e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(7); 1568-1574

Original Research Article

Comparative Study of Functional Outcome of External Fixation and Volar Plating in Unstable Distal Radius Fractures

Bimlendu Kumar[1], Mahesh Prasad[2], Rajeev Anand[3]

[1]Senior Resident, Department of Orthopaedics, Patna Medical College & Hospital, Patna, Bihar.
[2]Associate Professor, Department of Orthopaedics, Patna Medical College & Hospital, Patna, Bihar.
[3]Associate Professor, Department of Orthopaedics, Patna Medical College & Hospital, Patna, Bihar.

Received: 20-05-2023 / Revised: 21-06-2023 / Accepted: 25-07-2023
Corresponding author: Dr. Rajeev Anand
Conflict of interest: Nil

Abstract:

Background: One of the most frequent injuries seen in the emergency room is a distal radius fracture. In order to restore wrist function, it is essential to repair the anatomy as much as possible. Predicting the success of treatment depends heavily on determining if a fracture is "unstable." In this study, the functional outcome following surgery is compared between external fixation and volar plating, two main treatment techniques. The study's objective was to evaluate the recovery of grip strength and range of motion after fixing unstable distal radius fractures with external fixation versus volar plating using the Disabilities of the Arm, Shoulder, and Hand (DASH) scoring system. Hospital-based; randomized control trial settings and design.

Methods: Randomly divided into two groups of 40 each, 80 patients with unstable distal radius fractures underwent surgery. External fixation was given to one group, and open reduction with volar plate fixation was given to the other. Following surgery, DASH ratings were acquired and compared at predetermined intervals.

Results: According to our study findings, the volar plating group improved its mean DASH scores more than the external fixation group did at 3, 6, and 12 months.

Conclusions: With higher postoperative wrist motion and a reduced incidence of comorbidities, volar plating has a superior functional outcome overall thanks to its undeniable advantage of direct fracture imaging.

Keywords: Unstable, Distal radius fractures, External fixation, Volar plating, Functional outcome, DASH score.

Introduction

14% of all injuries to the extremities and 20% of all fractures treated in the emergency room are distal radius fractures.[1] They are brought on by high or low energy trauma that results in severe damage and impairment of upper extremity function. If appropriate articular surface reconstruction is not performed, intra-articular distal radius fractures are more likely to have an unsatisfactory functional outcome and develop early degenerative alterations. Thus, the focus has moved to restoring the anatomy as much as possible without sacrificing function.

Distal radial fractures are widely categorized as (a) articular versus non-articular, (b) reducible versus irreducible, and (c) stable versus unstable depending on their alignment and stability.

The incapacity to withstand displacement following an anatomical reduction may be referred to as fracture stability. Fractures that are irreducible or unstable require surgical stabilization. The presence of three or more of the following risk factors indicates a high likelihood of fracture collapse, according to Lafontaine et al.: (a) dorsal angulation greater than 200; (b) dorsal comminution; (c) intra-articular involvement; (d) associated fracture of the ulna; and (e) age over 60 years.[2]

Restoration of articular congruity, axial compression of >2 mm, dorsal angulation of >150, concomitant intra-carpal lesions, and intra-articular step-off of >1 mm are additional factors of utmost significance in predicting the development of post-traumatic osteo-arthritis.[3-6]

In unstable distal radius fractures, where maintenance of anatomic reduction is a primary requirement, there are several therapeutic approaches available to combat the loss of reduction. These include open reduction and internal fixation (ORIF), external skeletal fixation, and percutaneous pinning with casting. We have restricted our investigation to the treatment of extra-articular or minimally articular unstable distal radius fractures with either volar plating or external fixation. If a fracture dislocated following first treatment with closed reduction and splinting or if three or more of Lafontaine's criteria were met, the fracture was considered unstable.[7]

The treatment of unstable extra-articular and certain intra-articular distal radius fractures has traditionally included external skeletal fixation, either with or without the use of K wires. It reduces and restores articular congruity using the 'ligamentotaxis' approach. Numerous studies have confirmed its efficacy as a therapy method, with positive outcomes from its application. [8-12]

For unstable extra-articular fractures, open reduction and internal fixation with volar locking plates is the most popular form of therapy. By functioning as a single unit, the fixed angle locking device gives the fracture site more stiffness, preventing early collapse and malunion. Numerous investigations on the use of these plates have demonstrated successful union and low complication rates.[7,13-16]

Material and Methods

A randomized control, parallel group trial was undertaken as part of the investigation from January 2018 to December 2018 in the orthopaedics department of Patna Medical College and Hospital, Patna, Bihar. Patients needed to meet the following criteria in order to be included: (a) unstable distal radius fractures, as defined by Lafontaine et al.[2]; (b) extra-articular and simple articular fractures, as defined by the Orthopaedic Trauma Association (AO/OTA) types A2, A3, B1, and C1; and (c) age between 18 and 60 years. Patients with pathological fractures of the distal radius caused by primary tumor or bony metastasis, associated co-morbid conditions like uncontrolled diabetes mellitus, altered consciousness, immunocompromised states, and associated vascular injuries around the wrist were excluded from the study. Patients with open fractures of the distal radius, associated fractures of the distal ulna, distal radio-ulnar joint (DRUJ), and carpal bones were also excluded. The study's calculated sample size for external fixation and volar plating was 40 each based on a review of prior literature.[7] Treatment allocation was carried out using sealed, blank, numbered envelopes. Prior to surgery, the patients were informed of the chosen treatment option. The trial was only partially blinded due to the intervention's visible nature and lingering scars. All patients had a thorough history-taking and physical examination. At the time of presentation, standard radiographs (AP and lateral views) were taken, and fractures were categorized in accordance with the AO/OTA classification. Closed reduction and splinting were first used to treat all displaced fractures. On post-reduction radiographs, radiological characteristics such radial height, inclination, ulnar variance, and volar tilt were measured. Patients were reevaluated at one week to ensure that the reduction had been maintained both clinically and radiologically. If the reduction was lost or the fracture met Lafontaine's criterion for instability, surgery was required.[2] Patients were assigned to one of two groups, A or B, after randomization.

In Group A, we performed bridging external fixation with either the modular external fixator for distal radius or the universal mini external fixator system (UMEX) frame, with or without additional K wires. For the distal radius in group B, we used 3.5 mm titanium locking compression plates (LCP) to accomplish an open reduction internal fixation.

A preliminary reduction was carried out for the purpose of gross alignment of fracture fragments while the patient was supine, the injured arm propped up on a side table, and the fluoroscopic image intensifier was in place. In order to protect the superficial branch of the radial nerve (SBRN), which has an unpredictable course and is vulnerable to damage from a blind procedure, a 2 cm longitudinal incision was made at the level of the mid radial shaft about 10 cm proximal to the radial styloid and a minimum of 3 cm from the most proximal fracture line. Utilizing the space between the extensor carpi radialis brevis and longus muscles, the fixator was positioned in an oblique plane with respect to the forearm's horizontal plane. Two 4 mm Schanz pins were manually placed following soft tissue retraction across two cortices of the shaft that were parallel to one another. Over the second metacarpal, distal to the flare of the metacarpal base, a 1.5 cm longitudinal incision was made in the oblique plane. The first dorsal interosseous muscle and extensor tendon were reflected, exposing the metacarpal shaft. Two 3 mm Schanz pegs were bored across two cortices at an angle of 30^0 to 40^0 with the horizontal plane while the metacarpophalangeal joint was flexed. Fluoroscopy was used to check that all pins had bi-cortical purchases. Following a loose application of the external fixator frame to the pins, Agee's maneuver—a combination of longitudinal traction, ulnar deviation, and dorsal or volar translation of the carpus relative to the shaft of the radius—was used to reduce the size of the pins.[17,18] To obtain the radial length and inclination, pressure was applied over the radial styloid. In order to avoid the necessity for excessive positioning and to prevent secondary displacement, additional K wires were occasionally utilized to secure specific fracture fragments directly. To make sure that the carpus wasn't overly distracted, the radio-carpal joint's distraction was assessed, and the traction was modified. The K-wire pins were bent, clipped, and left outside of the skin for later, simple removal. The K wires were usually removed at 4 weeks and the fixator at 6 weeks.

A tourniquet was placed over the upper arm and inflated to 240 mm Hg while the patient was lying on his or her back with the arm extended on the hand table. Between the radial artery and FCR tendon, a modified Henry's technique was employed. By cutting the sheath, the FCR tendon was made mobile and retracted in an ulnar direction. Flexor pollicis longus (FPL) and the median nerve were both dissected bluntly after an incision was created in the tendon sheath's floor to expose them.

The pronator quadratus' transverse muscle fibers were then released by making an inverted "L" incision over the muscle, which was subsequently elevated subperiosteally from the radius in a volar orientation. The helper reduced the patient by applying longitudinal tension to the fingers and volar wrist flexion. A narrow periosteal elevator was used to identify, disimpact, and lift each fragment into place. The plate was applied to the flat palmar surface of the distal radius and was temporarily secured with one screw in the plate's oblong hole. It was carefully avoided to position the plate too far from the watershed boundary. After being finalized under fluoroscopic direction, the plate was fastened using locking head screws, which offer a fixed angle build that is substantially stiffer. To avoid fibrosis and mobility restriction, the pronator quadratus was not routinely closed.

Following surgery, passive ranges of motion (ROM) exercises for the fingers, elbow, forearm, and shoulder were started immediately for both groups. Beginning with strengthening exercises at two months, wrist physiotherapy was started at six weeks.

SPSS (Statistical Package for Social Sciences) version 20.0 was used for data analysis. The cutoff for significance was <0.05. Utilizing the intention to treat principle, all analyses were conducted.

Results

There were no discernible variations between the two groups in terms of the mean age (in years), sex distribution, dominant side (handedness), or affected side.

Between the two groups, there was a significant difference in the mean DASH scores at 3 months ($p \leq 0.001$), 6 months ($p \leq 0.001$), and 12 months ($p \leq 0.001$), with the volar plating group scoring higher.

At 6 months ($p <0.001$) and 12 months ($p <0.001$), the volar plating groups percentage of grip strength recovery was higher. At 6 months ($p <0.001$) and 12 months ($p <0.001$), there was a significant difference in the mean dorsiflexion and volar flexion between the two groups. At 3 months, there was a significant difference in mean radial deviation between the groups ($p<0.001$), but at 6 and 12 months, the differences were not significant. At 3 and 6 months, but not at 12 months, there was a statistically significant difference in the mean ulnar deviation between the groups ($p<0.001$). At 3 months, but not at 6 or 12 months, there was a significant difference between the mean pronation and supination ($p<0.001$). At 3 and 6 months, there was a substantial difference between VAS scores, but not at 12 months. The proportion of problems in the two groups, however, did not significantly differ.

Table 1: Demographic characteristics

	External Fixation (n=40) Mean(SD)	Volar plating (n=40) Mean(SD)	Total	p-value
Age (years)	38.35 (11.79)	36.95 (10.23)	80	0.572
Sex				
Male	32	31	63	0.999
Female	8	9	17	
Dominant Hand				
Left	5	11	16	0.162
Right	35	29	64	
Affected side				
Left	13	22	35	0.071
Right	27	18	45	

Table 2: The disabilities of arm, shoulder and head score (DASH)

	External Fixation (n=40)		Volar plating (n=40)		p-value	Favouring
	Mean	SD	Mean	SD		
Baseline	75.68	5.09	74.85	4.26	0.434	
3 months	23.90	4.28	16.30	3.35	<0.001	Volar plating
6 months	12.48	2.47	6.98	2.52	<0.001	Volar plating
12 months	4.40	2.09	1.00	1.75	<0.001	Volar plating

Table 3 : Recovery of mean grip strength at 3, 6 and 12 months

Grip strength	External Fixation (n=40)		Volar plating (n=40)		p-value	Favouring
	Mean	SD	Mean	SD		
3 months	49.53	6.99	70.03	2.95	0.434	
6 months	73.40	5.61	87.93	4.07	<0.001	Volar plating
12 months	88.70	3.62	94.05	1.92	<0.001	Volar plating

Table 4 : Pain score assessment on Visual Analogue Scale (VAS)

VAS	External Fixation (n=40)			Volar plating (n=40)			p-value
	Min.	Max.	Median	Min.	Max.	Median	
3 months	2	5	4	1	3	2	<0.001
6 months	0	2	2	0	1	0	<0.001
12 months	0	0	0	0	0	0	-

Table 5 : Post-operative complications in both groups

Complication	External Fixation	Volar plating	Total
Stiffness	3	2	5
Superficial pintract infection	3	0	3
Surgical site infection	0	2	2
CRPS	1	0	1
Extensor tendon irritation	0	1	1
Loss of reduction	1	0	1

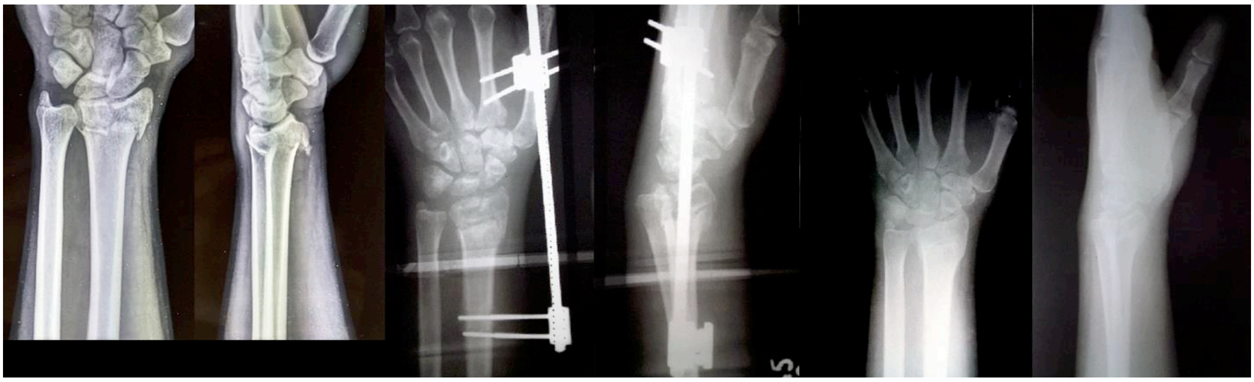

Figure 1: Pre OP, immediate post OP and 6 months post OP X-rays-external fixation

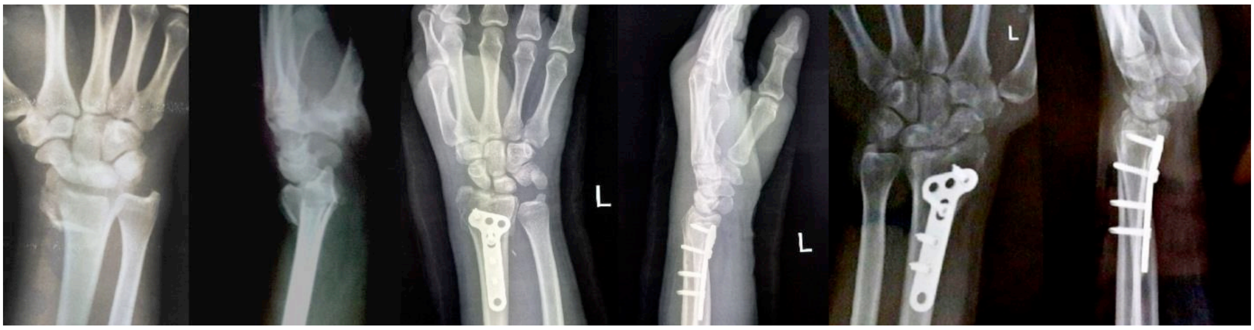

Figure 2: Pre OP, immediate post OP and 6 months post OP X-rays–volar plating

Discussion

Currently, unstable distal radius fractures are treated using bridging external fixation, open reduction, and volar plating. Both systems have a number of pros and cons. By utilizing the ligamentotaxis concept, external fixation is a relatively simple yet successful method of obtaining length and retaining the reduction in the appropriate position. By transmitting the forces of distraction to the bony fragments through the intact joint capsule and ligaments, the reduction is maintained, and a late collapse of the fracture pieces is avoided. Supplemental K wires improve the construct's stability and stop the fracture fragments from being displaced again. The treatment can't immediately decrease and align the intra-articular fragments, which prevents it from being used in complex intra-articular fractures. Additionally, it is inefficient in achieving and sustaining the decrease in Barton fractures, which are shear fractures affecting the dorsal or volar rim. Infections at the pin site, superficial radial nerve neuropathy, over-distraction causing finger pain and stiffness, and arthritic changes in the radio-carpal joint are complications of this operation.[24] Direct visualization of fracture fragments during open reduction and internal fixation results in a better reduction and an earlier return of wrist motion. It is also possible to overcome obstacles to reduction like small, comminuted fragments and soft tissue interposition. The treatment is nevertheless accompanied by a number of unique risks, including tendinitis and tendon ruptures, median nerve neuropathy, surgical site infections, and hardware issues.[24]

In a related study by Wilcke et al, 33 patients were randomly assigned to external fixing and 30 to volar plating. At 3 and 6 months, the patients who underwent volar plating had a considerably higher DASH score than those who underwent external fixation, but at 12 months, the differences diminished and were no longer statistically significant.[13] The volar plating group also had higher grip strength and range of motion, albeit these advantages gradually faded. The mean DASH score at the end of 3 months was significantly higher in the volar plating group than in the other two groups in a study by Wei et al. that compared the subjective functional outcome following fixation of unstable distal radius fractures by external fixation, volar plating, and radial column plating. The mean DASH score for the volar plating group, however, did not differ substantially from either of the other two groups at 6 months or 12 months.[7] At six months, the external fixation group had a considerably higher percentage of grip strength regained than the internal fixation group. In the analysis of range of motion, there were no discernible differences between the groups. VAS pain scores did not reveal any appreciable changes.

In a different recent study, Venkatesh Gupta et al. compared bridging external fixation with volar plating for unstable, comminuted distal radius fractures. They came to the conclusion that, at one-year, volar fixation results in a quicker recovery of wrist function with better DASH scores and a greater post-operative range of motion than the external fixation group.[25] The two groups pain scores did not significantly differ from one another.

A meta-analysis by Walenkamp et al. revealed improved DASH ratings in the plating group at 3, 6, and 12 months for unstable distal radius fractures treated with volar plating as opposed to external fixation.[26] No significant changes were seen for secondary outcomes such as grip strength and range of motion. In a meta-analysis by Wang et al., ORIF was found to have significantly higher DASH scores at 3, 6, and 12 months compared to external fixation.[27] At 3 months, the ORIF group's grip strength was noticeably better, but at 6 and 12 months, the difference was not statistically significant.

The results of a range of motion examination for volar plating indicated improved volar flexion at 6 months, dorsiflexion at 3 and 6 months, and supination at 3 months. Volar locked plating had a significantly lower DASH score than external fixation at 3, 6, and 12 months after surgery, according to a new meta-analysis by Li Hai et al.[28] Furthermore, it was discovered that volar plating considerably improved dorsiflexion, supination, and grip strength. Wei et al.'s meta-analysis revealed that ORIF performed considerably better than external fixation in terms of DASH scores and forearm supination. However, external fixation considerably improved grip strength recovery.[15]

In comparison to external fixation, ORIF appeared to have considerably lower DASH scores and lower infection rates, according to a meta-analysis by Eposito et al. Other than infection, there were no notable differences between the two modalities in terms of range of motion, grip strength, or complication rates.[16]

Similar to the results of the research mentioned above, our study's findings indicate that the volar plating group improved more than the external fixation group's mean DASH scores at 3, 6, and 12 months. At 12 months, the group with volar plating had a considerably higher percentage of grip strength recovery. At 12 months, there was a significant difference between the two groups' improvements in dorsiflexion and volar flexion range, with better recovery in the volar plating group. At 3 and 6 months, there was a substantial difference in the VAS scores between the two groups, with the volar plating group having lower VAS values. Complication rates were lower in the volar plating group than in the external fixation group, albeit the difference was not statistically significant. These findings imply that volar plating is superior to external fixation for unstable distal radius fractures in terms of achieving a better subjective outcome, with the added benefit of low rates of comorbidities.

Conclusion

The stability of a distal radius fracture can be affected by a variety of variables. The most important stage, which is frequently skipped and which ultimately determines how well a treatment will work, is identifying these contributing elements. These fractures should ideally be stabilized surgically because they have a significant propensity to redisplace after a conservative trial of closed reduction and casting. In order to achieve fracture union and the restoration of wrist function, it is effective to use external fixation with or without extra K wires, open reduction, and volar plating. With higher postoperative wrist motion and a reduced incidence of comorbidities, volar plating has a superior functional outcome overall thanks to its undeniable advantage of direct fracture imaging. The stiffer construction offered by the fixed angle locking plates reduces the possibility of fracture displacement. Volar plates are more adaptable than external fixation in terms of their applicability to a wide range of fracture patterns and their effectiveness in facilitating immediate postoperative motion, despite being a simpler, less expensive, and minimally intrusive process. Therefore, volar plating is unquestionably the best option for treating unstable distal radius fractures.

References

1. Jupiter JB. Current concepts review: fractures of the distal end of the radius. J Bone Joint Surg Am. 1991;73(3):461-9.
2. Lafontaine M, Delince P, Hardy D, Simons M. Instability of fractures of the lower end of the radius: apropos of a series of 167 cases. Acta orthopaedica Belgica. 1989;55(2):203-16.
3. Gartland J, Evaluation of healed Colles' fractures. J Bone Joint Surg Am. 1984; 33:747-9.
4. Trumble TE, Schmitt SR, Vedder NB. Factors affecting functional outcome of displaced intra-articular distal radius fractures. J Hand Surg Am. 1994;19(2):325-40.
5. Lindau T, Arner M, Hagberg L. Intraarticular lesions in distal fractures of the radius in young adults: a descriptive arthroscopic study in 50 patients. J Hand Surg Am. 1997;22(5):638-43.
6. Baratz ME, Des Jardins JD, Anderson DD, Imbriglia JE. Displaced intra-articular fractures of the distal radius: The effect of fracture displacement on contract stresses in a cadaver model. J Hand Surg Am. 1996;21(2):183-8.
7. Wei DH, Raizman NM, Bottino CJ, Jobin CM, Strauch RJ, Rosenwasser MP. Unstable distal radial fractures treated with external fixation, a radial column plate, or a volar plate. A prospective randomized trial. J Bone Joint Surg Am. 2009;91(7):1568-77.
8. Kapoor H, Agarwal A, Dhaon B. Displaced intra-articular fractures of distal radius: a comparative evaluation of results following closed reduction, external fixation and open reduction with internal fixation. Injury. 2000;31(2):75-9.
9. Kreder H, Hanel D, Agel J, McKee M, Schemitsch E, Trumble T, et al. Indirect reduction and percutaneous fixation versus open reduction and internal fixation for displaced intra-articular fractures of the distal radius: a randomised, controlled trial. J Bone Joint Surg Am. 2005;87(6):829-36.
10. Shukla R, Jain RK, Sharma NK, Kumar R. External fixation versus volar locking plate for displaced intra-articular distal radius fractures: a prospective randomized comparative study of the functional outcomes. J Orthop Traumatol. 2014;15(4):265-70.
11. Egol K, Walsh M, Tejwani N, McLaurin T, Wynn C, Paksima N. Bridging external fixation and supplementary Kirschner-wire fixation versus volar locked plating for unstable fractures of the distal radius: a randomised, prospective trial. J Bone Joint Surg Am. 2008;90(9):1214-21.
12. Navarro CM, Ahrengart L, Törnqvist H, Ponzer S. Volar locking plate or external fixation with optional addition of K-wires for dorsally displaced distal radius fractures: a randomized controlled study. J Orthop Trauma. 2016;30(4):217-24.
13. Wilcke MK, Abbaszadegan H, Adolphson PY. Wrist function recovers more rapidly after volar locked plating than after external fixation, but the outcomes are similar after 1 year: A randomized study of 63 patients with a dorsally displaced fracture of the distal radius. Acta orthopaedica. 2011;82(1):76-81.
14. Walenkamp MM, Bentohami A, Beerekamp MSH, Peters RW, van der Heiden R, Goslings JC, et al. Functional outcome in patients with unstable distal radius fractures, volar locking plate versus external fixation: a meta-analysis. Strategies in Trauma and Limb Reconstruction. Strategies Trauma Limb Reconstr. 2013;8(2):67-75.
15. Wei DH, Poolman RW, Bhandari M, Wolfe VM, Rosenwasser MP. External fixation versus internal fixation for unstable distal radius fractures: a systematic review and meta-analysis of comparative clinical trials. J Orthop Trauma. 2012;26(7):386-94.
16. Esposito J, Schemitsch EH, Saccone M, Sternheim A, Kuzyk PR. External fixation versus open reduction with plate fixation for distal radius fractures: a meta-analysis of randomised controlled trials. Injury. 2013;44(4):409-16.
17. Agee JM. Distal radius fractures. Multiplanar ligamentotaxis. Hand clinics. 1993;9(4):577-85.
18. Agee JM, Szabo RM, Chidgey LK, King FC, Kerfoot C. Treatment of comminuted distal radius fractures: an approach based on pathomechanics. Orthopedics. 1994;17(12):1115-22.
19. Hunsaker FG, Cioffi DA, Amadio PC, Wright JG, Caughlin B. The American academy of orthopaedic surgeons' outcomes instruments: normative values from the general population. JBJS. 2002;84(2):208-15.
20. Gummesson C, Atroshi I, Ekdahl C. The disabilities of the arm, shoulder and hand

(DASH) outcome questionnaire: longitudinal construct validity and measuring self-rated health change after surgery. BMC musculoskeletal disorders. 2003;4(1):11.

21. Mathiowetz V, Weber K, Volland G, Kashman N. Reliability and validity of grip and pinch strength evaluations. J Hand Surg. 1984;9(2):222-6.
22. MacDermid JC, Richards RS, Donner A, Bellamy N, Roth JH. Responsiveness of the short form-36, disability of the arm, shoulder, and hand questionnaire, patient-rated wrist evaluation, and physical impairment measurements in evaluating recovery after a distal radius fracture. J Hand Surg. 2000;25(2):330-40.
23. Petersen P, Petrick M, Connor H, Conklin D. Grip strength and hand dominance: challenging the 10% rule. Am J Occup Ther. 1989;43(7):444-7.
24. Richard MJ, Wartinbee DA, Miller M, Leversedge FJ, Riboh J, Ruch DS. Comparative analysis of the complication profile following palmar plating versus external fixation of fractures of the distal radius. Clinic Rhinol. 2010;1(1):1-7.
25. Venkatesh Gupta SK, Mandapalli P. Comparative Study between Bridging External Fixation vs Volar Plating (Ellis-T Plate) for Comminuted Fracture of the Distal End Radius. 2015: 20-4.
26. Walenkamp MM, Bentohami A, Beerekamp MS, Peters RW, van der Heiden R, Goslings JC, et al. Functional outcome in patients with unstable distal radius fractures, volar locking plate versus external fixation: a meta-analysis. Strategies Trauma Limb Reconstr. 2013;8(2):67-75.
27. Wang J, Yang Y, Ma J, Xing D, Zhu S, Ma B, et al. Open reduction and internal fixation versus external fixation for unstable distal radial fractures: a meta-analysis. Orthop Traumatol Surg Res. 2013;99(3):321-31.
28. Li-hai Z, Ya-nan W, Zhi M, Li-cheng Z, Hong-da L, Huan Y, et al. Volar locking plate versus external fixation for the treatment of unstable distal radial fractures: a meta-analysis of randomized controlled trials. J Surg Res. 2015;193(1):324-3.