



가변각 수장측 잠김 금속판을 이용한 원위 요골 골절의 치료 결과

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A Prospective, Multicenter, Observational Study to Assess Distal Radius Fracture Treatment Outcomes Using the Variable-Angle Locking Compression Plate

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Purpose: The 2.4 mm variable-angle locking compression plate (VA-LCP) is designed to treat a variety of distal radius fracture patterns. The purpose of this study was to evaluate the efficacy of the 2.4 mm VA-LCP in treating unstable distal radius fractures.

Methods: We recruited eligible patients treated with the device at two Korean sites. In total, we studied 61 enrolled patients. We assessed clinical outcomes and radiographic union, as well as the types of plates and the number of variable-angle locking screws used in the treatment of each fracture type. Radiographic parameters were evaluated at the immediate postoperative period and at 1 year after operation.

Results: A total of five complications occurred in 61 patients (8.2%). Radiographic union was achieved in 46/51 (90.2%), 50/51 (98.0%), and 51/51 (100%) patients at 3, 6, and 12 months, respectively. Radiographic parameters evaluated at the immediate postoperative period were 22.4±4.2 degrees (radial inclination), 4.7±0.4 degrees (volar tilt) and 0.8±0.2 degrees (ulnar variance). Radiographic parameters evaluated at 1 year after operation were 21.3±3.4 degrees (radial inclination), 4.1±0.4 degrees (volar tilt) and 1.2±0.3 degrees (ulnar variance). Wrist range of motion and grip strength measurements, as well as self-administered patient questionnaires showed continuous improvements at all follow-up time points. The mean number of screws that were inserted through variable-angle screw guide was 3.2±0.9, while that of screws inserted through fixed-angle screw guide was 3.5±0.9. The majority of patients (85.3%) were treated with a narrow plate.

Conclusion: The findings of this study show promising results for the treatment of unstable distal radius fractures using the VA-LCP System.

Key Words: Radius, Radius fracture, Variable-angle locking compression plate

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INTRODUCTION

Distal radius fractures are common, representing 10%-25% of all fractures^{1,2}. The treatment of choice for displaced, unstable fractures is anatomic reduction with stable fixation³. Furthermore, the main treatment goals include reconstructing the congruity of the articular surfaces as well as restoring radial height, radial inclination, and palmar tilt⁴. Various surgical options are available based on a number of external and internal fixation methods, but the most common external fixation technique is percutaneous pinning with K-wires. Internal fixation involves the application of several types of plates, particularly those with a stable angle design, which has increased in popularity over the last decade⁵. The choice of treatment method depends on the fracture type, surgeon preference, and local clinic policy.

The 2.4 mm variable-angle locking compression plate Two-Column Distal Radius (VA-LCP DR) Plate (Synthes, Oberdorf, Switzerland) is designed to treat a variety of distal radius fracture patterns. The VA-LCP DR Plate is the first implant to combine the freedom of variable-angle technology for fragment-specific fixation with the convenience of predefined fixed angles. Moreover, the surgeon is able to address fragments individually for each fracture, applying this plate that was conceptually designed up to 15 degrees off-axis screw angulation. Also, due to its anatomic shape, there is no need to contour the plates according to the bone anatomy. Other advantages of this design are the low profile of the plate and screw, polished surface, and rounded edges, which minimize potential tendon adhesions and soft tissue irritation. The VA-LCP DR Plate is the latest component of the LCP Distal Radius Plate System and has been approved for marketing in South Korea by the ministry of Food and Drug Safety in 2009. It is indicated for the fixation of intra- and extra-articular fractures and osteotomies of the distal radius.

The primary objective of this study was to observe functional and radiological improvements following surgery for distal radial fractures using the 2.4 mm VA-LCP DR Plate and screws system.

MATERIALS AND METHODS

This was a prospective multicenter observational study conducted from November 2010 to July 2013. Two medical centers participated in this study. This study was approved by the Institutional Review Board of Ewha Womans University Mokdong Hospital and CHA Bundang Medical Center (IRB No. EMCT026-1 and 2010-08-010).

Patients were eligible for the study if they met all the following inclusion criteria: (1) male and female subjects aged over 20 years; (2) they had a fracture of the distal radius with dorsal angulation greater than 10 degrees, volar angulation greater than 20 degrees, radial shortening more than 5 mm, radial inclination less than 10 degrees, or articular step-off more than 2 mm on radiographic findings after closed reduction; (3) they had an operation scheduled within 2 weeks of the injury; (4) they were psychologically, mentally, and physically able to fully comply with the protocol including adhering to scheduled visits, treatment plan, completing forms, and other study procedures; and (5) they personally signed and dated informed consent documents prior to any study-related procedures.

Patients were excluded from participation if they met any of the following criteria: (1) previous surgery of the distal radius; (2) active systemic or local infection; (3) known or documented history of communicable disease, including acquired immune deficiency syndrome or human immunodeficiency virus; (4) receiving medical treatment within two years for active hepatitis; (5) active rheumatoid arthritis, non-controlled diabetes mellitus, or any other medical conditions that would increase surgical risk or interfere with normal healing; (6) immunologically suppressed or received systemic steroids (excluding nasal steroids) at any dose daily for more than 1 month within the last 12 months; (7) known history of Paget's disease, osteomalacia, or any other metabolic bone disease; (8) previous known allergy to the materials contained in the device; (9) active malignancy; (10) current or recent history (within the last 2 years) of substance abuse; (11) pregnant or planning to become pregnant dur-

ing the study period; and (12) involved in any study of another investigational product that may affect study outcomes. A total of 61 patients were enrolled in the study.

1. Outcomes

The outcomes were evaluated postoperatively at 3, 6, and 12 months. Outcome measurement consisted of physical examination, patient self-assessments, and radiographic evaluation. Radiographic parameters including radial inclination, volar tilt and ulnar variance were evaluated at the immediate postoperative period and 1 year after operation. Wrist range of motion and grip strength were checked during the physical examination. Wrist range of motion in degrees included flexion/extension, pronation/supination, and radial deviation/ulnar deviation. Patient self-assessments included the Patient-Rated Wrist Evaluation (PRWE) questionnaire and Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire⁶. Evidence of articular step-off of more than 2 mm and bone union using bridging callus was assessed by the investigators at each follow-up time point. Other analyses included the number of screws that were inserted through variable or fixed angle screw guides. The mean number of screws that were inserted through variable or fixed angle screw guides was evaluated. The plate types used were also analyzed, including the number of plate types used among three types (Asian, narrow, or standard plates).

2. Statistical analysis

Continuous variables in different groups presented with mean values were compared using paired t-test. All statistical analysis was performed using IBM SPSS Statistics for Windows ver. 24.0 (IBM Corp., Armonk, NY, USA). The significance level was set at p-value less than 0.05.

RESULTS

1. Patient demographics

Preoperative patient demographics are reported in Table 1. The average patient age was 57.7 ± 14.35 years, and 75.4% were female. The average body mass index was 22.8 ± 2.34 kg/m² and patients who had underlying diseases were 34.4% of the subjects. C2 was the most common fracture type in thirty-one patients of the subjects. Low energy injuries were the most common injury mechanism in 91.8% of the subjects, followed by high energy injuries (8.2%). Thirty-two patients (52.5%) injured their right distal radius and none of the injuries were open. Ten patients were lost during follow-up at postoperative 12 months.

Table 1. Demographic and preoperative profile

Characteristic	All (n=61)
Age (yr)	57.7±14.35
Sex	
Male	15 (24.6)
Female	46 (75.4)
Body mass index (kg/m ²)	22.8±2.34
Underlying diseases	
No medication	40 (65.6)
Regular intake of medication	21 (34.4)
Fracture type (AO classification)	
A2	6
A3	4
B1	0
B2	11
B3	2
C1	2
C2	31
C3	5
Mechanism of injury	
Low energy	56 (91.8)
High energy	5 (8.2)
Fracture side	
Right	32 (52.5)
Left	29 (47.5)

Values are presented as mean±standard deviation, number (%), or number only.

2. Intraoperative data

Intravenous antibiotics were perioperatively delivered for 48 hours and oral antibiotics were administered for three days after the period. No intraoperative complications occurred and the mean operation time was 48.9 (range: 17-95) minutes. The majority of patients were treated with a narrow plate (n=52). Postoperatively, none of the devices were broken and there were no surgical site infections. No patient had to be reoperated during their hospital stay.

3. Complications

Of the 61 patients treated with a VA-LCP DR Plate, five (8.2%) experienced complications during the course of this study (Table 2). Of these complications, three experienced an implant-related complication. The complication reported in three patients was residual pain. Two of these were related to the plate, and one was likely related to the plate.

4. Outcomes

Of 51 patients with postoperative radiographic data, 46 patients demonstrated union by 3 months, four patients by 6 months, and one patient by 12 months. All 51 patients (100%) achieved union by 12 months. Only

one patient showed a step-off of more than 2 mm at 3 months. But this was resolved on a later follow-up, and there was no evidence of arthritic change during the course of this study. Radiographic parameters evaluated at the immediate postoperative period were 22.4 ± 4.2 degrees (radial inclination), 4.7 ± 0.4 degrees (volar tilt) and 0.8 ± 0.2 degrees (ulnar variance). Radiographic parameters evaluated at 1 year after operation were 21.3 ± 3.4 degrees (radial inclination), 4.1 ± 0.4 degrees (volar tilt) and 1.2 ± 0.3 degrees (ulnar variance). There were no significant differences between radiographic parameters evaluated at the immediate postoperative period and 1 year after operation (Table 3). Wrist range of motion increased continuously until the end of the study (Fig. 1). Also, the PRWE and DASH scores during the follow-up period showed continuous improvements (Table 4). The grip strength of the injured limb was compared to that of the non-injured limb at each follow-up visit (Fig. 2). The difference decreased between the 6- and 12-month time points, indicating that the grip strength normalized following fracture union.

5. Types of screws and plates

A total of 0-5 variable-angle locking screws were used for fracture fixation in 61 patients, while 2-8 standard locking or cortex screws were placed after fracture reduction (Table 5). Variable-angle screws were not used in

Table 2. Summary of all complications

Patient No.	Complication	Fracture type (AO)	Relationship to plate
006	Residual pain	C2	Not related
008	Residual pain	A2	Related
009	Residual pain	C2	Not related
012	Residual pain	C3	Related
016	Residual pain	B3	Probably

Table 3. Radiographic outcomes

Radiographic parameter	The immediate postoperative period	1 year after operation	p-value
Radial inclination (deg)	22.4 ± 4.2	21.3 ± 3.4	0.58
Volar tilt (deg)	4.7 ± 0.4	4.1 ± 0.4	0.26
Ulnar variance (deg)	0.8 ± 0.2	1.2 ± 0.3	0.31

Values are presented as mean±standard deviation.

only two patients. The mean number of screws that were inserted through variable-angle screw guide was 3.2 ± 0.9 , and that of screws inserted through fixed-angle screw guide was 3.5 ± 0.9 . There was no correlation between fracture type and mean number of variable screws.

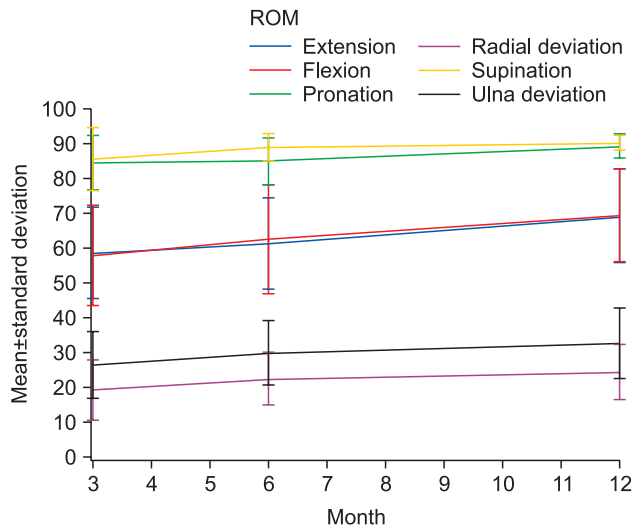


Fig. 1. The mean wrist range of motion in degrees including flexion/extension, pronation/supination, and radial deviation/ulnar deviation increased continuously until the end of the study. ROM: range of motion.

Table 4. Summary of the PRWE scores and DASH scores

Self-administered patient questionnaire	Score
PRWE scores (mo)	
3	20.61±8.06
6	14.24±8.84
12	7.56±8.25
DASH scores (mo)	
3	16.14±12.21
6	10.16±12.89
12	6.34±9.30

Values are presented as mean±standard deviation.

PRWE: Patient-Rated Wrist Evaluation, DASH: Disabilities of the Arm, Shoulder, and Hand.

Table 5. Mean number and standard deviation of screw used

Screw guide used	Fracture type (AO)						
	A2	A3	B2	B3	C1	C2	C3
Variable angle	3.3±1.6	3.5±0.6	4.1±0.3	4.0±0	3.0±1.4	2.6±1.0	4.0±0.7
Fixed-angle	3.5±1.2	3.0±0	3.0±0	3.0±0	3.5±0.7	4.0±1.1	3.0±0.5

Values are presented as mean±standard deviation.

The majority of patients were treated with a narrow plate ($n=52$, 85.3%). The Asian type of plate was used in six patients ($n=6$, 9.8%) and the standard plate was used in three patients ($n=3$, 4.9%).

DISCUSSION

Volar plate fixation with fixed-angle locking screws for the treatment of unstable distal radius fractures has shown generally acceptable outcomes in terms of functional and radiographic parameters⁷⁻⁹. The use of variable-angle locking screws has been introduced to allow increased flexibility in plate positioning and subchondral screw placement, which may possibly improve fracture purchase and maintain the reduction. Most patients (46/51; 90.2%) achieved union by the 3-month time point, consistent with other research^{10,11}. In 98% of the fractures, an articular congruence was achieved at the 12-week

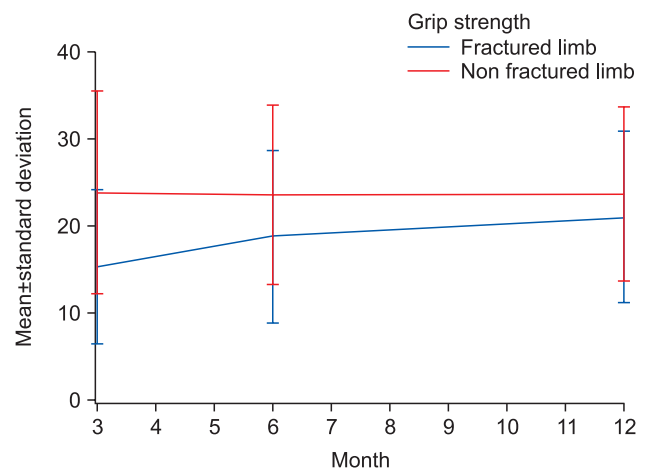


Fig. 2. Grip strength in kilograms of the fractured limb compared to the non-fractured limb at each follow-up visit. The difference decreased between the 6- and 12-month time points, suggesting recovery of grip strength following fracture union.

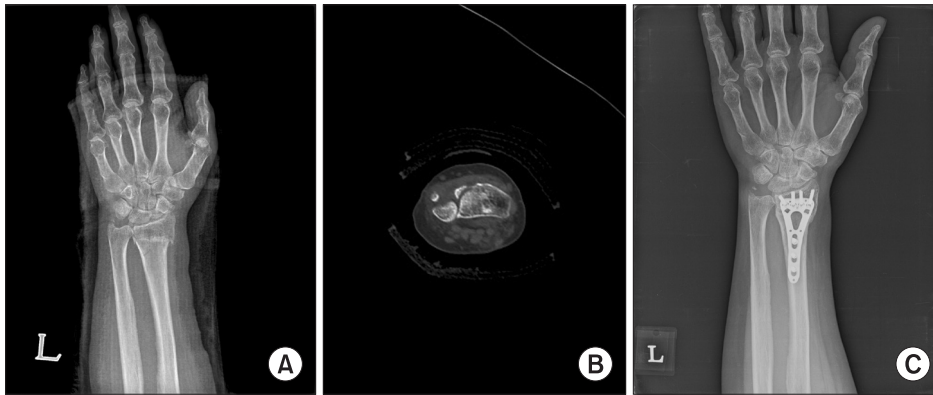


Fig. 3. (A, B) In intra-articular fractures with sigmoid notch involvement, (C) distal fragment that involved sigmoid notch could be fixed more stably by varying the angle of the ulnar-most screw.

follow-up visit. Furthermore, sustained improvements in the range of motion and grip strength were also noted over the 12-month follow-up period. These results are in line with previous work by MacDermid^{12,13}, who demonstrated that patients rapidly achieved most of their range of motion improvement and grip strength by 6 months, although they may continue to improve. At 6 and 12 months after surgery, patients reported low pain scores, good PRWE scores, and high levels of satisfaction. There were no cases of wound infection, tendon injury/irritation, hardware failure, or loss of fracture reduction.

In this study, the mean number of variable screws used was 3.15 in 59 patients and variable-angle screws were not used in only two patients. Stanbury et al.¹⁴ reported that the variable-angle fixation exhibited a distinct mechanical advantage over fixed-angle fixation in the setting of smaller radial styloid fragments. Hart et al.¹⁵ concluded that variable-angle screws provided 3 mm of leeway in both sagittal and coronal directions without sacrificing construct strength, which may considerably facilitate the fixation of AO C3 fractures. The recent trend toward volar plating systems with variable-angle screws has the advantage of allowing surgeons to orient screws to avoid crossing articular surfaces and allow for a more precise capture of the fragments. The flexibility of variable-angle screws can allow for fixation of the plate proximal to the watershed line while acquiring the rigid fixation of distal fragments and avoiding penetration of the subchondral bone.

In our study, we inserted screws through variable-angle guide when screws inserted through fixed angle guide

might have a risk to penetrate the articular surface, or screws inserted through variable-angle guide provided better position to stably purchase the distal fragments than screws inserted through fixed angle guide. In intra-articular fractures with sigmoid notch involvement (Fig. 3A, 3B), distal fragment that involved sigmoid notch could be fixed more stably by varying the angle of the ulnar-most screw (Fig. 3C).

Therefore, variable-angle screws have advantages in fixation of comminuted fractures and reconstruction of the complex geometry of the articular surface while avoiding potential tendon irritation and joint penetration^{16,17}.

With the exception of only three patients, the majority of patients were treated with narrow and Asian types of plates (n=58, 95.1%). According to size of plate head, there are three types of plates (Asian type: width 19.5 mm, narrow type: width 22 mm, standard type: width 25.5 mm). The standard type of plate was designed based on anatomical characteristics of Western populations. Therefore the standard type of plate is larger than other types. Korean people have anatomical characteristics different from Western populations, such as a relatively small and short radius, especially in women¹⁸. In this study, 75% of patients were females, and as the size of the standard type of plate was too large for the small radius of Korean women, narrow and Asian types of plates were used in the majority of patients. Thus, we can conclude with confidence that distal radius fractures occur mostly in older females and therefore a relatively small plate system is useful in Korean populations.

This study has several limitations. First, this was not a randomized controlled study and we did not compare our results with patients treated with other plate systems. Also, because of the difference in surgeon preference and surgical technique, there was a variability in screw selection (variable-angle screws versus traditional screws). Finally, the outcomes were captured by the treating surgeons and not independently by another researcher.

CONCLUSION

The findings of this study show promising results after volar plating of unstable distal radius fractures using the VA-LCP DR Plate System.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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가변각 수장측 잠김 금속판을 이용한 원위 요골 골절의 치료 결과

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목적: 본 연구에서는 가변각 수장측 잠김 금속판을 이용하여 원위 요골 골절을 치료한 결과를 분석하여 유효성을 평가하고자 한다.

방법: 2010년부터 2013년까지 원위 요골 골절을 진단받고 관혈적 정복술 및 가변각 수장측 잠김 금속판을 이용한 내고정술을 시행한 61명의 환자를 대상으로 관찰 연구를 시행하였다. 골절의 AO 분류에 따라 방사선적 소견, 금속판 종류, 가변각 나사 가이드를 이용하여 삽입된 나사의 수, 임상적 결과, 합병증 발생을 분석하였다.

결과: 총 5예(8.2%)에서 합병증이 발생하였으며, 수술 후 3개월, 6개월, 12개월 추사에서 46/51 (90.2%), 50/51 (98.0%), 51/51 (100%)의 방사선적 유합을 보였다. 수술 직후 측정된 요골 경사, 수장측 경사, 척측 변위는 각각 $22.4 \pm 4.2^\circ$, $4.7 \pm 0.4^\circ$, $0.8 \pm 0.2^\circ$ 였으며, 수술 후 1년에 측정된 요골 경사, 수장측 경사, 척측 변위는 각각 $21.3 \pm 3.4^\circ$, $4.1 \pm 0.4^\circ$, $1.2 \pm 0.3^\circ$ 였다. 또한, 추시 기간 동안 관절의 운동 범위와 파악력은 지속적으로 증가하였고, PRWE 및 DASH 점수는 지속적으로 감소하였다. 가변각 나사 가이드를 이용하여 삽입된 나사의 수는 평균 3.2 ± 0.9 였으며, 고정각 나사 가이드를 이용하여 삽입된 나사의 수는 평균 3.5 ± 0.9 였다. 사용된 금속판의 종류는 총 52예(85.3%)에서 narrow 금속판을 사용하였다.

결론: 원위 요골 골절의 치료로써 가변각 수장측 잠김 금속판을 이용한 내고정술은 만족할 만한 결과를 보였다.

색인단어: 요골, 요골 골절, 가변각 수장측 잠김 금속판

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