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External versus internal fixation of intra-articular distal radius fractures: a randomised controlled trial

M. GUPTA[1], A. GOYAL[1], R. ROHELA[1], C.P. PAL[2]

[1]Department Of Orthopaedics, Sarojini Naidu Medical College, Agra, Uttar Pradesh, India; [2]Principal, Kannauj Medical College, Kannauj, Uttar Pradesh, India.

Correspondence at: Dr. Mayur Gupta, Department Of Orthopaedics, Sarojini Naidu Medical College, Agra, Uttar Pradesh, India - Email: mayur29.mg@gmail.com

Background: **Aim of the randomised controlled trial was to compare the long-term outcomes following external fixation with wrist distractor and Kirschner wires (EF) with those after internal fixation with volar locking plates (IF) of displaced, intra-articular distal radius fractures in patients 18 to 65 years of age.**

Methods: **Surgery was performed after taking informed written consent following inclusion and randomisation. The primary outcomes were the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) score and Jakim's score, and secondary outcomes included wrist range of motion, grip strength and pain. Linear mixed models were employed to assess and compare the 2 groups.**

Results: **The patients in both groups had comparable mean Quick DASH and Jakim's score, range of motion, and grip strength with no significant differences between the groups at all follow-ups. The overall complication rate was equivalent between the 2 groups, although, the rate of reoperations was higher in the IF group (p=0.03). Implant prominence or impingement was responsible for the IF group result values falling short of normal limb values even on long-term follow-up. While, results of EF group homogenously and successfully achieved normal limb functionality. At 3 years the rate of follow-up was 97%.**

Conclusions: **Biological healing through EF offers more natural anatomical restoration of the distal radius as evident by better long-term scores and statistically significant low reoperations rate. Absence of long-term bone-implant contact in EF group is identified as the sole factor promoting complete functional and clinical recovery.**

Level of Evidence: **Therapeutic Level I.**

Keywords: External fixation, Internal fixation, Distal Radius, Volar locking plate.

INTRODUCTION

Intraarticular fractures of the distal end radius continue to be prevalent clinical scenarios presenting to the emergency room. Depending upon the modes and mechanisms of trauma, a variety of fracture patterns depending upon the line of direction of energy forces causing the injury can occur. The precise treatment of such fractures should be directed towards neutralizing these deforming forces and correcting all misaligned fracture fragments so as to attain congruent articular surface. The key to achievement of superior results is to identify and correct the basic anatomical structure and alignment of the wrist joint. Anatomical congruency of articular reduction is cardinal in prevention of the most common postsurgical complication of wrist joint osteoarthritis in patients who experience this injury. The treatment of intraarticular distal end radius fractures is being emphasised upon since the instigation of internal fixation techniques with volar locking plates having pioneering structural advancements like radial shape contouring and variable angle locking holes[1,2]. This has steered a transposition around the globe from basic methods of external fixation and casting[3,4]. But the slightly higher incidence of complications has put question marks over either's superiority and necessity as the treatment of choice[5,6,7]. Basic technical operative skills required to prevent them and produce better results are required to be investigated, discussed, revised and applied homogenously in all cases.

Abundant studies concluded in the developed and developing countries have shown an advancing practice of internal fixation for intraarticular distal

end radius fractures[8,9]. In order to make evidence-based decisions we require studies that include only intraarticular distal end radius fractures while most randomised clinical studies showing reassuring results of internal fixation included both extraarticular and intraarticular fractures[10]. Contemporary meta-analyses deduce that further explorative investigations are obligatory for interpretation of the best choice of surgical treatment between external and internal fixation. Existing literature lacks sufficient studies identifying long-term results, clinical recovery and safety associated with either surgical treatment in homogenous intraarticular fracture patterns. The aim of this study was to evaluate and compare the patient-reported functional outcomes, clinical and radiological results of external and internal fixation in adults presenting with displaced, intraarticular distal radius fractures. Objectives were to identify variations in long-term results of both treatment groups, identify the associated complications, modifiable causal factors and explore their clinical relevance to find out the optimal treatment option.

MATERIALS AND METHODS

This single center prospective interventional study was conducted at Sarojini Naidu Medical College and Hospital, Agra, a level-I trauma center and tertiary care center with a catchment area population of 23,67,554 (2023).

Ethics

The study was conducted according to the Declaration of Helsinki and approved by the Ethics Committee of Hospital and the local data protection officer. Informed written consent was documented for each patient.

Enrollment

Patients from 18 to 65 years of age presenting to Hospital with an intraarticular distal end radius fracture were analysed for suitability for registration into the study between September 2016 and January 2023. Patients qualifying the following inclusion criteria were queried to get enlisted: an intra-articular fracture of distal end radius (OTA/AO C1 to C3) with either an intraarticular step-off of >2 mm or >10 degrees of dorsal tilt or any volar displacement or dorsal or volar bony comminution or radial shortening of >3 mm. Exclusion criteria included a Gustilo-Anderson type-3 compound fracture, a congenital anomaly, a pathological fracture other than an osteoporotic fracture, alcohol and drug abuse and history of previous or concurrent illness or injury biasing the rehabilitation and evaluation protocol.

Randomisation

We present a comparative clinical study of patients randomly divided in the two groups of external and internal fixation surgery. Patients of distal end radius fractures with intra articular extensions were admitted, investigated radiographically and initially treated with below elbow plaster of Paris slab application so as to control pain and swelling. A CT scan was done in desired patients for better surgical planning. The allocation of fixation surgical method was based on a computer-generated permuted block randomisation. Staff nurse was involved in preparing and drawing a sealed opaque envelope promptly prior to surgery for randomly designating operative procedure either as external or internal fixation surgery. The patients were operated on by the surgeon on call, among 4 senior surgeons or 3 consultants depending on availability. Blinding was not availed of as treating surgeon was involved in patient education, rehabilitation guidance, outcome assessment and fulfilling patient-doctor relationship responsibilities. Lack of blinding was deemed necessary to maximize patient follow-up, limit differential attrition and it might have positive effects on the results.

Surgical Technique

All surgeries were performed under constant supervision of the senior surgeons by surgeons having minimum 5years experience. For both fixation surgeries, operative planning was done and discussed for reaching a judicious consensus about operative techniques and steps to be executed after careful pre-operative clinical assessment of general health and local soft tissue status of the patient.

Common initial operative steps were to view the fracture under traction in C arm machine and perform manual reduction and alignment of the major fracture fragments by using longitudinal traction-countertraction method and carefully manipulating the hand into palmar and ulnar deviation. Fracture was reduced by manually holding the fractured volar and dorsal radial cortices and using gentle hand pressure to align them anatomically. Radial styloid bony fragment is reduced and radial height maintained by placing divergent K-wires from dorsal and volar borders at base of radial styloid, 45 degrees across the fracture into proximal bony cortex of radial shaft along the interosseous border. K wires can be placed wisely from available dorsal rim bony fragment, reduced by ligamentotaxis and skilful dorsal digital pressure applied distally

by the surgeon's opposite hand, passing underneath the present overlying fractured dorsal cortex bony fragments and inserted deep into the lateral or volar surface of proximal radial shaft to prevent postsurgical collapse (Fig. 1). Clinical and surgical experience is availed of while gently creating a path for percutaneous K-wires between tendons and muscle fibres while keeping in mind the course of nearby neurovascular structures. Gradual fingertip pressure is used to reduce the volar cortex and volar ulnar fracture fragment. K-wires can then be judiciously inserted them into the bare volar rim and passed underneath the overlying volar cortex bony fragments to be hinged proximally into the posterior or lateral surface of radial shaft (Fig. 2). Lastly, the distal radioulnar joint is reduced in neutral or supination position of forearm and fixed by passing a K-wire parallel to the medial radiocarpal joint line from distal ulna, through the sigmoid notch into the lateral surface of distal radial cortex.

External fixation group (Wrist Distractor)

To provide sustained ligamentotaxis a spanning bridging external fixator having a distraction unit attached to the connecting rod was applied. Care should be taken to prevent over-distraction of the fracture site while increasing distraction from the attached distraction unit. The fracture ends must be in contact for bony healing to occur (Fig. 3).

Internal fixation group (Distal Radius Volar Locking Plate)

Modified Henry approach to the distal end radius was used to access the fracture. Minimal periosteal

Fig. 1 — Pre-operative X-rays, intra-operative C-arm images showing technique used for initial percutaneous fixation.

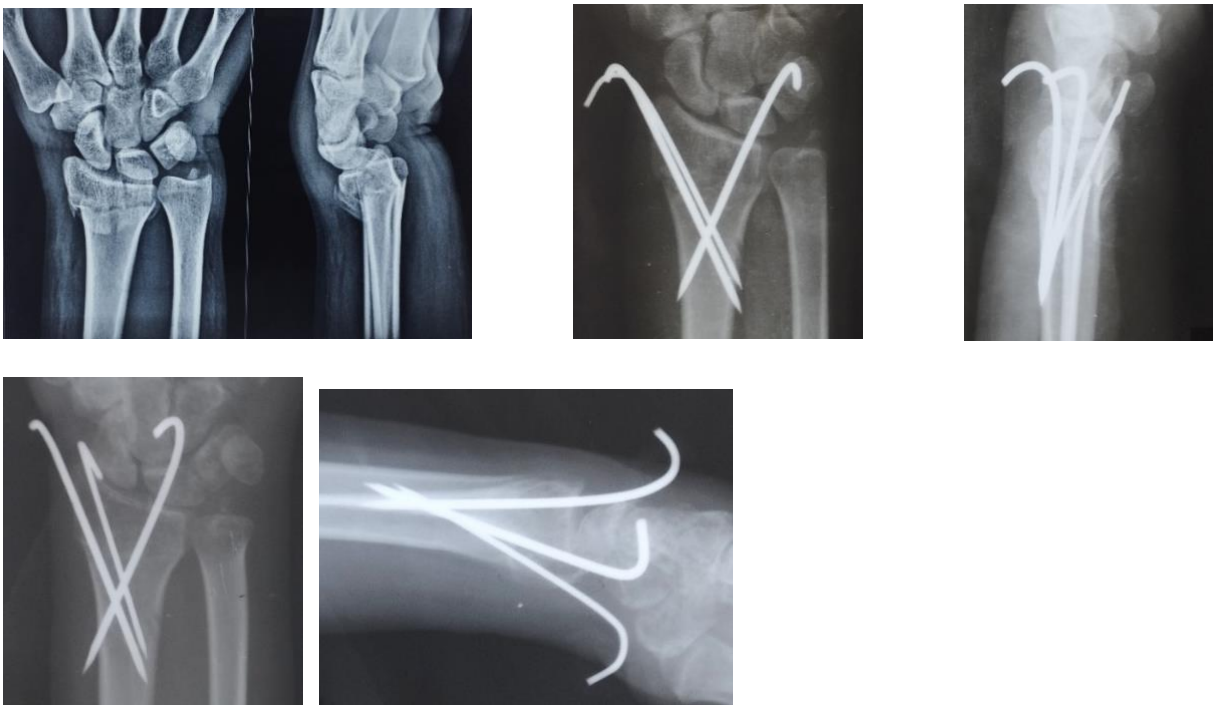


Fig. 2 — Pre-operative, postoperative and 1 month follow-up X-rays showing successful early bony union, when supported by ligamentotaxis, in a patient having volar ulnar fracture fragment fixed percutaneously by K-wire.

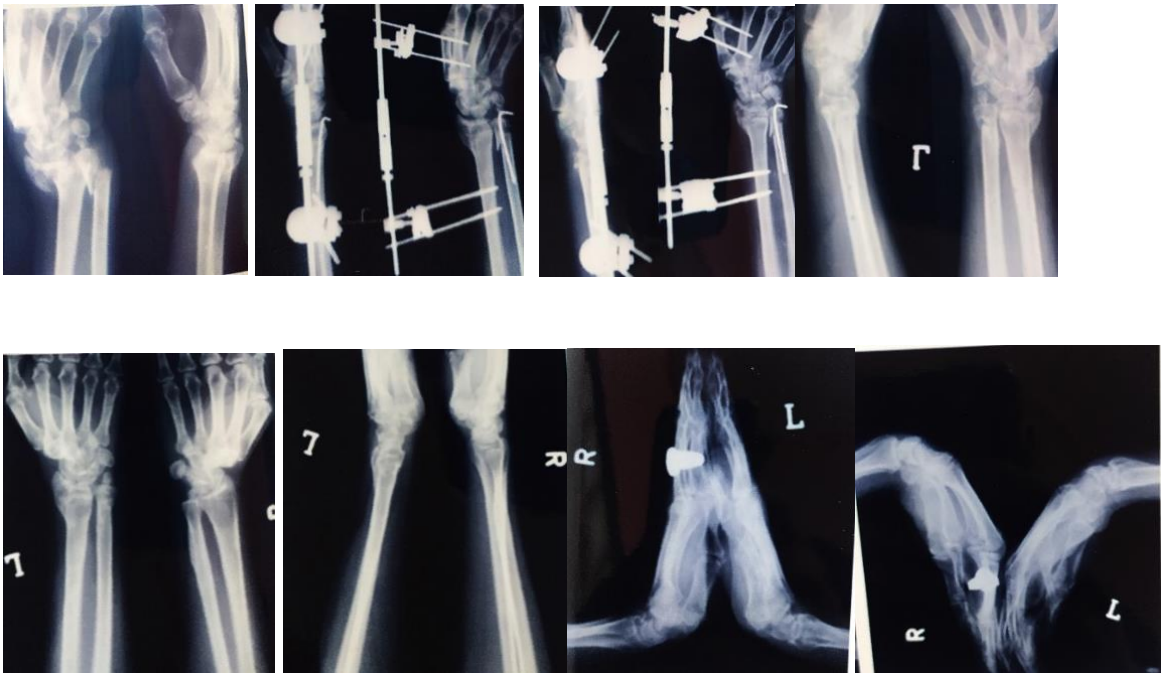


Fig. 3 — Preoperative X-ray, postoperative, 1, 2months follow-up X-rays, 6 months and 3 years follow-up radiographs along in comparison with those of normal limb of a patient in EF group.

stripping was performed and pronator quadratus muscle was gently reflected off the lateral border of radius and retracted using a small Hohmann retractor. The joint capsule was protected and left intact. Now a volar locking plate of appropriate size was placed proximal to the attachment of volar radiocarpal and cortical screw was placed in the shaft near the fracture site so to provide gliding effect and exact buttressing of the distal fracture fragments. Distal locking screws in the plate should be applied only after assessment of the bony stock available capable of providing firm screw hold and directing them superiorly parallel to the wrist joint surface. Care should be taken to avoid placement of screws in fracture lines and placing screws of exact sizes to prevent excessive dorsal cortex penetration (Fig. 4).

Postoperative Care

An above elbow Plaster of Paris slab was applied and kept in an arm pouch for 3 weeks in all patients. Postoperative radiographs were taken and repeated at 4 weeks for visualising fracture union. Patients were further managed with supervised passive and active exercise physiotherapy of the adjoining joints to prevent muscle mass wasting. Fixator was removed after satisfactory clinical and radiological healing of fracture, at an average of 4 to 5 weeks after the surgery as an outpatient procedure. A below elbow plaster slab was given for 1 week for sterile pin-tracts healing. Monitored passive and active wrist mobilization was soon started. In the IF group the patient was advised to move the wrist with a free range of motion after 3 weeks. Patients were advised not to apply any weight for the first 6 weeks. Considering fracture to be healed, after 6 weeks, all patients were instructed to follow a defined written protocol of independent exercises. At 8 weeks light work was allowed. Resistance training and heavy works were allowed after 12 weeks as tolerated by the patient.

Outcomes and Evaluation

In-person patient assessments were conducted at 8 weeks, 12 weeks, 6 months, 1 year, 2 years and 3 years by 2 of the authors. The assessors were not blinded to the group assignment as it could lead to errors in measurements. The primary outcome measures were 1) the abbreviated version of the Disabilities of the Arm, Shoulder and Hand Outcome Measure (QuickDASH)[11,12], with scores ranging from 0, representing an excellent result, to 100, representing the worst possible outcome and 2) Jakim's scoring system, with scores ranging from 100, representing an excellent result, to 0, representing the worst possible outcome[13]. Health-related quality of life was assessed with the EuroQol-5 Dimensions (EQ-5D)[14], which provides an index ranging from 0, indicating the worst possible state of health, to 1, indicating excellent health. Grip strength was measured in kilograms using a handheld dynamometer (Jamar Digital Hand Dynamometer), and range of motion was measured

Fig. 4 — Preoperative x-ray, 3D CT scan, postoperative, 1, 6months and 3 years follow-up radiographs of a patient in IF group showing functional range of motion in clinical pictures.

with a goniometer. Both were compared with the measurement on the uninjured side, providing baseline (preinjury) values. The grip strength on the nondominant side was adjusted down by 10%for right-handed patients[15]. Left-handed patients were assumed to have equal grip strength on the 2 sides[16]. The patients quantified their pain on a visual analogue scale (VAS) ranging from 0 to 10, with 10 being the worst[17]. Major complications were defined as those leading to a reoperation, permanent nerve injury, or a persistently reduced level of function (including complex regional pain syndrome). Minor complications were either transient or did not affect the patient's final level of function.

Sample size was estimated by applying power calculations to illustrate a difference of 10 points between 2 groups on QuickDASH scale having assumed standard deviation of 15 points, 5% maximum risk of type 1 errors and 80% power. It was increased finally from required 72 to total 200 patients in order to

make subgroup analysis feasible and substantiate study power regardless of loss of follow-up and missing data.

Statistical Methods

Baseline and demographic characteristics were described as means and SDs or as frequencies and percentages. Continuous variables were compare using an independent t-test. Chi square test was employed to compare dichotomous variables and the number of complications between groups. To avoid intra-patient correlation present due to repeated measurements for each patient, a linear mixed model with a random slope for the time component and random intercepts for patients grouped according to primary surgeon was estimated for each outcome variable. Each model had fixed effects for the time component up to second order, the group indicator, and the interaction between the time and group indicator. A significant interaction term implies between group differences in time trend. The results were presented as the mean difference and corresponding 95% confidence interval (CI). p values were derived from the Likelihood Ratio Test to know differences in two hierarchically nested models using the Chi square distribution. p values of <0.05 were considered significant. All analyses were based on the intention-to-treat principle. Missing data was reproduced using mean imputation. All statistical analyses were performed with version SPSS 24.0 (IBM).

RESULTS

Total 1054 patients, 18 to 65 years of age, presented with a distal radial fracture during the study period; 387 of them had an OTA/AO type-C fracture. 145 undisplaced fractures were treated either nonoperatively or by percutaneous pinning. Of the 243 patients with a displaced intra-articular fracture, 200 were enrolled in the study (Flow diagram CONSORT)). The mean age of the excluded patients was 52.4years, with a 44%/56% male/female distribution. High energy road traffic accidents were responsible for majority of the cases in both groups. All of the 200 patients, having mean age of 41years, underwent closed reduction and splinting in the emergency room. There were no significant demographic differences between the EF and IF groups, which also had the same baseline mean QuickDASH values, Jakim's score, VAS score, ranges of motion, and grip strength. The subcategories according to the OTA/AO classification system were evenly distributed between the groups (Table I). Patients in the EF group were operated and discharged comparatively earlier than those in the IF group.

The postoperative radiographs were evaluated by a single experienced radiologist. The reduction was deemed satisfactory if the dorsal tilt was <10 degrees, the intra-articular gap or step was <2 mm, and the radial shortening was <3 mm. There was no significant difference ($p = 0.3$) in the percentage of acceptable reductions between the EF group (95 of 100) and the IF group (93 of 100) (Table II). All fractures healed. In 1 case, the healing was uncertain at 5 weeks, so the fixator was kept in place for another 1 week. On average, the patients attended 9 physiotherapy visits in the IF group and 11 in the EF group. At long-term follow-of 3 years, mean volar tilt was 8.1degrees, radial inclination was 19.9degrees and radial length was 10.4mm in EF group patients. The mean difference from contralateral side was nominal and standard deviation showed bell shaped distribution curve in the normal range values. Respective values for IF group were 7.7degrees, 19.7degrees and 10.2mm. Findings of patients in the IF group show similar trends, although they were seen approaching those of EF group. Both intra-articular step and gap had a mean value of 0.1mm in EF group which was relatively lesser than that in IF group (0.2mm).

Clinical Outcome

The average QuickDASH score was marginally better in the IF group than in the EF group at 8 weeks, 12 weeks and 6 months, but at 1 year, 2 years and 3 years the difference was in favour of EF group (Fig. 5). At 3 years the mean difference was 1.8 points in favour of EF. The 2 groups had an equivocal level of pain as measured by VAS at all points of investigation with EF showing lesser values throughout the study (Table III). At 3years the mean difference was 0.1 points in favour of EF (Fig. 6). There was no significant difference in grip strength and range of motion as compared with the uninjured side. (Table IV) Scores were superior to a slight extent in the IF group for the first six months, but at 1, 2 and 3 years the EF group had better scores. Mean values at 3 years have recovered to more than 95% of uninjured side in both groups. Mean flexion was 68.4degrees in EF and 66.8 degrees in IF group. Average grip strength was 31.8 kg in EF and 30.5kg in IF group with a mean difference of 2.5kg (CI -0.5,7.5). All cases operated in both groups had healed healthy wounds at 6 months follow up. To find out the long-term clinical relevance and sustainability of the above results, all patients were followed up and assessed at 36 months postoperative follow up by Jakim's scoring system (for clinical and radiological correlation) which

Table I. — Baseline and Demographic Characteristics in EF and IF groups*

Characteristic	EF(n=97)	IF(n=96)
Age at injury*(year)	42(10.2)	40(12.1)
Male/female (no. [%])	54/43 (56%/44%)	56/40 (58/42%)
OTA/AO fracture type (no. [%])		
C1	25 (26%)	22 (23%)
C2	39 (40%)	38 (40%)
C3	33 (34%)	36 (37%)
Injury in dominant hand (no. [%])	45 (46%)	50 (52%)
Mechanism of injury (no. [%])		
Low-energy trauma	43 (44%)	40 (42%)
High-energy trauma	54 (56%)	56 (58%)
Occupation (no. [%])		
Office work	33 (34%)	38 (40%)
Manual labour	35 (36%)	32 (33%)
Retired	18 (19%)	22 (23%)
Other	11 (11%)	4 (4%)
Closed reduction prior to surgery (no. [%])	97(100%)	96(100%)
Time until surgery* (days)	4.5 (4)	6 (4.7)
Outpatient (no. [%])	62 (64%)	60 (62%)
Inpatient (no. [%])	35 (36%)	36 (38%)
EQ-5D score*	1 (0.1)	1 (0.1)
*The values are given as the mean and SD		

Table II.

	EF(N=97)			IF(N=96)			
Measure	Mean	Mean Difference *	SD	Mean	Mean Difference *	SD	P value
Prior to reduction							
Volar tilt(degrees)	-22	16.8	19.2	-23.9	18.1	16.3	0.2
Radial inclination(degrees)	9.4	5.7	5.5	10.4	4.9	5.1	0.7
Radial length(mm)	3.9	2.4	3.1	4	2.6	3.0	0.9
Intraarticular step(mm)	2.4	1.9	1.3	2.3	1.7	1.1	0.3
Intraarticular gap(mm)	2.8	2.3	1.1	2.7	2.2	1.2	0.05
At 3 years							
Volar tilt(degrees)	8.1	4.2	6.5	7.7	4.7	6.1	0.5
Radial inclination(degrees)	19.9	1.5	4.6	19.7	1.7	4.1	0.4
Radial length(mm)	10.4	1.1	3.1	10.2	1.0	2.8	0.7
Intraarticular step(mm)	0.1	0.2	0.7	0.2	0.2	0.6	0.8
Intraarticular gap(mm)	0.1	0.2	0.5	0.2	0.2	0.6	0.8
* Mean Difference from Contralateral Wrist							

showed excellent results in 174 cases, good results in 16 cases (EF=7, IF=9) and fair results in 3 cases (EF=1, IF=2) according to Jakim's scoring system, with none patient showing poor results. The trend of recovery towards normal limb values was seen to be more closely associated with EF. Clinically relevant differences were noticed in outcome responses, with EF revealing more patient satisfaction over long-term as normality is restored gradually. IF group patients, although gain equivocal functionality, but implant presence causes the patient clinical response to relatively lag behind in the long-term, in the form of mild discomfort reported seldomly during certain activities involving hyperflexion/extension of wrist.

Complications and Additional Procedures

There was no significant difference in the overall complication rate and the occurrence of major complications (Table V). However, a tendency toward more reoperations was clearly seen in the IF group, mostly due to plate removal. The overall complication rate was equivalent between the 2 groups, although, the rate of reoperations was higher in the IF group (p=0.03). Loss of reduction due to

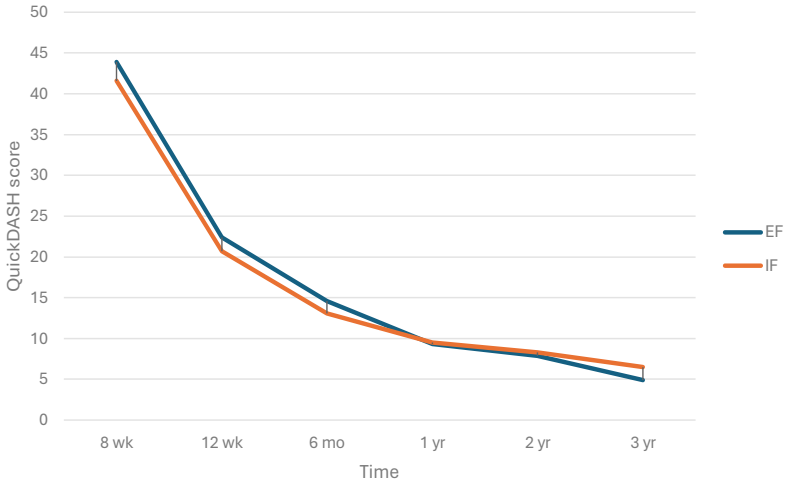


Fig. 5 — QUICKDASH Score.

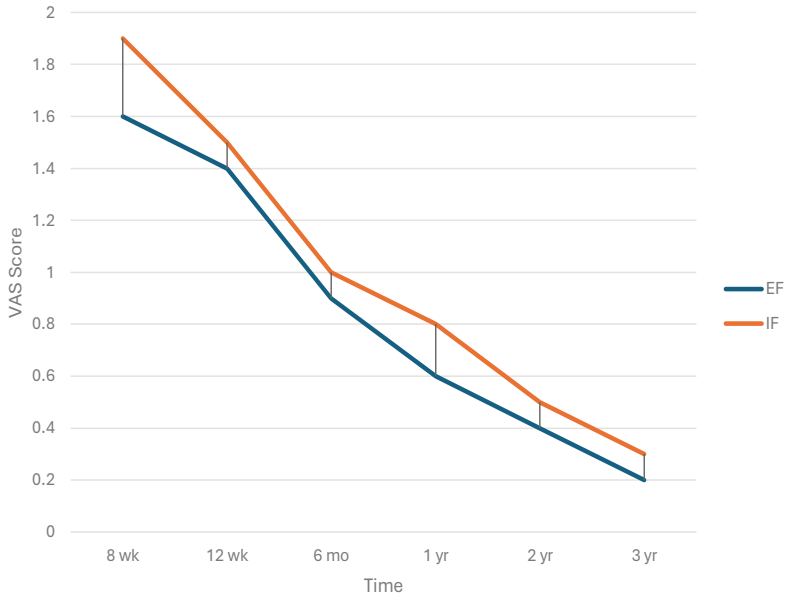


Fig. 6 — VAS Score.

Table III. — Patient-Reported Outcome Measures at 6months and 3years Follow-up Evaluations in EF and IF Groups.

	Mean(SD)			
	EF(N=97)	IF(N=96)	Mean Difference (95% CI)	p Value
QuickDASH score				
Pre-injury	2.2(6.7)	1.9(6.2)		
6 months	14.6(12.8)	13.1(14.3)	1.8(-0.2,2.4)	0.5
3 years	4.9(8.3)	6.5(9.7)	-1.8(-2.5,0.1)	0.3
VAS Score				
6 months	0.9(1.3)	1(1.4)	-0.1(-0.3,0.4)	0.4
3 years	0.2(1)	0.3(1)	-0.1(-0.4,0.3)	0.2

*The mean difference with the 95% CI and p value were estimated by a linear mixed model adjusting for intra-patient correlations. The mean difference is for EF relative to IF.

Table IV. — Functional Outcomes at 6month and 3years Follow-up Evaluations in EF and IF group.

	EF (N=97)		IF (N=96)			
	Mean (SD)	% of Uninjured Wrist	Mean (SD)	% of Uninjured Wrist	Mean Difference (95% CI)*	p value
6 Months						
Range of motion (degree)						
Flexion	52.2(8.6)	76	53.1(9.8)	78	-1.6(-2.8,1.1)	0.9
Extension	57.8(8.8)	79	59.7(9.6)	82	-1.4(-2.6,0.8)	0.9
Pronation	81.7(7.3)	92	83.1(8.5)	93	-1.3(-2.1,0.4)	0.9
Supination	77.7(13.1)	89	80.5(8.8)	92	-2.2(-5.3,0.8)	0.4
Grip Strength (kg)	24.4(8.1)	76	26.5(7.3)	83	-1.8(-3.8,0.7)	0.3
3 Years						
Range of motion (degree)						
Flexion	68.4(7.2)	97	66.8(8.1)	95	1.3(-2.2,6.8)	0.4
Extension	71.7(9.9)	99	70.3(10.1)	97	1.5(-1.8,5.7)	0.3
Pronation	88.9(8.7)	99	87.3(5.6)	98	1.9(-3.8,5.1)	0.4
Supination	88.7(5.9)	100	87.7(6.7)	99	2.2(-0.8,6.4)	0.5
Grip Strength (kg)	31.8(11.2)	99	30.5(8.8)	95	2.5(-0.5,7.5)	0.1

Table V. — Registered Complications during 3-Year Follow-up in EF and IF Groups.

	EF(N=97)		IF(N=96)		p-value
	No	%	No	%	
Major complications*					
Suboptimal osteosynthesis leading to secondary surgery	2	2	3	3	0.1
Complex regional pain syndrome	6	6	4	4	0.3
Carpal tunnel syndrome	1	1	2	2	0.5
Ulnar neuropathy	0	-	1	1	-
Prolonged pain in wrist/hand	1	1	7	7	0.1
Total	9	9	17	17	0.1
Minor complications					
Transient nerve dysfunction	4	4	6	6	0.5
Loosening of EF	1	1	0	-	-
Superficial wound/pin-tract/operative site infection	4	4	5	5	0.1
Minor stiffness of wrist and fingers	5	5	3	3	0.6
Trigger finger	0	-	2	2	-
Dupuytren contracture	1	1	2	2	0.6
Ganglion	1	1	3	3	0.8
Scar adhesions	2	2	3	3	0.7
Total	18	18	24	24	0.1
All (major and minor) complications	27	27	41	41	0.1
Secondary surgery					
Minor scar corrections with local anesthesia	1	1	2	2	0.2
Peripheral nerve decompression (median and ulnar)	0	-	2	2	-
Plate removal	0	-	7	7	-
Secondary osteosynthesis	2	2	3	3	0.1
All (minor and major) secondary surgery/reoperations	3	3	14	14	0.03

intraoperative errors, postsurgical fracture collapse due to osteoporosis, misplacement of implant or loss of plate screws hold were the main modifiable causal factors among the cases receiving secondary surgeries. Implant prominence or impingement was responsible for the IF group result values falling short of normal limb values even on long-term follow-up. While, results of EF group homogenously and successfully achieved normal limb functionality. Intermediate pain because of the implant material volume inside the distal forearm creating soft tissue tensioning during certain works was the most common factor causing implant removal, postsurgical disappearance of which resulted in swift pain free recovery. Although

the EF group showed a higher frequency of complex regional pain syndrome and the IF group had a higher frequency of suboptimal placement and hold of implants, the differences were not significant. There were 3 crossovers from the IF group due to insufficient fracture reduction and wound complications. The patients underwent EF 10 days later and went on to have a good functional result. 2 crossovers were also present from EF group due excessive bone comminution, fragmentation or loss. The patients were subjected to IF with iliac bone grafting and had good clinically functional union. Pin-site local infection was treated by sterile dressing and a short course of oral antibiotics. Proper patient training and education regarding pin tract dressing and personal hygiene at regular follow up visits resulted in low infection rates. Wrist and finger stiffness significantly improved after physiotherapy involving resistance exercises. At 3 years follow-up all observations matched with the normal limb findings in 90% patients.

DISCUSSION

The main finding of this study was that the QuickDASH and Jakim's scores did not differ between the 2 groups at all follow-ups, albeit the IF group had better scores throughout the first six months and EF had higher scores at longer 1,2,3 years follow-ups. Both treatment options efficiently provide comparably successful outcomes in the present set of patients having homogenous fracture patterns. Correspondence with majority of the findings of same design randomised controlled trials conducted around the globe in the last decade provides further support to present research results[9,18-21].

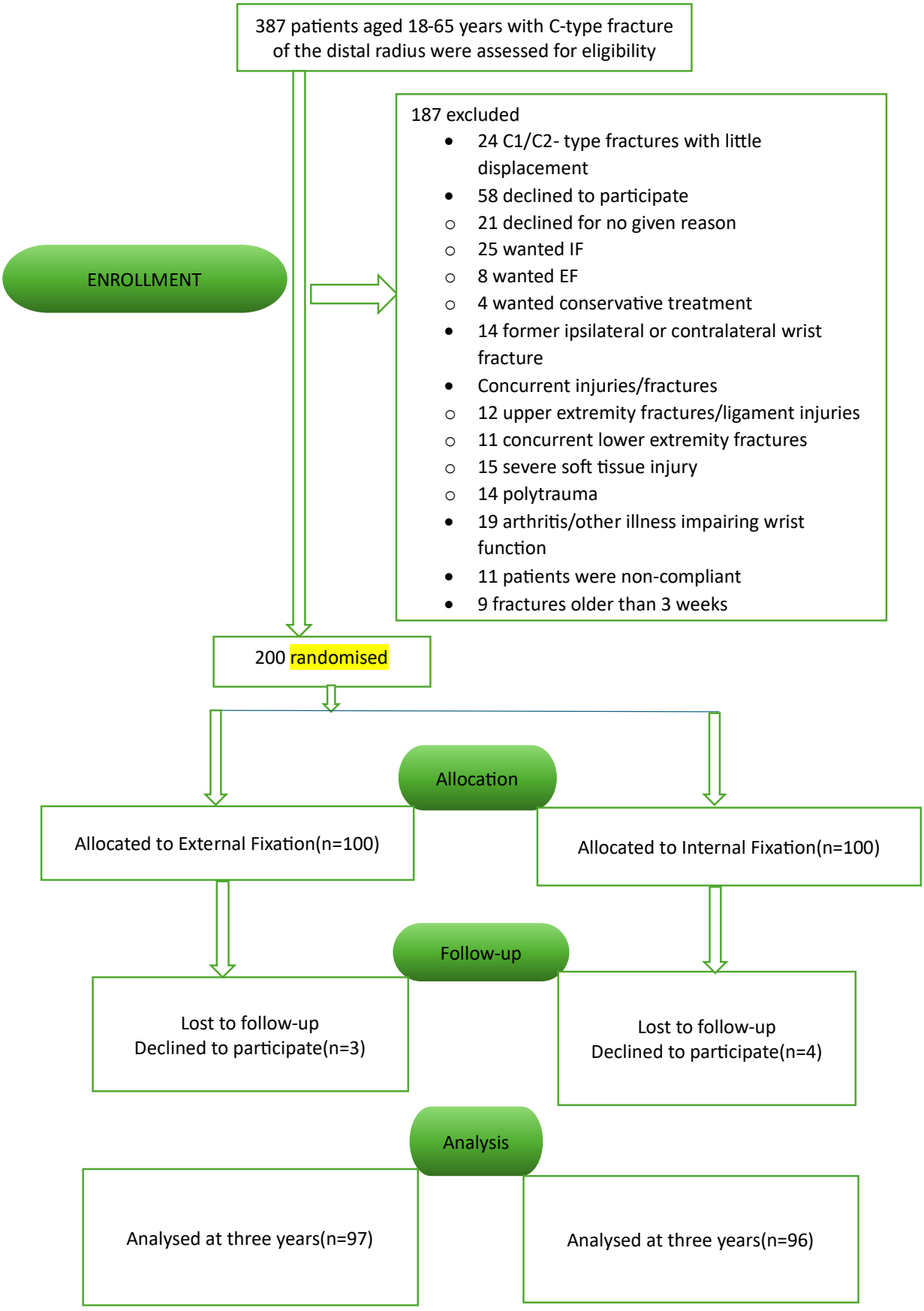
Achievement of pre-injury level range of motion at the wrist joint postoperatively is the major clinical factor that modifies the functional outcome of the patient. It is arduous to discern the clinically pertinent difference in degrees of range of motion that effects the final functional outcome. Each difference was <5 degrees in present research at 3 years follow-up. Yet curtailment of a few degrees in all 3 planes when added may cause impairing loss of range of motion. Hence, it is noteworthy that the final range of motion remained diminished to varying extents in both surgical groups in comparison with normal side even at 3 years. This insignificant decrease in range of motion has minimal effect on functional recovery. Since the study subjects sustained high energy intraarticular comminuted and fragmented fractures, the above finding probably indicates wrist joint cartilage damage, posttraumatic arthritis, soft tissue injury contracture, scar or capsular adhesions. In Quick-DASH scores, the minimal clinically important difference ranges between 8-17 points[22]. We found analogous QuickDASH and Jakim's score in both groups during all follow-ups, with both groups showing approaching scores and positive correlation between functional, clinical and radiological outcomes. Marginal gains in EF group scores were seen in longer follow-ups of 1 year and above.

Evidence of refinement in clinical and functional results of IF group sustaining for not less than 2 years are substantiated by our current results[23,24]. Both extra-articular and intra-articular fractures of the distal end radius were covered in these trials. Conceivably, intraarticular fractures have worse prognosis than extraarticular fractures because of association with higher energy traumatic forces causing the injury and direct joint cartilage damage. This seems to be the basic causative factor for rapid clinical and functional benefits provided by IF lasting for a shorter period, culminating in a comparatively slower recovery pace and not completely reaching pre-injury status in our trial of intra-articular fractures. Even the achieved range of motion persisted just beneath the normal limit at 3 years regardless of the surgical intervention done. No significant difference in pain (VAS) existed between EF and IF groups at any follow-up. We found a tendency toward more cases of complex regional pain syndrome in the EF group (6 versus 4). Past trials have found a high complication rate of complex regional pain syndrome associated with EF25, percase owning to fracture site over-distraction[26,27]. Judicious employment of Kirschner wires for achieving and maintaining reduction as an alternative to over-distraction, adequate postoperative Vitamin C supplementation and complete upper limb regular physiotherapy in current research appears to have diminished the rate of development of complex regional pain syndrome after EF.

The radiographic evaluation in the current study did not demonstrate the failure of EF to maintain radial length to the same extent as IF, a finding that is corroborated by other researchers[9,18-20]. This is also valid with respect to radial inclination (Fig 7). Rates of complications are equal or smaller in comparison to other trials[18]. There were 10 major reoperations (7 for plate removal) in the VLP group compared with 2 in the EF group, with the difference being clinically significant. Past studies have shown rates of plate removal up to 21% due to intraoperative mistakes and two times higher chance of second surgery after IF[29].

Fig. 7 — Preoperative X-ray, 3D CT scan, postoperative, 1 and 2months follow-up X-rays of a complex C3 type fracture pattern patient in EF group showing clinical bony union with well maintenance of radial height and inclination.

CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



In contrast, in our study, only 7% patients underwent plate removal after consolidated bony union, all following intermediate pain during activity due to implant prominence.

Clinically relevant surgical learnings deduced from study manifest that distal radius fractures need careful manual manipulation by surgeon's thumb on dorsal aspect and to compress the bony fragments together anatomically, thereby, preventing any sharp impingement of bony fracture ends on surrounding soft tissue cover. The dorsal plate placement is not clinically feasible to apply in most of the cases due to scarcity of soft tissue cover over dorsal distal end radius surface that produces continuous friction between plate and the overlying tendons causing patient discomfort during range of motion exercises. This restoration of the original bony form should never be done at the cost of the covering soft tissues. Biological fixation of the fracture should be the top most aim of surgery so as to attain good biological union and functionality post-surgery. Soft tissue cover and bony blood supply is essential in attaining pre injury level functional status in treatment of this complex fracture. Patients having grossly unstable and multiple fracture fragments that require buttressing by a plate application are reduced beforehand using manual anatomical contouring and provisional percutaneous K wire fixation techniques. Plate is used to wall the cancellous bony comminution present over the distal end radius so that they remain in anatomical alignment and osteoinduction can occur. Adjuvant percutaneous K wiring of the dorsal fracture fragments prevent postsurgical collapse and misalignment. Preserved biological soft tissue cover over the relatively superficial dorsal surface of distal end radius enhances fracture union rates by providing a close osteoconductive environment for secondary fracture healing by callus formation of the multiple comminuted bony fragments present.

IF offers rewarding results in cases having multiple fracture lines extending from the articular surface of wrist joint to proximally deeper into the radius shaft. Cases having multiple fracture lines confined only to the extreme distal end of radius and its articular surfaces fail to attain stability by internal fixation because of unavailability of distal screws bony purchase in the extremely comminuted cancellous bone present. These fractures are variants of distal radial epiphyseal injuries seen in the paediatric population. Treatment is similar for such fracture patterns and includes manual reduction by careful ligamentotaxis and percutaneous fixation by thin smooth K wires used wisely in a divergent fashion. K-wire is inserted from inner articular rim of reduced intraarticular fracture fragment and gradually advanced into the proximal radial shaft. Transverse K-wires placed beneath the joint surface from lateral surface to sigmoid notch provide a platform for articular bony fragments to rest upon. Few cases may require minimum open reduction for accurate intraarticular reduction. A wrist distractor is applied in patients having grossly unstable fracture cases so as to secure and maintain radial height, angle, tilt and provide sustained anatomical soft tissue tension for veritable healing process. Correct alignment of fracture reduction leads to swift secondary cancellous bone healing. Maintenance of biological integrity of such close complex fracture patterns is essential for restoration of original primary anatomy. Wrist distractor may not be adequate to maintain articular congruity in intra-articular wrist fractures, but additional Kirschner wire fixation enhances EF and offers stability that approaches that of IF[25,26,30]. As both methods yielded similar functional and radiographic results at 3 years, the clinical outcome response, patient satisfaction ratio and risk of associated complications/reoperations should be considered when choosing the method of treatment. Current study performed to find out the optimal surgical option for treatment of intraarticular distal radius fractures, prefers EF over IF.

IF should be delicate to the surrounding soft tissue biology and initially minimally open indirect reduction is preferred under fluoroscopic guidance using thin blunt K wire or small artery forceps tip in case-based decision making. Once reduction is achieved percutaneous K wiring is used to fix and secure it. Thereafter, intraoperative assessment of reduction adequacy and stability is performed by taking anteroposterior, lateral and oblique fluoroscopic views. If articular congruency is present a wrist distractor is applied to sustain the fracture reduction. If articular reduction is grossly unstable than a buttressing plate is applied to achieve articular congruency by open reduction and internal rigid fixation. All anatomical structures cut during surgery are scrupulously repaired. Primary healing of the fracture ends relies on the intact vascularity of the fractured bone and covering soft tissues.

Employment of randomised controlled design while dividing patients having homogenous fracture patterns into surgical treatment groups, managing complexity of such high-grade injuries through similar surgical techniques and ensuring strict adherence to rehabilitation protocol allowed us to evaluate, compare and find that successful normal

recovery is possible in majority of patients of both EF and IF groups. However, the rate of reoperations in IF group is significantly higher in comparison to EF group. This significant difference between groups can translate into major clinical problems if precise surgical techniques are not availed of intraoperatively. Higher attention and efforts are needed to attain desirable initial percutaneous reduction and fixation during surgery and convert it into nonrigid stable/ rigid fixation, without increasing operative time, surgical exposure, bony vascular damage and patient morbidity. The study clearly achieved its primary objective of finding the optimal treatment option as EF for homogenous intraarticular distal radius fracture patterns. The simplicity, safety, augmentation capacity, cost-effectiveness and short-term application time are advantages of adopting this method. Long-term results of patients in EF group comfortably reaching normal limb values were consistent novel clinically significant findings of study. It is of utmost clinical relevance in the light of the fact that associated long-term complications are nominal, patient outcome response and satisfaction are rewarding to the extent of normally attaining sustainable pre-injury status.

This study has limitations as blinding was not done and response bias may occur. It was conducted at a single center by a relatively small team of surgeons over a long duration of time. Occurrence of COVID-19 pandemic during the study period did not affect the outcomes significantly due to regular patient monitoring through virtual clinics and telemedicine. There was a wide age span, and it is likely that some elderly patients were osteopenic and some younger patients had higher-energy trauma with additional soft-tissue injuries that may cause biasing. The postoperative rehabilitation protocol differed between the groups and is a cause of potential bias. However, it is insignificant in the long-term evaluation. The major strengths of the study are the relatively large sample with similar baseline demography, randomised control trial design, low number of patients lost to follow-up as well as the uniform type of fractures included. Power study done using functional means showed a sample size of 844 patients in order to get significant differences. Current study is planned to be extended in future to increase the sensitivity.

Future research is recommended to testify validity, reproducibility and increase generalisability of result findings in multicenter studies having different patient populations to ascertain the effects of demographical, socioeconomic and surgeon-hospital related factors on patient outcome measures. Studies with larger sample sizes and prolonged follow-up might show functional differences between the 2 methods in rates of development of osteoarthritis and other late complications with advancing age.

In conclusion, current randomised controlled study shows that both EF and IF provide predictable good outcomes when used to treat displaced intraarticular distal radius fractures. Both procedures have a variable span of complications. Biological healing through EF offers more natural anatomical restoration of the distal radius as evident by better long-term scores and lesser reoperations rate. Absence of long-term bone-implant contact in EF group is identified as the sole factor promoting complete functional and clinical recovery. Prolonged follow-up of a much larger sample can increase the sensitivity in future studies.

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