrist dorsi flexion at 6,12 and 24 weeks

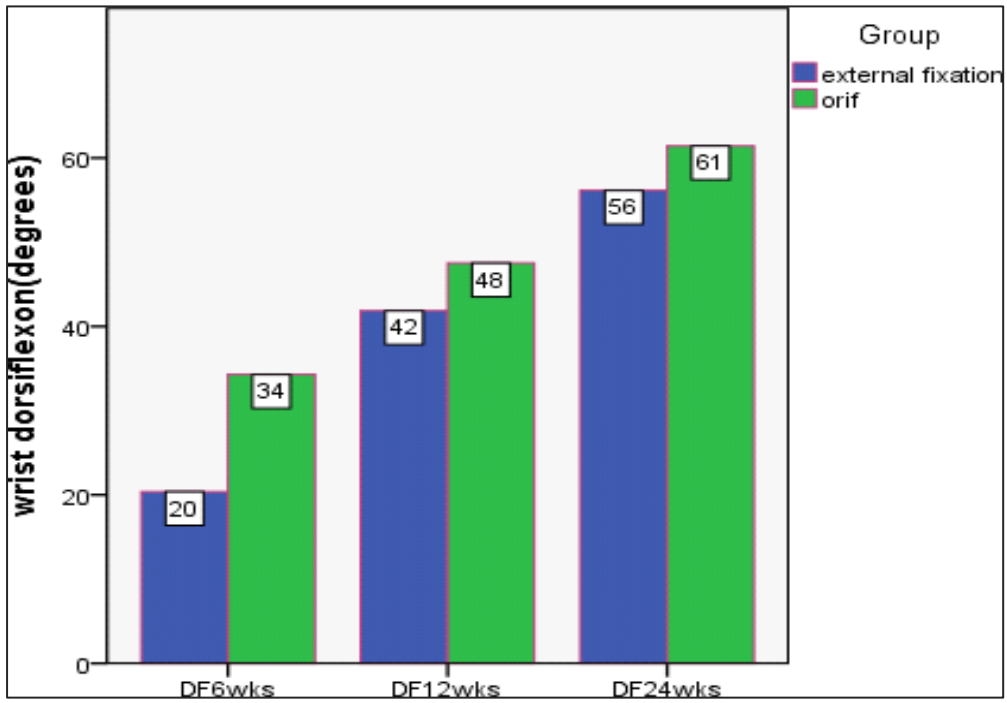


Figure 9: Bar diagram comparing Wrist dorsiflexion (in degrees) measured 6,12 and 24 weeks

There is highly significant lower degree of dorsiflexion of wrist in external fixation group in comparison to ORIF group at 6 weeks follow up. However degree of dorsiflexion in both the groups showed highly significant increase at 12 weeks follow ups($p<0.001$) and then again at 24 weeks in comparison to 6 and 12 weeks follow- ups($p<0.001$). wrist dorsiflexon was found to be lesser but not significantly different in external fixator group at 12 and 24 weeks follow-ups.

Follow up	Wrist palmar flexion in degrees (Mean ±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
6 weeks	27.90± 9.534	29.86 ± 11.934	0.248	Not significant
12 weeks	47.86 ± 6.011	47.33± 9.041	0.075	
24 weeks	60.19 ± 8.292	59.62± 11.020	0.055	

Table 22: Comparison of wrist palmar flexion at 6,12 and 24 weeks

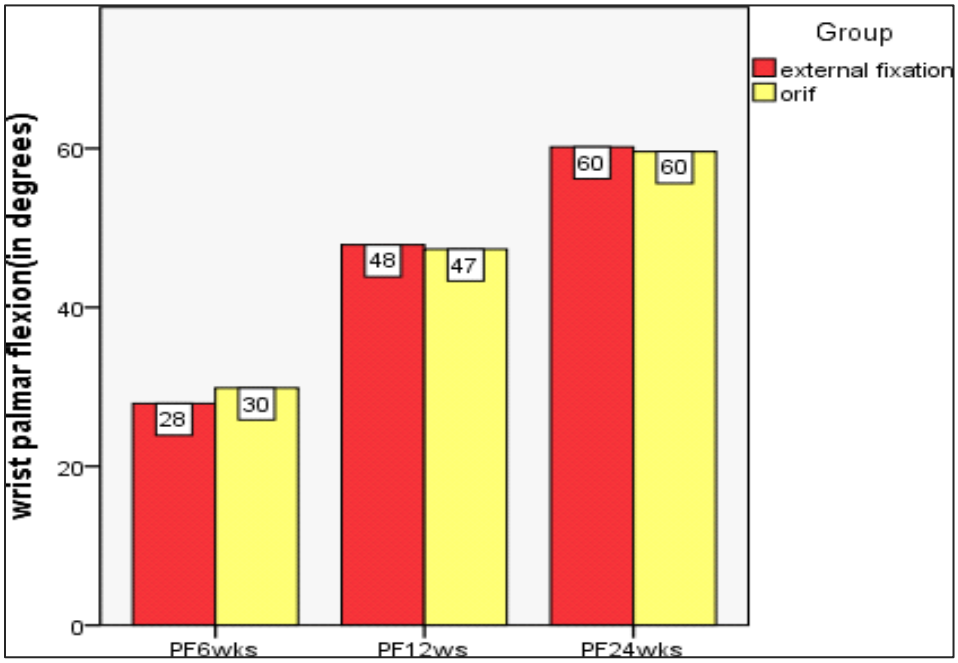


Figure 10: Bar diagram comparing Wrist palmarflexion (in degrees) measured 6,12 and 24 weeks

Palmar flexion at wrist was lesser in the group external fixation at 6 weeks follow-up. However degree of palmar flexion in both the groups showed highly significant increase at 12 weeks follow-ups ($p<0.001$) and then again at 24 weeks in comparison to 6 and 12 weeks follow-ups ($p<0.001$). Wrist palmar flexion was found to be lesser but not significantly different in external fixation group at 12 and 24 weeks follow-ups respectively.

Follow up	Wrist ulnar deviation in degrees (Mean±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
6 weeks	19.48± 6.501	19.76 ± 1.338	<0.001	significant
12 weeks	25.43 ± 4.308	25.76± 3.491	0.368	Not significant
24 weeks	27.24 ± 4.939	29.14± 2.920	0.008	

Table 23: Comparison of Wrist ulnar deviation in degrees at 6,12 and 24 weeks

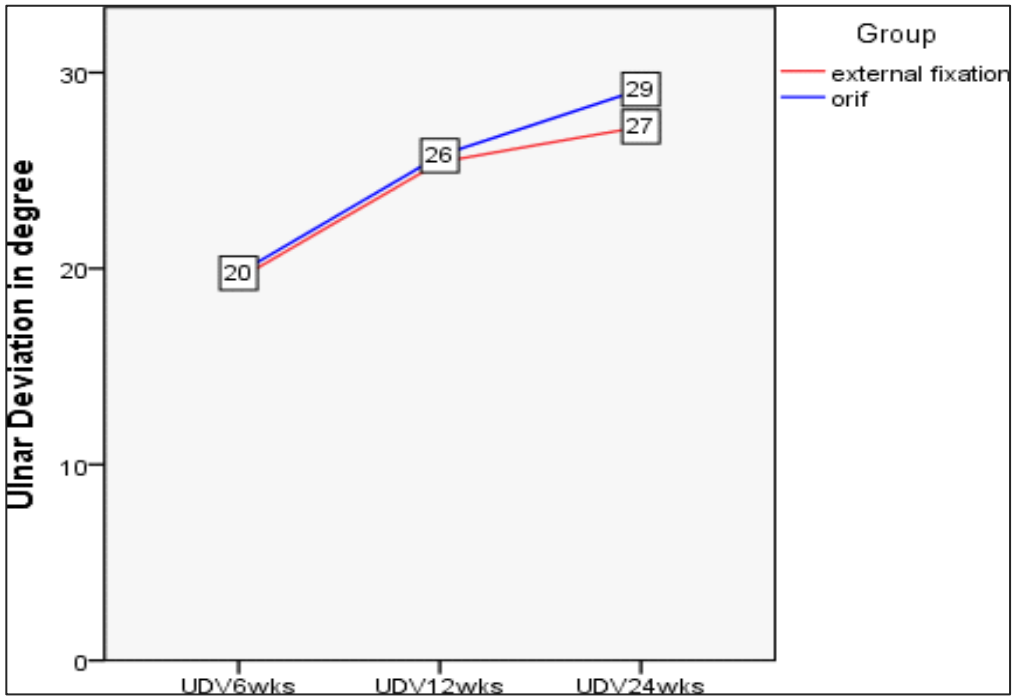


Figure 11: Chart showing ulnar deviation in degree at 6, 12 and 24 weeks

Ulnar deviation was statistically significant between both the groups at 6 weeks follow-up ($p<0.001$). However degree of ulnar deviation in both the groups showed highly significant increase at 12 weeks follow-up($p<0.001$) and then again at 24 weeks in comparison at 6 and 12 weeks follow-up($p<0.001$).Ulnar deviation was found to be lesser but not significantly different in external fixation group at 12 and 24 weeks follow-up respectively.

Follow up	Wrist radial deviation in degrees (Mean ±SD)		P-value	Remarks
	External fixation (n=21)	ORIF (n=21)		
6 weeks	9.29± 6.182	12.76 ± 2.528	<0.001	significant
12 weeks	15.29 ± 4.941	17.76± 2.682	<0.001	
24 weeks	19.05 ± 3.442	19.86± 3.087	0.135	Not significant

Table 24: Comparison of Wrist radial deviation in degrees at 6,12 and 24 weeks

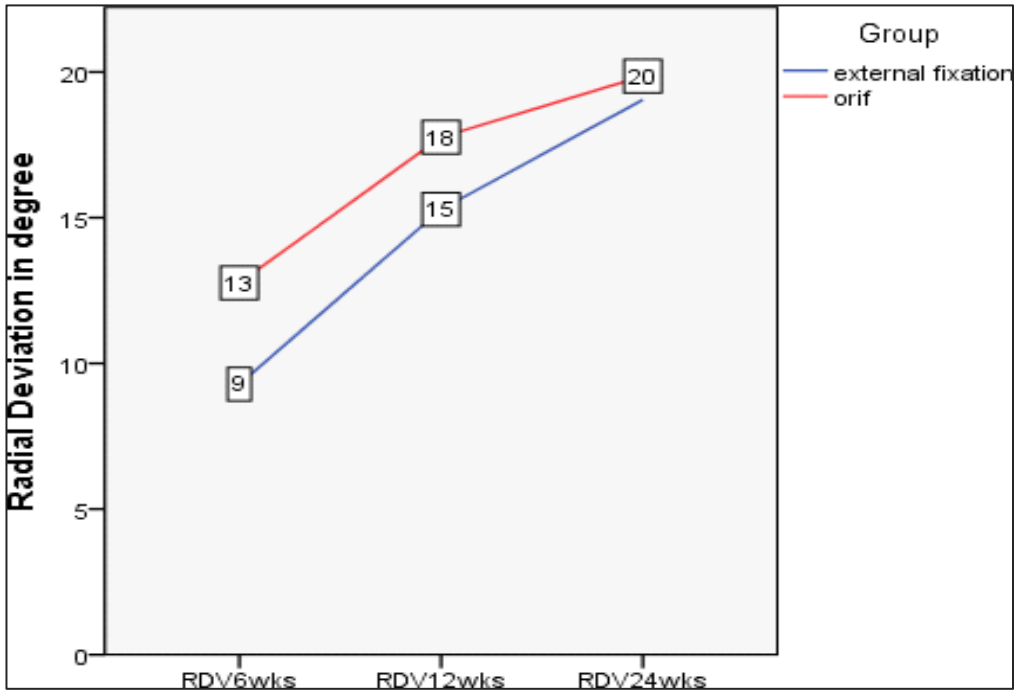


Figure 12: Chart showing radial deviation in degree at 6, 12 and 24 weeks

Radial deviation was significantly lesser in external fixation group at 6 weeks follow up (P<0.001). However degree of radial deviation in both the groups showed highly significant increase at 12 weeks follow-ups (p<0.001) and then again at 24 weeks in comparison to 6 and 12 weeks follow-up (p<0.001).Radial deviation was found significantly lesser at 12 weeks follow up in external fixation group and lesser but not significantly different in external fixation group at 24 weeks follow up.

Radiological union at 6 wks	Group		P-value	Remarks
	External fixator	ORIF		
Yes	17	17	1.000	Not Significant
No	4	4		

1

7(80.9%) patients shows sign of clinical and radiological union at 6 weeks follow up in both the group and 4(19.04%) patient didn't show signs of union at 6 weeks follow- up. However all the patients showed the signs of radiological and clinical union at subsequent 12 weeks follow-up.

The values are not statistically significant between the two groups (p value =1.000).

Variable	Group		P-value	Remarks
	External fixation	ORIF		
Green and O'Brien score (Mean ± S.D.)	2.14 ± 1.49	3.14 ± 3.11	0.187	Not Significant

Table 26: Green and O'Brien score at 24 weeks

The mean Green and O'Brien score at 24 weeks in ORIF with volar locking plate group was 3.14 (SD 3.11) while it was 2.14 (SD 1.49) in external fixation group.

The values are not statistically significant between the two groups (p value =0.187).

		Group		Total	P value	Remarks
		External fixation (n=21) (%)	ORIF (n=22) (%)			
Final results	Excellent*	12(57.1%)	17(81.0%)	29	0.187	Not significant
	Good*	6 (28.6%)	4(19.0%)	10		
	Fair*	3(14.3%)	0	3		
	Poor*	0	0	0		
Total		21	21	42		

*Green and O'Brien score results 90-100 is excellent, 80-89 is good, 65-79 is fair and <65 is poor

Table 27: Final results using Green and O'Brien score

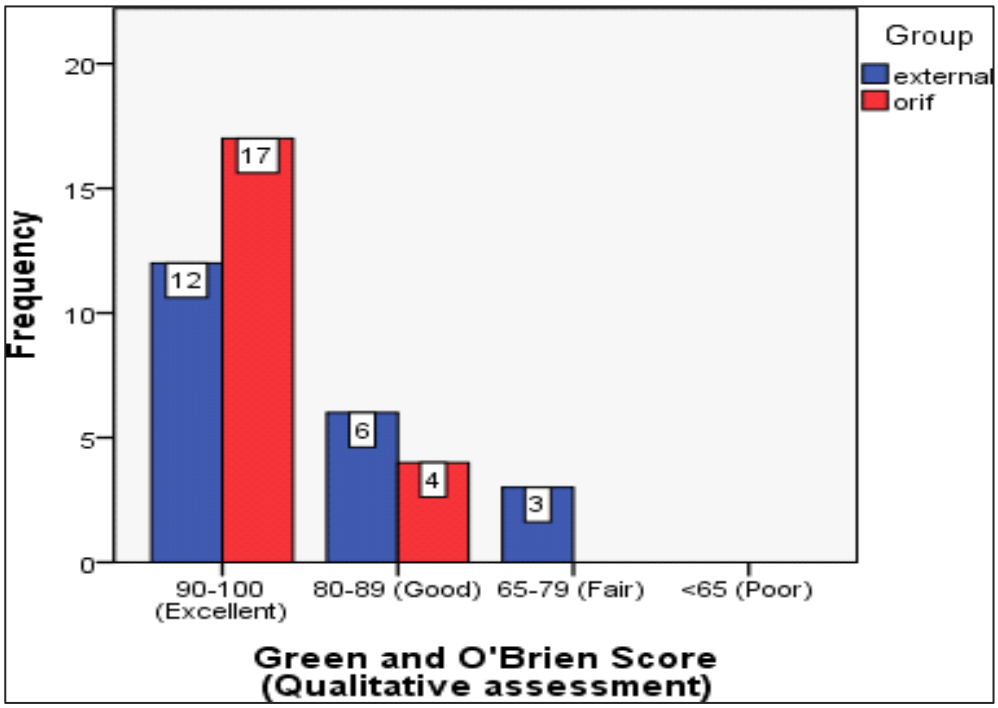


Figure 13: Bar diagram showing final results

Among the 42 patients analyzed until 6 months, the outcome in ORIF with volar locking plate was found to be excellent in 17 patients (81.0%) and good in 4 patients (19.0%). In external fixation group it was found to be excellent in 12patients (57.1%), good in 6 patients (28.6%) and fair in 3 patients (14.3%).

The values are not statistically significant between the two groups (p value =0.187).

		Group		Total	P value	Remarks
		External fixation (n= 21) (%)	ORIF (n=21) (%)			
Complications	None	16(76.2%)	19 (90.5%)	35	0.146	Not significant
	Infection	2 (9.5%)	1(4.8%)	3		
	stiffness	3(14.3%)	0	3		
	CRPS	0	1 (4.8%)	1		
Total		21	21	42		

Table 28: Incidence of complications

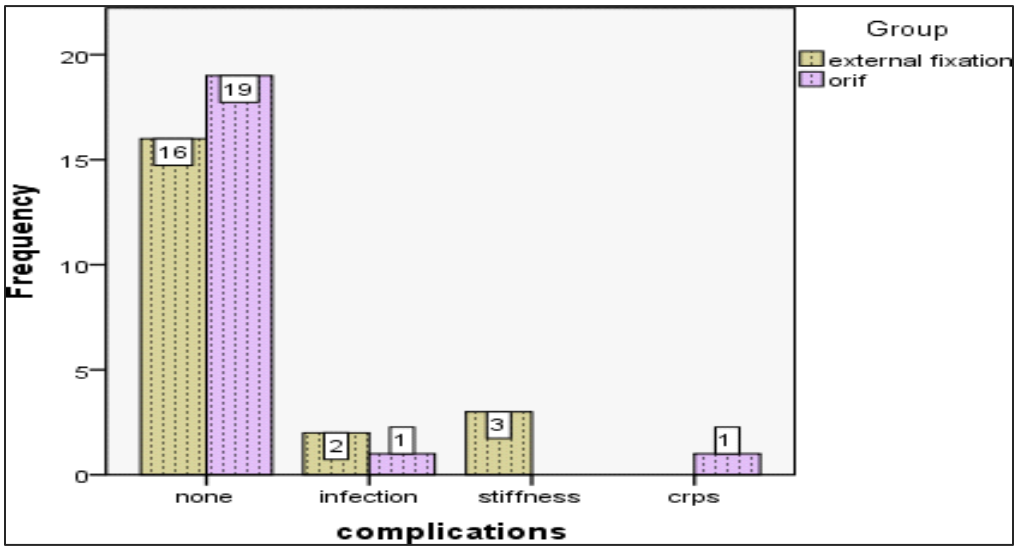


Figure 14: Bar diagram showing incidence of complications

Among the 42 patients analyzed until 6 months, 35 patients did not develop any complications; 19 (90.5%) in ORIF with volar locking plate and 16(76.2%) in external fixator group. There were 2(9.5%) cases of infection in external fixation group. There was 1 (4.8%) case of surgical site infection in the volar locking plate group. There were 3(14.3%) cases of stiffness in external fixation group. There was 1(4.8%) cases of CRPS in volar locking plate group.

The differences in the incidence of complications were not statistically significant between the two groups (p-value 0.146).

Discussion

In our study, a total of 42 patients were randomized into the two groups and all of them underwent operative intervention. There was a female predominance in our study. In external fixation group; 13(61.9%) and in ORIF 12(57.1%) patients were female. Out of 42 patients 25(59.2%) were females and 17(40.47%) were males. However in a study conducted by Tarallo et al(23) and Zamzuri Z et al(21) in 2004 in Malaysia, male patients were predominant because male constituted 81% of study population and probably male population in this part of world is more commonly involved in outdoor activities leading to high energy trauma such as RTA. Maybe due to small sample size and clustering of cases our study revealed female predominance.

In our study, most of the patients were middle aged adults, with the mean age being 37.76 years (S.D. 14.124 years) in the ORIF with volar locking plate group and 42.76 years (S.D. 14.237 years) in the external fixation

group. The mean age was lesser in ORIF group and higher in external fixation group in our study as compared to Rajeev Shukla et al(12), however the values were similar between the two groups in both studies and the difference between them was not statistically significant. Since we consider intra-articular fracture of distal end radius which is a high energy trauma, most of the patients were in middle age group, in contrast to the extra articular fracture which has bimodal distribution with high velocity injury in middle age and low velocity or fragile fracture in elderly patients especially in female.

Patients presented with injury to the left side; the non-dominant side were more than right side, which was true for both the groups. The left side was injured in 24 patients with 12 (57.1%) patients in volar locking plate group and 12 (57.1%) patients in external fixation group and the right side in the remaining 18 patients, with 9 (42.9%) patients in plate group and 9(42.9%) in external fixation group. Our result was comparable with the study done by Wei DH et al(9) (2009) where 48 fractures of non-dominant wrist and 43 fractures of dominant wrist were analysed.

In this study, the most common mode of injury was fall RTA, with 20 patients in total, 9 (42.9%) in plate and 12 (57.1%) in external fixation group. Fall from height was second most common mode of injury, total 14 patients, 6(28.6%) in external fixation group and 4(19%) in ORIF group. Fall on level ground was the 3rd most common mode of injury with 3(14.3%) in external fixation group and 5(23.8%) in ORIF group. Physical assault was cause of injury in 3 (14.3%) patients in plate group. Considering the geographical and topographical situation of Nepal especially eastern part fall injury is one of the common mode of injury followed by RTA. Other studies have not observed the mode of injury in their sample and so our findings could not be compared with them.

In our study the mean duration of presentation to hospital in the ORIF with volar locking plate group was 1.33 days (S.D. 0.577 days) and in the external fixation group was 1.43 days (S.D. ± 0.676 days). Late presentation may reflect the ignorance, lack of knowledge, improper referral system, transportation etc.

In this study, the mean duration from injury to surgery in the plate group was 2.62 days (S.D. 0.740 days) and in the external fixation group was 2.57 days (S.D. 0.746 days. The duration were comparable between the two groups and their difference was not statistically significant. Long duration due to constrains like lack of OT time adequate no of OT room and other reasons.

In our study the average duration of surgery in ORIF with volar locking plate was 55.48 minutes (S.D. 3.842 minutes) and 39.52 minutes (S.D. 3.842 minutes) in the external fixation group. The difference was statistically significant (p-value< 0.001). It took more time for ORIF with volar locking plate compared to

external fixation as plating needed soft tissue dissection . Mean surgery time was 35.1(S.D2.5) in the external fixation group and 56.5(S.D 2.7) minutes in the volar plate fixation group in a study done by Rajeev Shukla et al(12)

In this study, the mean duration of hospital stay in the plate group was 4.24 days (S.D. 0.436 days) and in the external fixation group was 4.14 days (S.D. 0.359 days). In the study by Rajeev Shukla et al(12) the mean duration of hospital stay in the plate group was 5.33 days and in the external fixation group was 4.4 days. The duration were comparable between the two groups and their difference was not statistically significant.

The mean no of shots in ORIF with volar locking plate group was 6.05 (S.D.0.740) and in the external fixation group was 3.43 (S.D. 0.507). The difference in mean in no of shots were not statistically significant between the two groups (p-value 0.257). The no of shots in plate group were slightly more than that in external fixation group.

The mean blood loss in ORIF with volar locking plate group was 140.48 ml (SD 40.679ml) while it was 32.86ml (SD 6.036ml) in external fixation group. The values are statistically significant between the two groups (p value <0.001). Blood loss in plate group was much more due to more soft tissue dissection required. There may be minimal internal blood loss too in external fixation group but it is not possible to measure. Other studies have not observed blood loss in their study so our findings could not be compared with them.

In our study, the average Visual Analog Scale (VAS) score for pain in the immediate post-operative period (24 hours after surgery) was 5.68 (S.D. 1.086) in ORIF with volar locking plate group and 3.45 (S.D. 1.335) in external fixation group. The difference between the values was statistically significant (p-value <0.001). The pain profile in the immediate post-operative period in plate group was significantly more than in external fixation group as soft tissue dissection is required during plating. Other studies have not considered VAS scores for post-operative pain, so our findings could not be compared.

Only 2 (9.5%) patients developed postoperative wound infection in the ORIF with volar locking plate group at 2 weeks follow up and was treated with wound debridement and intravenous antibiotics. The infection resolved in the subsequent follow up visit at 6 weeks. 1 patient had pin tract infection in the external fixation group and the remaining 39 patients had healthy surgical wounds at 2 weeks follow up. However, this difference in wound infection rate between the two groups was not statistically significant. In the study by Rizzo M et al(32), two patients developed pin tract infection in external fixation group.

Immediate post-operative radial inclination (p<0.001) was found to be statistically significant in the external fixator group compared with ORIF group however the radial length(p value:0.940) and ulnar variance(p

value 0.705) was comparable and not statistically significant. Hove LM et al(1997)(13) also noticed significant improvement in radial angulation on external fixation. A plausible explanation can be that the longitudinal traction is transmitted mostly through volar radio-carpal ligaments correcting the radial height efficiently. However immediate postoperative articular step off was found to be greater in external fixator group but statistically not significant (p: 0.189). In a study by J.jeudy et al(14) there was no significant difference in the restoration of the articular profile (p value 0.34) which is comparable with our study. Explanation for this finding may be found in one of the drawbacks of external fixation mentioned by Vasenius J that it cannot reduce a depressed lunate fossa.38 Abramo et al(3) further added that this inability to achieve articular congruity in the comminuted intra-articular fractures of the distal radius could be because of external fixation alone does not expand crushed cancellous bone and cannot work without soft tissue hinges.(14)

At 6 weeks follow up both the groups demonstrated loss of radial inclination, radial length and change in ulnar variance. This change however was significant only in external fixation group and not so in ORIF group. There was a not significant increase in articular step off in external fixator group. Loss of reduction in both groups in later follow up radiographs has also been noticed in studies by Abramo A et al(2009) and Gereli A (2010) but not significant, most likely because of augmentation by other methods like k wires or bone grafts in external fixator study groups by these authors(33). Studies have documented that external fixation alone may not be sufficiently rigid to prevent some degree of collapse seen in up to 50% of patients and significant collapse in up to 10% patients. There is usually a gradual loss of initial distraction force through stress relaxation of soft tissues causing partial loss of immediate improvement in radial height, radial inclination and volar tilt by the time of fixator removal.

Oshige T et al had mentioned the secondary displacement with loosening and toggling of the distal screws too be observed frequently with the use of conventional T-plates, particularly in osteopenic bone(17).Lee BP also found similar findings of loss of reduction with the use of T plates and suggested use of bone graft to prevent it25. In our study we did not see further loss in radiological parameters beyond 6 weeks. The radiological parameters like radial inclination, radial length, articular step off and ulnar variance remained statistically non-significant at later follow ups at 6, 12 and 24 weeks comparing external fixation with volar locking plate. In a study done by John H.Wiiliksen et al majority of the radiological values varied insignificantly between the group. However VLP resulted in a statistically significant better ulnar variance (p value 0.004) which is almost comparable with our study(9).

We found that at 6 weeks dorsiflexion, palmar flexion, ulnar deviation and radial deviation at wrist were restricted in external fixator group in comparison to volar plating group. However both the groups show

highly significant improvement in wrist ROM at subsequent follow ups of 12 and 24 weeks and was found comparable to each other. Plausible explanation for this could be that all external fixators used in our study went beyond the joint and were not dynamized. Thus, mobility was started much earlier in the volar plating group, less stiffness was observed in the wrist joint at 6 weeks and better ROM. There was a progressive increase in ROM (wrist flexion-extension and forearm supination-pronation) in both the groups during patient follow up. At 6, 12 and 24 weeks there was a comparable increase in ROM in both the groups due to supervised physiotherapy although at 6 months follow up the ROM in the ORIF with volar locking plate group was slightly more (wrist flexion-extension 147.39 ± 11.95 degrees and forearm supination-pronation 158.04 ± 5.16 degrees) than the external fixation group (wrist flexion-extension 144.56 ± 8.9 degrees and forearm supination-pronation 156.3 ± 5.26 degrees). However, the differences in the values were not statistically significant. In the study by Yetkin H et al41 mean wrist ROM was 149 degree in ORIF with volar locking plate group and 146 degree in external fixation group, the results were similar to our study. So we can conclude that there is no significant difference in terms of ROM in between the two groups.

In our study at 6 months follow up the mean ulnar deviation in ORIF with volar locking plate group was 29.14 degree (SD 2.920 degree) at 24 weeks follow-up while it was 27.24 degree (SD 4.939 degree) in external fixation group. The values are not statistically significant between the two groups (p value = 0.933).In study by Yetkin H et al(41) mean ulnar deviation was 31 degree in plate group and 30 degree in external fixation group which were comparable with our results.

In our study at 6 months follow up the mean radial deviation in ORIF with volar locking plate group was 19.86 degree (SD 3.087 degree) while it was 19.05 degree (SD3.422 degree) in external fixation group. The values are not statistically significant between the two groups (p value =0.713). In study by Yetkin H et al(41) mean radial deviation was 23 degree in plate group and 22 degree in external fixation group which were comparable with our results.

In this study the Green and O'Brien score in ORIF external fixation group was 2.14 (SD 1.49) while it was 3.14 (SD 3.11) in ORIF with volar plating group. The values are not statistically significant between the two groups (p value =0.18). In study by Yetkin H et al41 the score was found to be 1.2 (SD 0.3) in the group that underwent volar locking plate fixation and it was 2.8 (SD 2.1) in the group that underwent external fixation.

In our study among the 42 patients analyzed until 6 months, the outcome in ORIF with volar locking plate was found to be excellent in 17 patients (81.0%) and good in 4 patients (19.0%). In External fixation group it was found to be excellent in 12 patients (57.1%), good in 6 patients (28.6%) and fair in 3 patients (14.3%). The values are not statistically significant between the two groups (p value =0.19). In study by Yetkin H et

al (41) The outcome was found to be excellent in 11 patients (73.3%) and good in 4 patients (26.7%)in plating group. In the group that underwent external fixation, the outcome was found to be excellent in seven patients (46.6%), good in seven patients (46.6%) and moderate in one patient (6.8%). There was no significant difference in the union, both clinical and radiological, in the two groups. The patients of group external fixator (80.9%) and ORIF group (80.9%) showed signs of union by 6 weeks and remaining all patients showed sign of union both clinical and radiological by 12 weeks on subsequent follow-ups.

In this study among the 42 patients analyzed until 6 months, 35 patients did not develop any complications; 19(90.50%) in ORIF with volar locking plate and 16(76.2%) in external fixation group. There was 1(4.8%) cases of CRPS in ORIF group which eventually got better with oral medication and physiotherapy. There was 1(4.8%) case of surgical site infection in the volar locking plate group. There were 2(9.5%) cases of pin tract infection in external fixation group. All of these were superficial pin tract infection which resolved with proper pin tract dressing alone. None of patients had any sign of pin loosening or osteomyelitis. We believe the complications may be due to inadequate instruction and supervision given to patients with regard to pin tract dressing after discharge from ward. There were 3(14.3%) cases of stiffness in external fixation group. Late presentation, late surgery and late mobilization also may lead to post-operative stiffness. Supervised physiotherapy was advised to all patients for stiffness. By 12 weeks stiffness resolved in all patients. Increased stiffness in external fixator group was plausibly due to use of bridging external fixators in our study which were not dynamised leading to no movements at wrist for 6 weeks. Also low attendance and lack of compliance to physiotherapy might be added factor for high rates of stiffness in general. In study by Rizzo M et al(32) there were 2(14.29%) cases of pin tract infection and 1 (7.14%) case of finger stiffness in external fixation group and no complications in plate group. The differences in the incidence of complications were not statistically significant between the two groups (p-value 0.296).

Hence, intra-articular fractures of the distal end radius in adults showed similar results whether fixed with volar locking plate or external fixation. However, the surgeon must be careful for adequate reduction and fixation and prevention of complications. Otherwise, provided the surgeon has adequate expertise, both of the above methods are similar with respect to functional outcome and related complications.

Conclusion

The surgical procedures – ORIF with volar locking plate and external fixation were identical in terms functional outcome, intraoperative parameters and rate of complications. Thus, based on the preference of the operating surgeon either procedure can be safely used for fixation of fractures of intra-articular distal end radius in adults, provided the basic surgical principles are followed strictly.

Limitations and Recommendations

Our study had limitations as it was a study with a small sample size done in a single institution and follow-up was done for a smaller period of time due to which management of complications like stiffness could not be evaluated properly. So a longer duration of study with large no of subjects is recommended for better evaluation and management of complications.

The strength of our study was that follow-up assessment of every patient was done by the same doctor during the entire study period. In addition, even though the surgeries were performed by multiple surgeons, all of the operating surgeon has similar level of competency with adequate no of years of training and experiences. Moreover the basic principles followed by them were almost similar as they all were trained from similar conditions and constraints, though it is natural to have variations in the intraoperative and postoperative parameters.

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