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Fractures of the Distal Radius: A Randomized Controlled Trial of 180 Patients Comparing Volar Locking Plates and Alternative Fixation Methods

Chere McCamley[1]*, Peter Tamblyn[1], Cheryl Kimber[1], Steve Quinn[2], Amy Watts[3] and Ruurd Jaarsma[4]

[1]*Department of Orthopaedics, Flinders Medical Center, Flinders Drive, Bedford Park, Adelaide, South Australia, Australia*
[2]*School of Medicine, Flinders University, Bedford Park, Adelaide, South Australia, Australia*
[3]*Department of Clinical Research, School of Medicine, Flinders University, International Musculoskeletal Research Institute, Bedford Park, Adelaide, South Australia, Australia*
[4]*Orthopaedic Trauma Flinders Medical Centre, Flinders Drive, Bedford Park, Adelaide, South Australia, Australia*

Abstract

For intra-articular and extra-articular distal radius fractures do volar locking plates (VLP) provide patients with functionally, clinically and radiologically superior results compared to fixation methods before their introduction; Kirschner wires, non-locking plates and external fixators? In this prospective, randomized controlled trial 180 participants with a median age of 65 (range 18-96) were followed up for 1 year. Outcome measures included Disability of Arm Shoulder and Hand (DASH) score, range of motion (ROM) and grip strength, radiological measurements (radial length, angle, tilt, ulnar variance and articular step) and complications. There was no statistical difference of DASH scores between groups at any time point. ROM differed at one and six weeks post operatively, favoring the VLP fixation. However these results were not sustained at 12 and 52 weeks. The results have confirmed VLP's ability to maintain fracture reduction over 12 weeks compared to alternative fixation methods.

Keywords: Distal radius fracture; Fixation; Volar locking plates; Alternative fixation methods; Randomized control trial

Introduction

Distal radius fractures are recognized as a common orthopedic injury, accounting for approximately one sixth of all fractures seen in emergency departments [1-7]. In 2007 in the US, approximately 640,000 distal radius fractures were diagnosed [3,8]. Research suggests that given the aging population, the incidence of distal radius fractures in people 50 years and older will increase by 81% within 25 years [9].

In the past decade the volar locking plate (VLP) has claimed increasing acceptance within the marketplace [8,10-14]. In the US in 2007, 81% of fractures were treated surgically compared to 42% in 1999 [6]. By 2010 over 30 designs of VLPs were recognized worldwide [15].

Surgical treatment aims to achieve early and sustained function without pain [16,17]. It is widely accepted that restoration of anatomical alignment and preservation of the articular surface facilitates these goals [1,2,5,11,12,18-20].

VLP provides anatomical advantage over dorsal plating by easier surgical access to the distal radius and protection of the tendon sheaths by pronator quadratus [3,21]. The locking head screw and plate is designed to provide a stable construct, supporting the chondral surface while maintaining dorsal reduction thereby allowing early mobilization [2,11,22,23]. Despite the frequency and costs of distal radius fractures, only recently has Level-1 evidence become available and optimal treatment remains uncertain [2,12,13,16,17,24]. The WRIST study group has recognized that further randomized clinical trials are required for an evidence based approach to treatment of distal radius fractures [25].

The aim of this trial was to investigate whether the VLP provides patients with functionally, clinically and radiologically superior results compared with a control group of alternative fixation methods (K-wires, non-locking plates and external fixators) for intra-articular and extra-articular distal radius fractures at one year. The primary outcome of the present study is to compare functionality between groups using the disabilities of the arm, shoulder and hand (DASH) questionnaire score. Secondary outcomes include clinical and radiological assessment.

Patients and Methods

This was a single-centre, prospective, randomized controlled trial completed by the Orthopedic Department of a Level 1 Trauma Centre tertiary care institution in Australia. It was approved by the research ethics committee and registered on the Australian New Zealand Clinical Trials Registry with the trial ID (ACTRN12614000323628). The CONSORT guidelines were used for the transparent reporting of this randomized controlled trial [26].

From August 2005 to April 2009, 180 patients presenting to the trauma service with a fracture of the distal radius were enrolled. Patients over the age of 18 were invited to participate in the study if they were undergoing surgical fixation of an unstable distal radius fracture. Exclusion criteria included fractures amenable to closed reduction, patients with cognitive incapacity (e.g. dementia), neurological disorder affecting function, pre-existing or concurrent upper limb disability or those refusing randomization were excluded.

Sample size was calculated utilizing the DASH score as the primary outcome. Based on previous studies a difference of 10 points in the DASH score was considered the minimal clinically significant difference [27,28]. A sample of 180 participants with an equal allocation ratio

***Corresponding author:** Chere McCamley, Department of Orthopaedics, Flinders Medical Center, Flinders Drive, Bedford Park, Adelaide, South Australia, Australia, Tel: +61418467795; E-mail: mccamley4312@hotmail.com

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(90:90 participants) provides 80% power, assuming 23 as the standard deviation of change [27]. All patients were followed-up according to the intention to treat. Statistical significance was 0.05.

Consented patients were randomized by a sealed envelope method into the study group (VLP) or control group (any procedure other than volar locking plate, such as external fixation, K-wires, non-locking plates or combination thereof based on surgeon preference). Both groups were reviewed in the research clinic at 1, 6, 12 and 52 weeks post-operatively (Figure 1). Clinical and radiological assessment was performed by independent assessors. All patients received educated on ROM and strengthening exercises upon completion of wrist immobilization. The VLP group was mobilized upon week 1 review whereas the control group generally commenced mobilization at 6 weeks. Access to further services (e.g. hand therapy) was not restricted in either group.

Surgery

Implants used for the 90 VLP patients were DVR® (DePuy, Leeds, UK) 47, Synthes® (USA) 25, Smith and Nephew® (Cordova, USA) 12, Medartis® (Switzerland) 4, Austofix® (Australia) 1, Stryker® (Germany) 1 all inserted via the flexor carpi radialis approach. Implants in the control group were K-wire 57, non-locking plate 23 and bridging external fixation 10. The surgery was performed by 46 surgeons, the majority of whom were surgical registrars under supervision.

Functional outcome

The validated self-administered questionnaire DASH was utilized as our primary outcome measure at postoperative time points 1, 12 and 53 weeks [1,29]. The score is between 0-100 with a lower score indicating better functional capacity and a difference of 10 points is considered a clinically and statistically significant [27,29].

Clinical outcomes

At each review, both wrists were assessed for ROM and grip strength. ROM was measured in three planes (flexion/extension, supination/pronation and radial/ulnar deviation) with a goniometer placed at the axis of wrist motion. Results were expressed in degrees and compared as a percentage of the uninjured side. Grip strength, recorded in kilograms, was measured with a Dynamometer (Jamar, Sammons Preston, US) in handle settings 2, 3 and 4 to accommodate variable hand size of participants. The mean grip strength readings were expressed as a percentage of the uninjured side to reduce inter-subject variability.

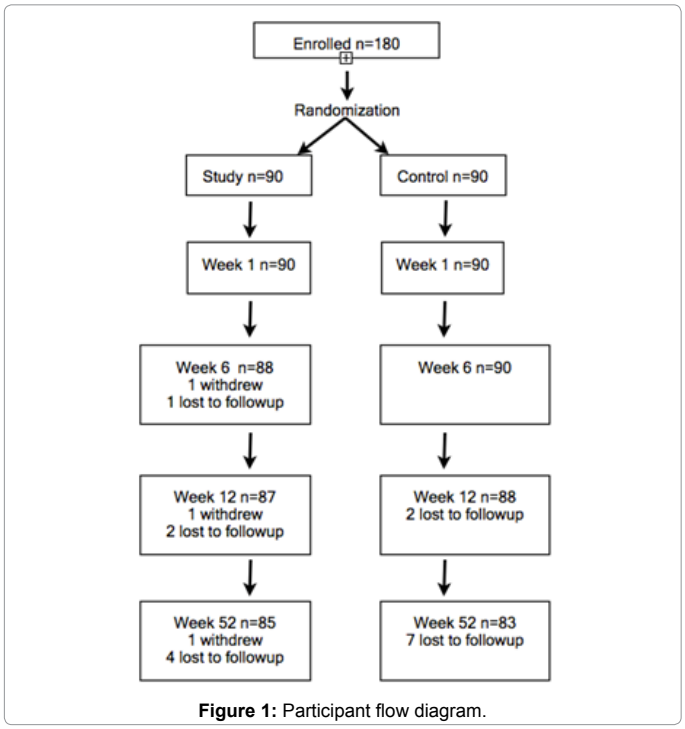

Figure 1: Participant flow diagram.

Figure 2: Radiological measurement methods.

Radiological outcomes

Plain radiographs were completed at the initial presentation, in the operating theatre and at 1, 6 and 12 weeks post-operatively. The picture archiving and computer system (PACS, GE Healthcare, UK) was utilized. The fractures were classified, into type A, B or C (AO system) by a senior orthopedic surgeon who was blinded to DASH and clinical results [30].

All patients underwent surgery and imaging at the same facility with the same imaging equipment. Antero-posterior (AP) images were measured for radial length, angle, ulnar variance and articular step. Lateral images were measured for radial tilt and articular step. Patient positioning and imaging technique was standardized according to protocols developed [31]. To scale the images, at the post-operative examinations 10 mm metal balls were placed in the 1st and 2nd web spaces in line with the distal radius. Measurement of the ball image indicated the magnification. Scaled measurements of the pre-operative and theatre films were achieved using the known ulnar head width and lunate height. Accurate scaling of the images was required to measure radial length and articular steps (Figure 2).

Complications

We defined a complication as an unplanned physiological process that may be attributed to surgery which caused the patient distress or had a negative impact on recovery. Complications were divided into general (wound infection requiring antibiotics, paraesthesia) or

surgical (tendon repair, unplanned revision of distal radius fixation, carpal tunnel release).

Statistical methods

All analyses were conducted on an intention to treat basis with missing data imputed using multiple imputation and resampling 20 times. T-tests or Mann-Whitney U tests were used for comparisons of means or medians according to whether the outcome was normally distributed or not. *Chi-squared* tests or Fisher's exact test were used to compare proportions, according to whether or not the expected cell number was greater than 5. The estimation of the primary outcome was performed using quantile regression (Stata's qreg command) and to obtain the p-values. A p-value of less than 0.05 (two-tailed) was considered statistically significant.

Results

Commencing August 2005 and over the subsequent 56 month period, a total of 180 patients were recruited. At the final assessment there were 11 participants lost to follow-up (Figure 1). Overall, 4.4% of the study patients and 7.7% of the control patients did not complete the 52 week follow-up. One patient withdrew from the trial. No patient died within the study period.

	VLP Group (N=90)	Control Group (N=90)
Gender (female)	69 (77.8)	68 (75.6)
Age (years)	58.1 (20.4)	61.3 (18.0)
Hand dominance (right)	80 (90.9)	86 (95.6)
Dominant side injured	34(40.0)	45 (50.6)
AO Fracture classification		
Type A	19 (21.8)	17 (20.0)
Type B	10 (11.5)	6 (7.1)
Type C	58 (66.7)	62 (72.9)
Missing x-ray	3 (3.3%)	5 (5.6%)

Table 1: Demographics and clinical characteristics.

Outcome	VLP Group	Control Group	P-value‡
Week 1			
DASH	64.8 (20.0)	65.9 (16.1)	0.68
Flexion/extension	26.5 (13.6-38.7)	0 (0-0)	<0.001
Ulnar/radial deviation	32.7 (14.8 – 44.9)	0 (0-0)	<0.001
Supination/pronation	50 (11.1-75)	0 (0-13.3)	<0.001
Av.Grip Strength	1.3 (0-5)	0 (0-0)	<0.001
% Grip Strength	6.2 (0-22.4)	0 (0-0)	<0.001
Week 6			
DASH†	-	-	-
Flexion/extension	53.0 (24.7)	28.8 (22.4)	<0.001
Ulnar/radial deviation	60.0 (27.4)	35.0 (27.6)	<0.001
Supination/pronation	86.1 (63.3-97.2)	45.8 (16.7-70.8)	<0.001
Av. Grip Strength	7 (1.8-13)	2.5 (0-6)	<0.001
% Grip Strength	32.8 (12.5-57.2)	10.2 (0-27.6)	<0.001
Week 12			
DASH	28.8 (22.4)	23.9 (17.9)	0.13
Flexion/extension	72.9 (23.9)	70.4 (23.0)	0.5
Ulnar/radial deviation	78.6 (25.1)	71.4 (25.2)	0.06
Supination/pronation	94.4 (88.9-100)	88.9 (77.8-97.2)	0.002
Av.Grip Strength	13.1 (9.3)	14.3 (10.9)	0.43
% Grip Strength	55.8 (28.4)	54.5 (25.6)	0.75
Week 52			
DASH	15.0 (16.7)	13.4 (15.4)	0.61
Flexion/extension	90.3 (18.2)	87.6 (17.2)	0.33
Ulnar/radial deviation	88.5 (23.5)	88.3 (23.5)	0.96
Supination/pronation	100 (97.2-100)	100 (94.4-100)	0.007
Av.Grip Strength	20.0 (11.4)	21.0 (11.9)	0.58
% Grip Strength	83.9 (23.2)	84.6 (19.5)	0.84
† DASH score not recorded at week 6 ‡ t-test or Mann-Whitney as appropriate			

Table 2: Clinical outcomes.

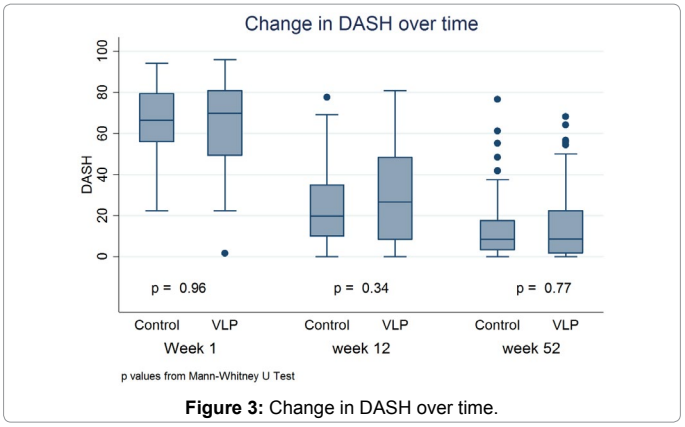

Figure 3: Change in DASH over time.

The demographic characteristics of our sample are given in Table 1. Twenty-three percent of patients were male (n=43). The median age was 65 (range: 18-96). Patient demographics and fracture classifications did not differ between groups at baseline.

Primary outcome: DASH results

At 52 weeks the median DASH scores in the study and control groups were 9.2 and 8.9 respectively (p=0.88). There was no significant difference at any time point in the number of incomplete data between the groups with 25 (9.3%) incomplete control questionnaires and 22 (8%) incomplete study questionnaires. There was no statistical difference in the DASH between the VLP and control group at the 3 time points within the study (Table 2).

The mean improvement in DASH scores from week 1 to week 12 was 36 points VLP and 42 points control. Week 12 to week 52 improved by 13.8 points VLP and 10.5 points control. These improvements exceed the minimally clinically important difference of 10 points, no significant difference was found when comparing VLP and control groups (Figure 3).

Secondary outcomes

Clinical results: At 1 and 6 weeks after surgery the VLP group had significantly better ROM and grip strength than the control (Table 2). In the VLP group grip strength was 6% of the uninjured wrist at 1 week and 0% in the control group. At 6 weeks, grip strength was 33% in the VLP group and 10.2% in the control group (Figure 4). Average flexion/extension at 1 week was 26.5° in the VLP and 0° in the control group. At 6 weeks, this improved to 53° and 29° respectively. This difference however was not sustained at 12 or 52 weeks post-operatively (Figure 5).

Radiological results: 172 of 180 fractures were able to be classified. Initial radiological images of 3 VLP and 5 control cases were produced external to our hospital and were unable to be located for analysis. Type C injuries formed the majority of the fractures (70%). Fractures identified in the VLP group were 17 A, 6 B and 61 C and similarly in the control 17, 10 and 60 respectively (Table 1).

Initial (injury) films and intra-operative films were assessed and no difference in the baseline radiological measures between the groups was found.

Radial tilt was determined as variance from the normal 10° volar tilt to allow for volar or dorsal displacement. In the VLP group the median radial tilt was significantly better at 1, 6 and 12 weeks (p<0.001). The median radial tilts were 6.1° and 10° for the VLP and control groups respectively (Figure 6). Radial length was also significantly better at 6 and 12 weeks with VLP 11.1 mm and control 9.2 mm at week 12 (both p<0.001) (Figure 7) as was ulnar variance.

Of the 136 cases of intra-articular fractures, 28 cases had an articular step greater than 2 mm (16 VLP, 12 control) on initial x-rays. However, articular steps in post-operative films were difficult to measure because of the implant obscuring the view of the articular surface. Post-operative films showed 9 cases with an articular step greater than 2 mm (3 VLP, 6 control). Articular gaps were not included in this analysis.

Subgroup analysis

A sub analysis was performed to account for fracture severity. Analysis was completed at the end time point for each outcome measure, the DASH scores and clinical outcomes were assessed at week 52 and radiological results at week 12. Results showed no difference in the DASH result between the VLP or control groups.

Complications

A total of 95 complications in 73 patients were documented. 51 complications occurred in the VLP group (37 patients) and 44 in the control group (36 patients). The majority of complications (49) were minor paresthesia, of which all but one had resolved by 52 weeks. One VLP study patient developed stiffness and contracture following a wound hematoma related to suture damage to the radial artery (Table 3).

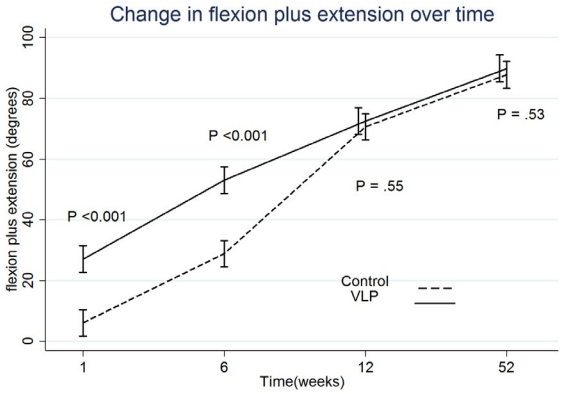

Figure 5: Change in flexion plus extension over time.

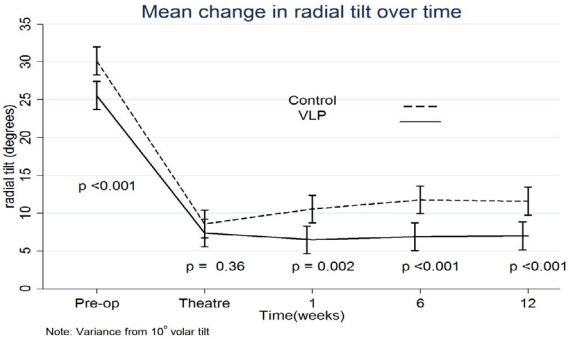

Figure 6: Mean change in radial tilt over time.

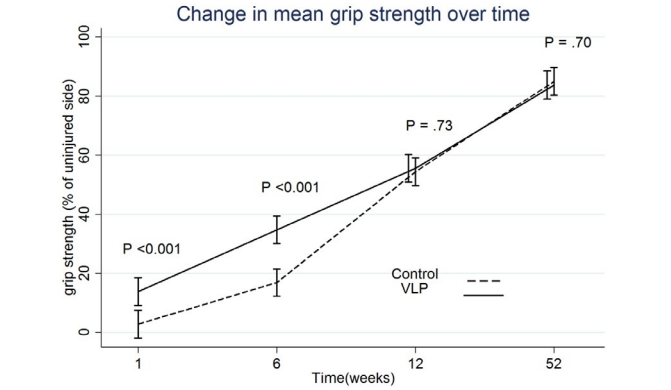

Figure 4: Change in mean grip strength over time.

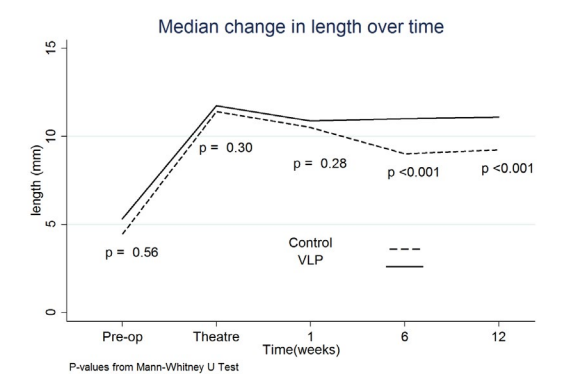

Figure 7: Mean change in radial length over time.

Category	Totals		One week		Six weeks		Twelve weeks		Fifty two weeks	
	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study
General										
Wound Inflammation	5	2	2	2	2	0	1	0	0	0
Infection requiring antibiotics	5	2	0	1	5	0	0	1	0	0
Minor paraesthesia	23	26	12	24	5	1	5	1	1	0
Other	0	1								
Surgical										
Revision of fixation	6	3	2	0	2	1	1	0	1	2
Carpal tunnel release	0	4	0	0	0	0	0	1	0	3
Removal of implant	1	12	0	0	0	1	0	1	1	10
Tendon repair	2	0	0	0	0	0	1	0	1	0
Other surgery	2	1	0	0	1	1	1	0		
Total	44	51								

Table 3: Complications by randomisation.

There was no difference in general complications between groups (p=0.5). A total of 31 further procedures were performed in 23 patients. VLP group reoperations occurred from 3 weeks to 11 months (12 cases, median 142 days, median DASH score 28.8), all requiring removal of implant. Four were operated for median nerve symptoms, undergoing carpal tunnel release, 3 for prominent screws, 2 for pain and stiffness and 3 revised for loss of reduction. Two more cases were scheduled for removal of the VLP during the study period but did not undergo surgery within the 12 months.

Control group re-operations occurred significantly earlier (9 cases, median 42 days, median DASH score 6.7) with adjustment of external fixator (1 case, 2 weeks), removal buried K-wires (1 case, 6 weeks) and 5 cases of loss of reduction (3 K-wires, 1 external fixator and 1 volar buttress plate) converted to VLP between 6 days and 12 weeks. Two cases underwent extensor pollicis longus reconstruction, one at 9 months, another combined with radial osteotomy and VLP fixation at 4 months. The re-operation group's median DASH scores at 52 weeks of 6.7 (control) and 28.8 (VLP) did not reach statistical significance (Mann-Whitney U test), p=0.11, due to low numbers, but the difference is clinically significant [27].

Discussion

Our study shows that despite early mobilization, VLPs afforded no functional advantage as measured by the DASH score, compared to the control group at any time point. This result is comparable however contradictory for findings where VLP showed significantly better functional scores found within the first 12 weeks [12,32].

In the present study, the mean DASH score at 52 weeks was 15.0 VLPs and 13.4 controls similar scores were found in previous studies [1,33]. By using VLP in 63 patients and reported mean DASH score of 19.1 at 3 months, 17.6 at 6 months and 14.4 at 52 weeks. Other research suggests that functional improvement may occur for up to two years following surgery [1,15,23].

The VLP group experienced an increased range of motion in the first 6 weeks compared to control, most of whom were immobilized. However clinical advantage of the VLP declined over time. Despite ongoing improvements to 12 months in both groups, the injured side never regained full ROM (except for supination/pronation).

Our study confirms that the VLP was statistically superior in maintaining fracture reduction. The mean difference between groups in radial tilt was 3.9 and radial length 1.9 mm. Whilst statistically significant, the actual clinical and functional importance of these differences remains to be qualified. Intra-articular incongruity is the main factor for post-traumatic arthritis with a measure of >2 mm considered important [13]. Despite the use of PACS and magnification calculations, radiological measurement of post-operative intra-articular step was difficult, with articular surface obscured by implants. Future research should consider the use of computerized tomography (CT) for examination of articular surfaces [20].

Post-operative VLP complication rates have been reported between 8.7% [12] to 39% [34,35]. There was no difference in the number of complications between the VLP and control group. However, the majority of complications in the control group were minor transient paraesthesias which resolved by week 52, and VLP group showed similar implant removal rates (13%) to other literature 14% and 15% [36,37]. Type C fractures were most common (70%), and increase the potential for complications.

In the elderly population, regaining independence may be considered the primary goal [13,38]. Given that radiological deformity is not always associated with a poor functional outcome the benefits of VLP in elderly patients must be reviewed especially with our aging population [20,38-40].

Limitations of this study may include the involvement of multiple surgeons and often surgeons in training; we believe that this reflects a real life situation, limits surgeon bias and increases the generalizability of our findings. Similarly the 'control group' involved a variety of treatment options (57 K-wires, 23 non-locking plates, 10 bridging external fixators), while this is a true representation of treatment options used within the institution, it may have a confounding effect on results. Sealed envelope randomization was a practical method for this study however there is still potential for bias using this method. Plain radiographs were unable to display articular step accurately, CT scanning would have produced more accurate assessment. Our results cannot determine whether the brief period of earlier mobilization of the VLP group is of sufficient benefit to justify its use. Also whether the superior restoration of anatomy of the VLP group will lead to longer term improvement in function and reduction of degenerative changes.

In summary, VLP allows early mobilization and maintains fracture reduction. However, compared to control group, the advantages afforded by VLPs did not translate into a patient perceived increased functional capacity. The VLP group did not demonstrate any clinical advantage beyond six weeks which corresponds to the period of immobilization of the majority of the control group. There was no difference in the DASH score, at any of the measured time points. There was however a higher late re-operation rate in the VLP group, including removal of the implant.

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