Flexafix: The development of a new dynamic external fixation device for the treatment of distal radial fractures

Goslings, J.C.

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Chapter 9

The Flexafix device in clinical practice

J.C. Goslings, A.H. Broekhuizen †, H. Boxma, E.J. Hauet, Y.E.A. van Riet, J.N. Keeman.
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9.1 Introduction

After the development of the first prototype, the successful application of the new dynamic external fixator in one patient and the subsequent modifications of the prototype, a clinical trial was initiated. This study should reveal the problems and positive events associated with the use of the device. Problems with the device might be related to the size, positioning and locking of the device. Potential post-operative problems could be related to the maintenance of fracture reduction. Positive findings could be related to the time interval between the operation and the time of maximum functional recovery, and to the occurrence of post-operative complications. To achieve this goal, the clinical and radiological outcome of distal radius fractures treated with the new dynamic external fixator (Flexafix) were evaluated during a follow-up period of at least four months.

9.2 Patients and methods

The study was designed as a prospective, non-comparative study. It started with a pilot series at the department of surgery of the Academic Medical Centre in Amsterdam (the Netherlands); hereafter at different time intervals the departments of surgery of the Zuiderziekenhuis Rotterdam, the Academic Hospital at the University of Utrecht and the Sint Lucas-Andreas Ziekenhuis in Amsterdam also participated in the study. Included in the study were patients over 18 years of age, able to give informed consent and available for a follow-up of at least four months. Fracture types which would otherwise be treated by rigid external fixation were included in the study, i.e. unstable fractures (judged by the degree of comminution, displacement and intra-articular fragments), re-dislocated fractures, open fractures and bilateral fracutres.[120] Fractures were classified according to Frykman.[61] In addition to standard operative equipment, small AO external fixator sets, Flexafix devices, and a dynamometer (Jamar Dynamometer, model 2a, Asimov Engineering, Santa Monica, USA) were used. The fixator was applied in a standard configuration with two pins proximal to the fracture in the radius (placed with a limited open surgical approach) and two pins in the second metacarpal.[131] The Flexafix device was positioned in a way that the centre of rotation of the device was located in the centre of rotation of the wrist, i.e. the proximal part of the capitate.[21] Before a surgeon from a participating clinic started with the use of the device an operating manual and instruction videotape were supplied. The first procedure in each clinic was performed in attendance of the senior trauma-surgeon from the development team and/or the author. After the operation a standard protocol for the post-operative management was used. Patients were seen after one or two days, 14 days, six to eight weeks, two weeks after removal of the fixator, after four months and at the time of completion of follow-up. Two weeks after the operation the fixator was dynamised and the patient encouraged to use the hand. Range of motion and complications were registered at these visits.

Standard antero-posterior and lateral X-rays were made two weeks after the operation (when the fixator was dynamised), after six to eight weeks, after four months and at the end of follow up. The primary end points of the study were the functional result according to the criteria described by Gartland and Werley (modified by Sarmiento), a grading system which takes into account residual deformity, the subjective evaluation of the patient, the objective findings and the complications directly arising from the fracture.[5,90] This results in an excellent, good, fair or poor score. The radiological result was classified according to Lidström (modified by Sarmiento).[6,97] Depending on the degree of residual deformity found by measurement of dorsal angle, radial angle and radial length on the follow-up X-rays the patients were divided into four groups: excellent, good, fair or poor (see Appendix A). The clinical and radiological data were converted into median values and interquartile

ranges. The interquartile range (IQR) is the difference between the 75th and 25th percentile and indicates that 50% of the values are in this range. Differences in radiological resp. clinical data during follow-up were analysed with Friedman's chi-square test.
The study protocol was approved by the medical ethical committees of the participating clinics. Informed consent was obtained from each patient prior to inclusion in the study. A detailed description of the protocol is presented in Appendix A.

9.3 Results

9.3.1 Patient and fracture characteristics

From April 1993 to March 1997 44 patients were included in the study. Of these, 21 (48%) were men and 23 (52%) were women. The average age was 45.8 yrs (range 28 - 66) and 57.7 yrs (range 35 - 77) respectively. The fracture was most often caused by a fall on the hand (31 patients, 70%). A fall from a height was the cause of trauma in ten patients (23%) and motorcycle accidents in three patients (7 %). The right hand was fractured in 19 cases and the left hand in 25 cases.
Associated injuries were noted in eight patients. These were fractures of the maxilla (1x), clavicle (1x), rib (1x), opposite wrist (1x), metacarpal (1x), lumbar vertebra (1x), acetabulum (1x), tibia (1x) and calcaneus (2x). One patient sustained a cerebral contusion. No associated cardiovascular, pulmonary or abdominal injuries were seen. Pre-existing illnesses included epilepsy (1 pat.), migraine (1 pat.), psychiatric disease (1 pat.), deafness (1 pat.), hypothyroidea (1 pat.), hypertension (3 pat.), chronic obstructive pulmonary disease (2 pat.), diabetes mellitus (1 pat.) and carpo-metacarpal arthrosis (1 pat.). The medication used by the patients in the study was related to the diseases mentioned.
The fractures were classified according to Frykman and AO (see Chapter 3). Most fractures were classified AO type C (complete articular) or Frykman type VII-VIII (intra-articular fractures of both the radiocarpal and distal radio-ulnar joint). Table 8 shows the distribution of the different fracture types in the study.

9.3.3 Operative procedure

The majority of the patients (77%) was initially treated with a plaster cast. Secondary dislocation was the indication for external fixation in these patients. After informing the patient about the procedure, informed consent was obtained. The operation was done in an outpatient operation facility or during a short stay admittance, excluding the patients with a secondary indication for prolonged hospitalisation. On average, the time between the trauma and the operation was seven days (range 2 - 18) for patients who were not treated primarily by external fixation.

Frykman	nr. pat.	AO-ASIF	nr. pat.
I - II	2	A1	2
III - IV	1	A2	1
V - VI	2	C1	8
VII - VIII	39	C2	13
		C3	20

Table 8.
Fracture types according to Frykman and AO.

In 18 cases (41%), the operation was performed by a resident in co-operation with a consultant and in 26 cases (59%) by a consultant. Length of application (defined as the complete operative procedure described in Chapter 8) was between 30 and 135 minutes (average 65 min.).
Additional fixation methods were used in 24 patients. Of these, 23 consisted of Kirschner wires to stabilise the fracture fragments. In two patients a bone graft was performed during the initial operation, one of them in combination with Kirschner wires. In six cases, Kirschner wires were used during the operative procedure only to facilitate the application of the fixator. At the end of the procedure the Kirschner wires were then removed.
The operative result, as judged by the surgeon, was excellent or good in 38 patients and fair or poor in six patients. Complications encountered during the operative procedure consisted of the shells of the sliding mechanism being very close to the skin (three cases) and suspicion of radial nerve damage (one case). The surgeons made remarks on the difficulty of the reduction in four cases and the complex aiming procedure in four cases.

9.3.4 Follow-up

Of the 44 patients included in the study two were lost to follow-up because trial forms were not filled in or the patient went to another hospital for further treatment. One patient dropped out of the study because she fell and re-fractured the wrist. Treatment was continued in another hospital. Two patients were re-operated before the end of the four months follow-up period. They will be described elsewhere in the chapter.
The results of the remaining 39 patients will be described below. After operation and discharge the patients were seen after one or two days, after two weeks, after six to eight weeks, two weeks after removal of the fixator and at four months. Most of the patient cohort (92%) was also seen more at than four months after the operation. The mean follow-up time was 19 months (range four months to four years).

9.3.5 Functional results

Two weeks after the operation, the fixating cross-bar was removed and the sliding mechanism was unlocked. The patient was then stimulated to use the hand again. Thirty-two patients (82%) received physical therapy during the dynamised period or after removal of the fixator.

Four weeks after dynamisation of the fixator, the median amount of flexion with the Flexafix device still mounted was 30 degrees (IQR 14 to 40°) and the amount of extension 18° (IQR 9 to 30°). These values significantly increased to 40° (IQR 30 to 50°) and 40° (IQR 20 to 50°) resp. two weeks after removal of the fixator, 45° (IQR 40 to 55°) and 50° (IQR 40 to 60°) at four months follow-up and finally 60° of flexion (IQR 40 to 68°) and 60° of extension (IQR 50 to 70°) at the time of end follow up (Fig. 83).

Four weeks after dynamisation the median radial deviation with the fixator on the wrist was 0 degrees (IQR -4 to 5°); the median ulnar deviation was 20 degrees (IQR 10 to 20°). This progressed to 15° (IQR 6 to 20°) and 20° (IQR 11 to 35°) resp. two weeks after removal of the fixator, 15° (IQR 10 to 25°) and 25° (IQR 20 to 30°) at four months, and 20° (IQR 15 to 25°) and 40°(IQR 30 to 45°) at the time of end follow-up (Fig. 84).

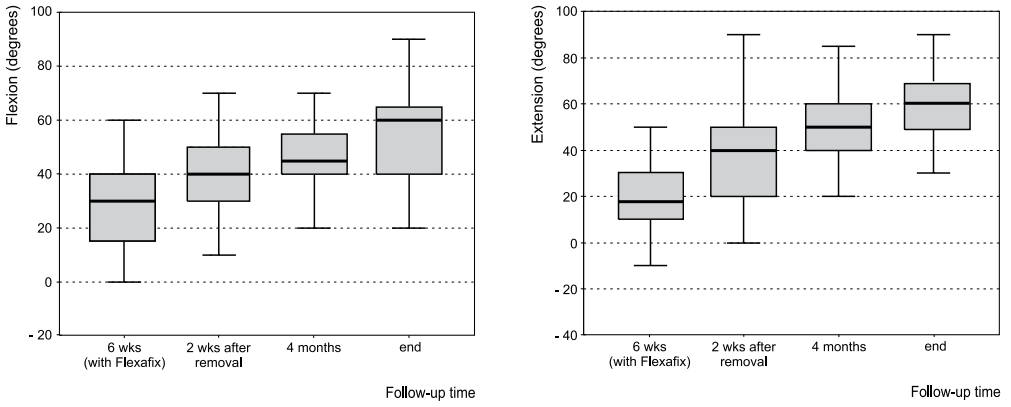

Figure 83. Flexion and extension in relation to time-interval after the trauma.

The median amount of pronation four weeks after dynamisation was 50 degrees (IQR 32 to 70°) compared to 30° (IQR 10 to 45°) of supination. Two weeks after removal of the fixator these values were 75° (IQR 58 to 90°) and 43° (IQR 20 to 66°) resp., at four months 80° (IQR 70 to 90°) and 70° (IQR 55 to 80°) resp. and at the end of follow-up 90° (IQR 78 to 90°) and 75° (IQR 63 to 80°) (Fig. 85).

The functional results according to the criteria described by Gartland and Werley (modified by Sarmiento) showed 10 (28 %) excellent, 16 (46%) good, 8 (23%) fair and 1 (3 %)

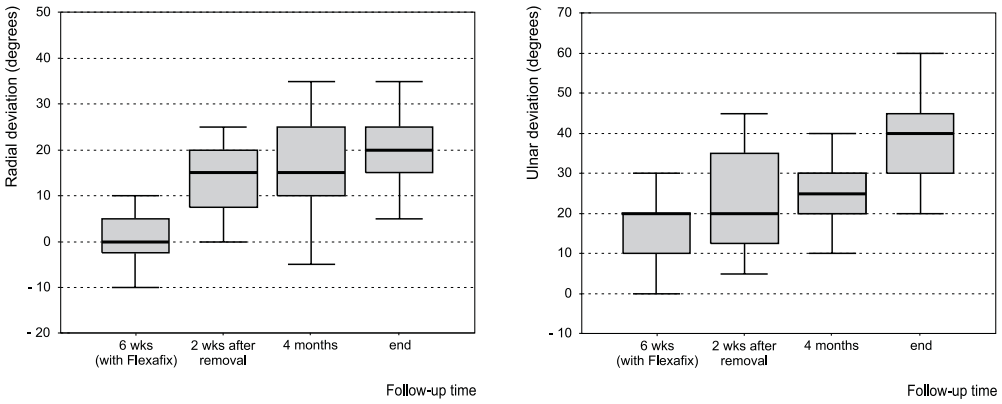

Figure 84. Radial deviation and ulnar deviation in relation to follow-up time.

poor results at four months' follow-up. No exact data regarding function were available in four patients. At the end of follow-up (average 19 months), the functional results had improved (Table 9). Detail data on function in two patients was lacking for this time point.

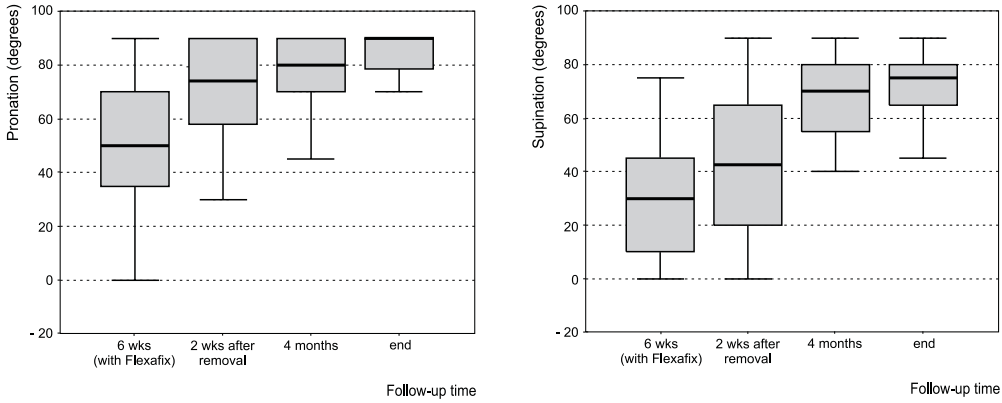

Figure 85. Pronation and supination in relation to follow-up time.

Functional result	**No. of patients (%)**
Excellent	25 (68%)
Good	9 (24%)
Fair	3 (8%)
Poor	0

Table 9. Functional results at the end of follow-up.

9.3.6 Radiological results

Since the sliding mechanism of the fixator was usually located on the lateral side of the wrist, it was not possible to perform reliable measurements (e.g. dorsal angulation) on the lateral X-rays until the fixator was removed. This problem was not seen on the antero-posterior X-rays. Therefore radial length and radial angle could be measured on all these X-rays.

Two weeks after the operation, the median radial length was 11 mm (IQR 9 to 13 mm), compared to 2 mm (IQR 0 to 8 mm) directly after the trauma. During the period of dynamisation, radial length remained the same with 11 (IQR 8 to 13 mm) at six weeks (removal of the fixator). In the time following, radial length tended to decrease slightly to a median of 10 mm (IQR 8 to 13 mm) after four months (not significant). At the end of follow-up (average 19 months), the median radial length was 10 mm (IQR 8 to 13 mm) (Fig. 86).

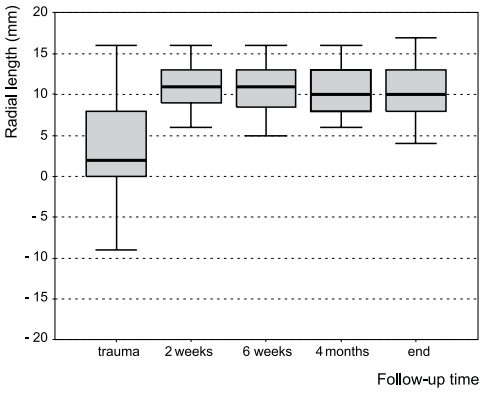

Figure 86. Progress in time of radial length.

The median radial angle was 13 degrees (IQR 8 to 19°) at the time of fracture and 24 degrees (IQR 20 to 28°) after two weeks. Six weeks after the operation the median radial angle was 26° (IQR 22 to 28°), after four months 26° (IQR 22 to 29°) and at the time of end follow-up 24° (IQR 20 to 26°) (Fig. 87). Dorsal angulation, as explained before, could only be measured at the time of trauma and after removal of the fixator. The median dorsal angle after the trauma was 26 degrees (IQR 9 to 36°). At six weeks the median dorsal angle was 2° (IQR -4 to 10°), at four months 4° (IQR -4 to 10°) and at the time of end follow-up 0° (IQR -4 to 8°) (Fig. 88).

When classified according to Lidström, at four months the radiological result was excellent in 11 cases (30%), good in 19 cases (51%), fair in two cases (5%) and poor in five cases (14 %). For two patients no radiological data at this time point were available.

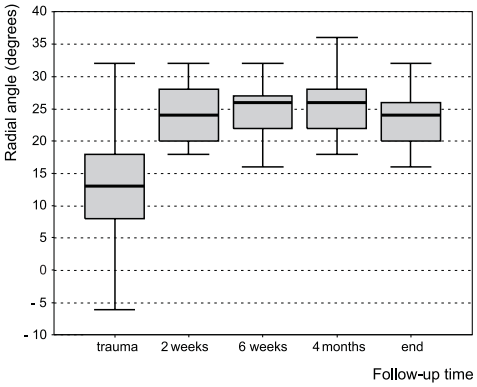

Figure 87. Progress in time of radial angle.

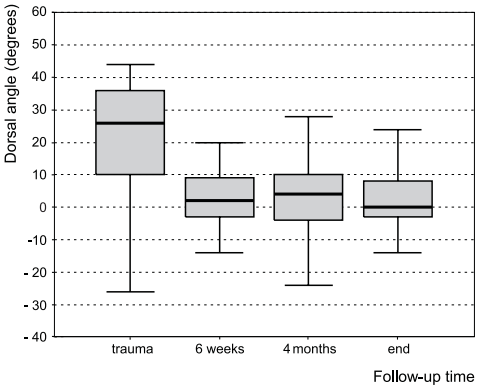

Figure 88. Progress in time of dorsal angle.

Table 10 shows the radiological result at the end of follow-up (average 19 months). For one patient no X-ray data were available at that time point. To give an impression of the course of treatment in individual patients in Appendix B four case histories are presented.

Radiological result	**no. of patients (%)**
Excellent	12 (32%)
Good	19 (50%)
Fair	2 (5%)
Poor	5 (13%)

Table 10. Radiological results at the end of follow-up.

9.3.7 Complications

At each visit the occurrence of complications was noted. These consisted of pin tract infections (nine patients, 22%), nerve impairment (seven patients, 17%), symptoms of reflex sympathetic dystrophy (four patients, 10%), mechanical problems (two patients, 5%), delayed union (one patient, 2%), re-operation (three patients, 7%, including the two patients who dropped out of the study).

The pin tract infections were all treated using conservative measures: moist bandages, elevation, pin care instructions and antibiotics (eight patients). None of the fixator pins had to be removed for reasons of infection but in one patient the Kirschner wires were removed due to infective complications. Nerve complications were frequently seen and occurred in the area of the superficial branch of the radial nerve. Most of the affected patients complained of reduced sensibility of the thumb. The hypesthesia was temporary in six patients and permanent in one patient. Mechanical problems consisted of decreased sliding capacities of the fixator. None of the sliding mechanisms broke down but several showed signs of wear during the period of dynamisation (Fig. 89).
Three patients were re-operated after the initial operation, two of them before they reached the four months' follow-up time and one five months after the initial operation. Of these patients, one showed a persistent dorsal angulation of 22 degrees which was not corrected at the time of fixator placement. This was the fifth patient who was included in the trial. A correction osteotomy was performed and a plate was applied. Two patients had severe pain in the distal radio-ulnar joint. Revision of the initial X-rays showed a luxation of the ulna for which a resection of the distal ulna was performed.

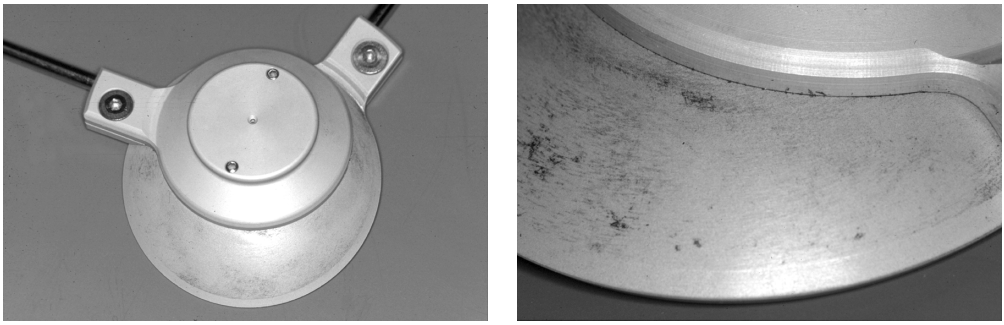

Figure 89 Example of wear at the surface of the shells of the sliding mechanism (left: overview, right: detail).

9.4 Discussion

The fracture of the distal radius can be a difficult fracture to treat, especially in the case of comminution or a secondarily dislocated fracture which is operated on a week or more after the trauma. The use of an external fixator is an accepted method to stabilise unstable fractures and to maintain the length of the radius. This form of treatment has become popular because of the versatility of the devices and the good results of treatment. On the other hand, studies with a long-term follow-up show a high percentage of post-

traumatic arthrosis, sometimes in excess of 50%.[14,16] Others have pointed out the importance of motion in a joint and the circulation of synovial fluid.[13] A generally accepted goal in the treatment of articular fractures is early mobilisation of the affected joint. It is remarkable that this goal is often not reached in fractures involving a joint as important as the wrist. The development of external fixators that provide a way of stability for the fracture in combination with the possibility of early mobilisation is an attempt to improve the recovery of an intra-articular and/or comminuted distal radial fracture.

In this study a newly designed and developed dynamic external fixation device for the treatment of severe distal radial fractures was used. The design of this dynamic external fixation device tested differs significantly from other dynamic fixators in that it allows three degrees of freedom while the centre of rotation of all these movements is in one point, located outside the device. This centre of rotation of the device can be brought in concordance with the assumed centre of rotation of the wrist. Previous devices had either ball-joints as dynamic part of the fixator or a sliding mechanism with only one degree of freedom.[17,18,19,20] The main goals of the present study were to gain experience with the Flexafix fixator and to reveal potential problems associated with its use.

The operative procedure took 65 minutes on average, which maybe somewhat longer than needed for the application of a standard external fixation device. This is explained by the part of the operation in which the sliding mechanism is positioned. The aiming with the help of the aiming device and image-intensifier can be difficult since the reduction has to be held while at the same time the wires of the aiming device are pointed towards the capitate bone (i.e. the centre of rotation) and the bolts are tightened. In six patients, the reduction was temporarily held by two Kirschner wires in the distal radius, which were removed at the end of the operation. This facilitated the application of the sliding mechanism. A certain disadvantage of the present aluminium construction of the Flexafix device is the fact that lateral image-intensifier and X-ray views are largely obstructed by the device. Therefore the operative result is sometimes hard to judge.

After the cross-bar was removed at the fourteenth day post-operatively, the patients started to move the injured wrist. Although some of the patients were afraid to use their hand or experienced pain, the majority were enthusiastic about the mobility of their hand soon after the injury. To enhance the sliding silicon spray was applied between the shells of the sliding mechanism when the fixator was dynamised. Several patients reported successful use of sunflower oil at home in order to keep the sliding properties good. It is not yet clear whether the moment chosen for dynamistion of the fixator (14 days post-operatively) is ideal. Pennig advised the Orthofix device to be released after three weeks, whereas Asche advises to start with movements as early as the third post-operative day.[18,20] More research is needed to select the best moment.

During the period of dynamisation, with a median flexion of 30 degrees, extension of 18 degrees, radial deviation of 0 degrees and ulnar deviation of 20 degrees, the range of motion needed to perform activities of daily life is approached. Palmer reported the normal functional range of motion used to perform these activities of daily living to be 5° of flexion, 30° of extension, 10° of radial deviation and 15° of ulnar deviation.[47] Ryu found that the majority of the evaluated tasks could be performed with 40° of combined flexion extension and 40° of combined radio-ulnar deviation.[48]
The functional result at the end of follow-up (average 19 months) of the patients in this study was excellent or good in 92% and fair or poor in 8%. These results are comparable to results published in reports using rigid external fixators.[9,16,119,120,122,124,143,144] There were eleven patients whose functional result at the last follow-up was better than at four months follow-up, implicating that the function can still improve after four months. From these data we cannot conclude that the dynamic fixator is superior to rigid external fixators. However, only two weeks after removal of the fixator the median range of motion was 40° of flexion, 40° of extension, 15° of radial deviation and 20° of ulnar deviation, which seems a good result for a short period after removal of the fixator. In comparison with other dynamic external fixators the results of the Flexafix device are certainly not inferior. Functional results were graded as excellent or good in 92% of our patients, compared to 73 to 90% in other studies (Table 11).[159,160,161,162,163,164]
The radiological results were excellent or good in 82% and fair or poor in 18%. These results are also comparable to reports with other dynamic external fixators (Table 11).[159,160,161,162,163,164] When the three radiological measurements in the course of follow-up are evaluated it is seen that the radial angle in our study was restored from 13 degrees (median) at the time of fracture to 24 degrees after operation. This was not significantly different at time of completion of follow-up. Average dorsal angulation after the trauma was 20.5 degrees compared to 1.0° at the time of end follow-up. Radial length was 2 mm (median) directly after the trauma and 11 mm at two weeks. During dynamisation it decreased only minimally to 10 mm at the end of follow-up (not significant). From these data we can conclude that in spite of the early mobilisation with the fixator still on the wrist, reduction was maintained.
Sommerkamp et al. in their study with the Clyburn dynamic external fixator observed an average radial length of 5 millimetres before the operation, 15 millimetres after application and 11 millimetres at the time of removal.[161] This means a loss of radial length of 4 millimetres between application and removal of the fixator. Dorsal angulation was 28 degrees before, 7° after the operation and 8° at the time of removal. Radial deviation was 7° before reduction, 23° after application of the fixator and 23° on removal of the fixator.

The radiological results obtained with the Flexafix device used in this study are hard to review in part because the lateral X-rays are obstructed by the Flexafix device. Therefore,

Author	Lennox	Merchan	Klein	Sommerkamp	Asche	Dienst	present study
Year	89	92	92	94	95	95	98
Number pat.	20	35	38	24	102	30	39
Female/	65%	20%	40%	42%	69%	80%	52%
male	35%	80%	60%	58%	31%	20%	48%
Age (mean)	55	37	46	34	54	45	52
Device	Clyburn	Clyburn	Pennig	Clyburn	Asche	Asche	Flexafix
Follow-up (months,mean)	16	12	20	12	7	6	19
Fracture type (Frykman)	all VII - VIII	all III - VIII	56% VII-VIII	75% VII-VIII	62% III-VIII	63% III-VIII	89% VII-VIII
Results (%)							
Functional							
excellent	70	51	32	32		20	68
good	20	29	41	44		67	24
fair	10	17	24	24	91	13	8
poor	0	3	3	0		0	0
Radiological							
excellent	no data	54	42	4	98	50	32
good		34	42	56		47	50
fair		9	8	12	2	3	5
poor		3	8	28	0	0	13

Table 11. Comparison of results with various dynamic external fixators. [159,160,161,162,163,164]

the dorsal angulation cannot be measured accurately until the fixator is removed. This problem is not seen with the antero-posterior views. Theoretically, it is possible that a sub-optimal radiological result was caused by a technical failure during the positioning of the sliding mechanism. A close review of the X-rays of the patients with a fair or poor radiological result revealed that in these cases the positioning of the device was probably not optimal. One cannot expect a good radiological end result if the radiological result (i.e. reduction) is not good at the time of operation. This means that conserted efforts should be made to obtain a good reduction and to carefully position the device during the operative procedure. Others have advised to achieve reduction with less than 20° of dorsal angulation, more than 10° of radial angulation and loss of radial length of less than 6 mm.[163] Additional Kirschner wire fixation of the fracture fragments could provide more stability but in the present study the functional and radiological results of the patients with and without additional K-wire fixation were equal. This could possibly be explained by the severity of the fracture types that were treated with additional K-wires.

As Vaughan found in his study, the patient group can be split in a two groups: elderly patients (above 55 years) who most often sustain a low-energy accident like a fall on the hand, and a younger group (below 55 years) who often sustain a more violent accident like motor vehicle accidents or falls at work from a height.[9] Radiological results in the present study were not substantially different between patients younger than 55 years and

those above 55 years of age. The functional results were excellent or good in 96% of the patients younger than 55 years compared with 81% in the group older than 55 years.
Complications were rather frequent in the present series. Pin-tract infections occurred in 22% of the patients. The majority of these infections were at the site of the pins in the radius. A possible explanation could be the interaction between the soft tissues and the pin during the period of dynamisation. All infections were treated by pin care measures, drainage and/or antibiotics. One patient had loosening of the pins with loss of reduction. Other studies with dynamic external fixators reported varying percentages of infections, possibly due to different classification. Klein found only three pin-tract infections in 56 patients; Merchan found four infections in 35 patients.[160,164] In his series of 34 patients Sommerkamp found a much higher rate with 13 of 24 patients showing signs of infection.[161]
Despite the use of a limited open surgical approach for pin placement, seven patients had paresthesia of the superficial branch of the radial nerve. Of these, six resolved and 1 was persistent. This could mean that either the surgical technique was inadequate or that mechanical irritation of the nerve occurred at the site of the pin. The rate of nerve complications was comparable to other studies, in which incidences varied between 2 and 17% (see Chapter 4).[124,126,127,146,147,148,149]
Although the device use in this study was newly designed, there was only one case in which the fixator could not be dynamised because of mechanical problems. Some fixators had minor problems with the sliding properties. This can be explained by the metal surfaces sliding over each other in the sliding mechanism or by the presence of blood in the device. Klein encountered four dislocations of the ball joint in the Orthofix device in 56 patients, after which the device was adjusted.[164] Lennox reported one failure of the Clyburn device in 20 patients.[159]

9.5 Conclusion

The present study reports experience with a new biomechanical concept of dynamic external fixation of distal radial fractures. The radiological result was excellent or good in 82% of the patients and the functional result was excellent or good in 92% of the cases. These figures are comparable to the treatment results with other dynamic and static external fixation devices. Regarding the severity of the fracture types and the fact that a new device was used this can be regarded as a positive conclusion. Also, it is important that reduction was maintained in spite of the early dynamisation of the injured wrist.
A beneficial effect of the dynamic aspect of the fixator could not be demonstrated clearly since the study was non-comparative. As mentioned before, the range of motion two weeks after removal of the fixator seems relatively good. Also, the response with

regard to this device was very positive in the majority of the patients though the effect of dynamisation on the quality of life is a point for further research. To show a distinct advantage of dynamic external fixation over static external fixation a prospective study with a long-term follow-up would be needed because none of the present available studies meets these criteria when critically reviewed. Only the long-term results can possibly show a presumed decrease in the rate of post-traumatic athrosis and disuse osteopenia explained by the advantage of early radiocarpal motion. Before we can conclude that dynamic external fixation is either advantageous or unnecessary, the design of the dynamic fixators needs to be be optimal.

The Flexafix dynamic external fixation device is a new acquisition in the range of available dynamic external fixators for the treatment of distal radial fractures. The new biomechanical construction and the first treatment results are encouraging. However, the device needs further development, especially to allow lateral X-ray views. The use of different materials or surface treatment methods could also further enhance the sliding properties of the fixator.