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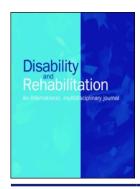
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ORIGINAL ARTICLE



The evolution of radiological measurements and the association with clinician and patient reported outcome following distal radius fractures in non-osteoporotic patients: what is clinically relevant?

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ABSTRACT

Introduction: Following distal radius fractures in young non-osteoporotic patients, clinical relevancy of outcome has been scarcely reported. Outcome can be put in perspective by using measurement errors of radiological measurements and Minimal Important Change when reporting on clinician and patient reported outcome. Aim of this study was to assess the clinical relevance of radiological measurements, clinician and patient reported outcomes following distal radius fractures in young non-osteopor-

Methods: Retrospective cohort study. Non-osteoporotic patients following a distal radius fracture were selected. Radiographs of both wrists were obtained at baseline, 6 weeks and at follow-up. Active range of motion and grip strength measurements were obtained at the follow-up visit and 4 questionnaires were answered to assess pain, upper extremity functioning, and health status.

Results: Seventy-three patients (32 women, 41 men) with a mean age of 33.5 (SD 9.2) years at the time of injury were included. Median follow up was 62 months (IQR 53.0-84.5). Several radiological measurements evolved statistically significantly over time, however none exceeded measurement errors. Flexion/ extension difference of injured compared to uninjured wrist (mean difference 11.2°, t = -7.5, df = 72, p < 0.001), exceeded Minimal Important Change, while grip strength differences did not. When comparing patients with DRFs to healthy controls, only the differences on Patient Reported Wrist Evaluation subscales "pain", "function" and total scores exceeded minimal important change (8, 10 and 13 points, respectively). Multivariable regression analysis revealed statistically significant relationships between residual step-off and respectively diminished flexion/extension (B = -36.8, 95% CI -62; -11.1, p = 0.006), diminished radial/ulnar deviation (B = -17.9, 95% CI -32.0; -3.9, p = 0.013) and worse ShortForm-36 "mental component score" (B = -15.4, 95% CI -26.6; -4.2, p < 0.001).

Conclusion: Radiological measurements following distal radius fractures seem to evolve over time, but differences were small and were probably not clinically relevant. Range of motion, in particular flexion/ extension, was impaired to such extend that it was noticeable for a patient, whereas grip strength was not impaired. The Patient Reported Wrist Evaluation was clinically relevantly diminished. Residual articular incongruency seems to influence range of motion.

> IMPLICATIONS FOR REHABILITATION

- Reporting Minimal Important Change regarding clinician and patient reported outcome following distal radius fractures is of more clinical value than reporting on statistical significance.
- Following distal radius fractures, the changes in radiological measurements do not seem to reflect a clinical relevant change.
- Range of motion, in particular flexion/extension, should be measured following distal radius fractures, as this might be impaired in a clinically relevant way.
- Measuring grip strength is of less importance following distal radius fractures, because grip strength does not seem to be affected.
- Residual articular incongruency seems to influence range of motion and therefore should be reduced to a minimum when treating non-osteoporotic patients.

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KEYWORDS

Distal radius; radiological measurements; functional outcome; patient reported outcome

Introduction

Associations of radiological measurements with outcomes in young non-osteoporotic patients who sustained a distal radius fracture (DRF) have been described in a limited number of studies [1-3]. Radiological measurements that have mostly been used to describe the anatomy of the distal radius following a fracture are ulnar variance, radial length, radial inclination and dorsal angulation [4-9]. Normal ranges for radiological measurements have previously been described [4–9]. Recent literature puts these measurements in perspective by reporting on questionable intraand interrater reliability and considerable error magnitudes of radiological measurements following DRFs [10]. In addition, it has been described that DRFs in young non-osteoporotic patients often have intra-articular involvement, since they are more involved in high-energy trauma than older people, who mostly sustain DRFs after low or medium energy trauma [11]. This can result in residual articular incongruence, which is usually described in step-offs and gaps [12-17]. Error magnitudes of residual gaps and/or steps have been reported to be within 1–2 mm [10]. As intra- and interobserver reliability of measuring residual gap and step were reported to be moderate to poor, it has been questioned if these radiographic measurements should be used as criteria for guiding treatment to be conservative or surgical [10,18]. Intercarpal ligamentous injuries, radiologically reflected in the distance between scaphoid and lunate (SL distance) and distal radio-ulnar joint (DRUJ) instability are also associated with DRFs and might influence outcome [11,19,20].

To interpret change scores of Clinician Reported Outcomes (CROs: range of motion or grip strength), and Patient Reported Outcomes (PROs: questionnaires) two benchmarks are required: the smallest detectable change (SDC) and the minimal important change (MIC), which the Consensus-based Standards for the development of Measurement Instruments (COSMIN) group defines as respectively "the smallest change that can be detected by the instrument, beyond measurement error" and 'the smallest change in construct to be measured which patients perceive as important [21-23]. Most literature reports on SDC when reporting on outcomes following DRFs. This is a statistical measurement and does not take into account change as experienced by patients. Clinically more relevant is the MIC, which is the smallest change in an outcome measurement that a patient would perceive as important [21-24]. If the value of the MIC is less than that of the SDC, the MIC is within the limit of measurement errors or change [25,26]. Therefore, the MIC represents true clinical change when the value of the MIC is more than that of the SDC. The MIC threshold is very important in daily practice, where clinicians can compare at a patients' individual level, the current and previous values of outcome measures of interest. MICs regarding outcomes following DRFs have been reported scarcely on CROs [27,28] and PROs [29-31].

The association between radiological measurements and CROs, such as active range of motion (aROM) and grip strength measurements, remains unclear [1,8,13,32-39]. The association between radiological parameters and PROs presents conflicting results regarding patients of osteoporotic ages [13,33,34,40]. However, in young patients malalignment and ligamentous injury following DRFs is significantly more often associated with poorer CROs and PROs than in patients over 60 years of age [2,3]. We hypothesize that non-osteoporotic patients have higher demands of their wrist, because of an active working life and therefore might experience more impact of diminished function in daily life.

Summarizing existing literature, there seems to be a need for better understanding of changes in radiological measurements,

their relation with outcomes and clinical relevancy of both radiological measurements and outcomes in young non-osteoporotic patients who sustained a DRF.

Aim

The aim of this study was to assess the clinical relevance of radiological, CROs, PROs following DRFs. The objective of this study was threefold; (1) to report on the clinical relevance of changes in radiological measurements, (2) to report on the clinical relevance of CROs and PROs and (3) to analyze associations between radiological measurements and CROs and PROs following DRFs in young non-osteoporotic patients.

Methods

This retrospective cohort study was approved by the Medical Ethics Committee (NL41587.099.13) and registered at the Dutch Trial Registration (TC 4002). Before entering the study, participants signed an informed consent form. All patients with a DRF who presented at a level II trauma center between January 2005 and January 2011 and who were considered to be in a non-osteoporotic age range (men 18-50 years, women 18-40 years at the time of the injury) were retrieved from the local trauma registry database. The age criteria were chosen to minimize the chance of including patients with pre-existent osteoporosis [41-43]. Medical histories regarding risk factors for osteoporosis and the radiographs were analyzed as well for signs of osteoporosis and patients were excluded if osteoporosis was present. Additional exclusion criteria were fractures treated after the 7th day following injury, open fractures, pre-existing osteoarthritis or risk factors for early osteoporosis (steroid use, alcohol abuse or early menopause), because outcomes in patients with these risk factors might not be representative for non-osteoporotic patients.

Patients were invited to pay a single visit to the hospital for functional measurements and radiographs of both wrists. Radiographs were retrieved before treatment, immediately after intervention (closed reduction or surgical treatment), at 6 weeks following injury and at the participants' visit at follow up. For this study, baseline radiographs were defined as the accepted position of the DRF (either not needing reduction or following intervention) within 7 days following injury. At the time of the participants' visit, lateral (Lundy) and posteroanterior (PA) wrist radiographs were made of both wrists. According to the international commission on radiological protection the estimated risk for the radiological procedure (4 x-rays per participant) is categorized as a very low level of risk of radiogenic cancer, >0.2 and <2 mSv [44]. All radiographs (baseline, 6 weeks and at follow up) were evaluated by a single radiologist specialized in musculoskeletal disorders with a special interest in hand and wrist anatomy.

Radiological parameters were measured according to the technique described by Kreder et al.; ulnar variance, radial length, radial inclination and dorsal angulation and step-off and gap (Figure 1) [18,45]. In addition, the SL distance [46,47] and the DRUJ space were measured [48,49] (Figure 1). Normal ranges and error magnitudes for radiological factors have previously been described and are depicted in Table 1.

To correct for anatomical variation between patients, radiographs of the uninjured wrist were obtained at follow up and used as a reference to interpret measurements of the injured wrist at baseline, at 6 weeks and at follow up.

At the visit to the hospital at follow up, a single hand therapist recorded all CROs: active range of motion (aROM) and strength

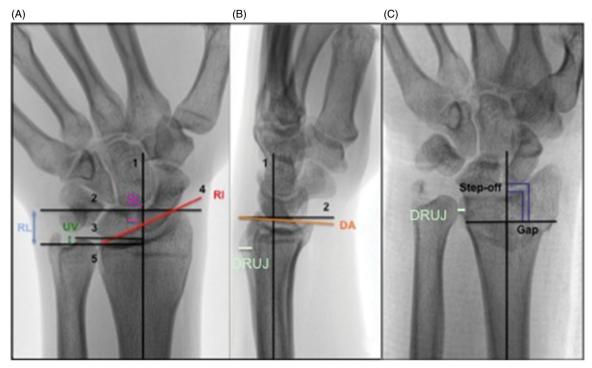


Figure 1. (A) Posteroanterior measurement guidelines: (1) The center of the radial shaft is determined at 3 cm and 5 cm below the mid-region of the proximal lunate articular surface. This line represents the central axis of the radius. (2) A line perpendicular to the central long axis of the radius is drawn at the level of the most distal aspect of the radial articular surface. (3) A line perpendicular to the central long axis of the radius is drawn at the level of the ulnar margin of the distal radial articular surface. (4) The radial and ulnar margins of the distal radial articular surface are connected. (5) A line perpendicular to the central long axis of the radius is drawn at the level of the distal ulnar articular surface. (B) Lateral measurement guidelines: (1) The center of the radial shaft is determined at 3 cm and 5 cm below the mid-region of the proximal lunate articular surface. This line represents the central long axis of the radius. (2) A line perpendicular to the central long axis of the radius is drawn at a convenient level. (3) The dorsal and anterior margins of the distal radial articular surface are connected. (C) Step-off and gap measurement. (1) Step-off at the articular surface of the distal radius was measured parallel to the central long axis of the radius by drawing perpendicular lines from the most distal margin of each side of the articular incongruence. (2) Gap deformity was measured along a perpendicular line to the central long axis of the radius. UV: ulnar variation; RL: radial length; RI: radial inclination; DT: dorsal tilt; SL: scapholunate ligament; DRUJ: distal radioulnar joint.

Table 1. Peteropee values error magnitudes for radiological measurements and SDCs and MICs for CDCs and DDCs

Radiological measurements	Normal ranges	Error magnitudes [10]		
Ulnar variance (mm)	-4 to 2 [4,5]	2–4	<u> </u>	
Radial length (mm)	8–17 [5]	4–6		
Radial inclination (°)	16–29 [6,7]	6–8		
Dorsal angulation (°)	0–22 [8,9]	6–8		
SL distance (mm)	<2.0 [47]	0 0		
DRUJ distance (mm)	Related to uninjured wrist [48,49]			
Step-off (mm)	NA	1–2		
Gap (mm)	NA	1–2		
CROs	Mean (SD) [50]	SDC	MIC	
Range of motion (°)				
Flexion/extension	150 (20)	4.3-5.0	5.0-7.1 [27]	
Ulnar/radial deviation	61 (12)			
Supination/pronation	164 (14)			
Grip strength measurements (kg)				
Grip strength	45.1 (14.3)	6.5	6.5 [28]	
Sustained grip strength	29.6 (10.6)			
Key pinch strength	9.0 (2.4)			
PROs	Mean (SD) [50]	SDC	MIC	
DASH	3 (6)	10.8	10.8 [29]	
PRWE	1.7			
Pain	1 (2)	6.5	1.5 [31]	
Function	0 (1)	4.5	10	
Total	1 (3)	11.0	11.5	

SDC: smallest detectable change; MIC: minimal important change: CROs: clinician reported outcomes; PROs: patient reported outcomes; DASH: disability of arm, shoulder and hand questionnaire; PRWE: patient reported wrist evaluation; MHQ: Michigan Hand Questionnaire, SF36: short form3.

measurements. The participants were positioned sitting at a table, with hips and knees flexed in 90 degrees. Elbows were positioned on the table and flexed in 90 degrees with wrists in neutral

position. The aROM of flexion/extension, ulnar/radial deviation and supination/pronation was measured using a digital protractor of Biometrics LTD and computed using E-Link® software and was

presented in degrees. Grip strength, sustained grip strength and key pinch strength were measured using a digital Jamar dynamometer using Biometrics LTD and E-Link® software and presented in kilograms and as percentage of the uninjured hand. Grip strength and key pinch strength were presented in kilograms, and were derived from the maximum peak strength sustained during at least 2s. The mean of three performances was calculated. For assessing sustained grip strength, patients were asked to grip as hard as they could using the dynamometer during a 30 s period. Sustained grip strength is the average grip strength in kilograms, computed over the last 18 s of this 30-s period. For people with right sided dominance it is known that the right hand has 10% more grip strength in comparison to the left hand [51]. This is not the case when people are left sided dominant or ambidexter; grip strength in both hands is similar. Therefore, correction for dominance with the 10% rule was performed for grip strength measurements in individuals with right sided dominancy. First, all aROM measurements were recorded and subsequently grip strength measurements were assessed. Measurements were performed for both wrists. In addition, reference values for CROs in a healthy population (n = 22, median age 48.5 years, IQR 39.5; 64.3) were derived from a previous published paper by our research group (Table 1) [50]. The SDCs en MICs as reported in literature for flexion/extension and grip strength are reported in Table 1 [27,28].

All patients completed 4 questionnaires involving pain scores, specific upper extremity functioning, and health status. Reference values for PROs in a healthy population were derived from the earlier mentioned 22 healthy controls (Table 1) [50].

The Disability of Arm, Shoulder and Hand (DASH) Questionnaire is a 30-item self-report measure assessing physical functioning and symptoms of the upper limb. DASH-scores range from 0 to 100 (higher scores indicate worse function). The DASH has a good validity, reliability and responsiveness in upper extremity disability assessment [52,53]. MIC of the DASH questionnaire has been described to be 10.83 points and SDC 10.81 points in 255 patients following upper limb musculoskeletal disorders with a mean age of 49 years and short follow up duration (Table 1) [29].

The Patient Rated Wrist Evaluation (PRWE) is a 15-item guestionnaire divided into two subscales: pain (5 items) and function (10 items). The PRWE was developed to assess pain and functioning in patients with DRFs [54]. The pain items were selected to represent the total spectrum of frequency and intensity. The function items were selected to represent a range of physical activities that require different ranges of motions or muscle strength capabilities. For both subscales the maximum score is 50 (most disability) and the minimum score is 0 (no disability). Although these subscales have been reported frequently in literature, it has been suggested that the PRWE measures a single dimensional trait, and a single (sum) score should be used [55]. The questionnaire has a good validity for symptoms and function of the wrist [56]. For the PRWE following DRFs in 102 patients with mean age of 59 years, MIC has been determined at 11.5 points, while SDC was achieved at 11.0 points (Table 1) [31].

The Michigan Hand Outcomes Questionnaire (MHQ) assesses hand outcomes that are of importance to patients and specifically for the impaired hand (left and right separately) and includes 6 subscales; general function, activities of general life, work, pain, esthetics and satisfaction. The subscale score is the sum of the outcome of each guestion and ranges from 0 to 100. A higher score on the pain subscale indicates less pain. For the other five subscales and the total score higher scores imply a better function. The MHQ compares favourably with other PROs regarding upper extremity in the area of test-retest reliability, validity and responsiveness. In addition it has high internal consistence [57]. The strength of the MHQ is its multidimensional construct in measuring symptoms, function, aesthetics and satisfaction [57]. It has been reported that no discriminative ability is present as captured in MIC for the MHQ following DRFs, because of the ceiling effect with high scores at 3 months follow up and only a mean change of 10 points (mean score 3 months 78, mean score 12 months 89) [30].

The SF-36 is developed to survey overall health status [58]. It contains 36 questions to assess limitations in (1) physical function, (2) role function, (3) social function, (4) bodily pain, (5) general mental health, (6) limitations in role function due to emotional problems, (7) vitality and (8) general health perception. Scale scores range from 0 to 100 with higher scores indicating a better health status. Scale scores can be used to calculate a physical and a mental component summary score [58]. Validity of this guestionnaire is sufficient for groups reporting varying extents of illness-health [59]. To our knowledge, no SDC or MIC values regarding the SF36 have been published.

Statistical analysis

Continuous data were presented as means (SD) or as median (IQR) if no normal distribution of the data was present. T-tests were performed when analyzing continuous variables if a normal distribution was found and outcome was presented with t-values and degrees of freedom (df). If continuous data did not have a normal distribution, Mann Whitney U tests were applied and outcome was presented with U-values. Explanatory variables were included in the multivariable regression analysis when the p-value was <0.2 in the univariable regression analysis. Multivariable linear regression analysis, using backward stepwise selection (until all p values were <0.2 to avoid excluding important risk factors) was performed analyzing radiological measurements as explanatory variables and CROs and PROs as dependent variables. Outcome of the multivariable regression analyses were presented with B-values (regression coefficient). Level of significance was set at $p \le 0.05$. All statistical analyses were performed using IBM SPSS, version 22.

Results

A total of 433 patients fulfilled the inclusion criteria and received an invitation to participate in the study. A notification of changed home address was received from 43 participants of whom current addresses could not be retrieved. From 306 patients, no response was received. Eighty-four patients responded of which seventythree patients (32 women, 41 men) with a mean age of 33.5 (SD 9.2) years at the time of injury, consented for participation after a median follow up of 62.0 months (IQR 53.0-84.5) (Table 2).

Radiological measurements

Baseline versus six weeks

DRUJ distance increased between baseline and 6 weeks postinjury (2.0 versus 2.4 mm, t = -2.3, df = 42, p = 0.024). No other statistical significant differences between the measurements at baseline and 6 weeks were present and all measurement changes were within magnitude error (Table 3). SL distance at baseline and at 6 weeks exceeded the normal range of <2.0 mm by 0.2 mm.

Six weeks versus follow-up

Between 6 weeks and follow-up, ulnar variance and radial inclination increased ((mean 0.4 mm versus 1.12 mm, t = -4.3, df = 49, p < 0.001 and 24.3° versus 25.2°, t = -2.3, df = 49, p = 0.028, respectively) increased (Table 3). In contrast, the step-offs and gaps diminished (step-off 0.4 versus 0.1 mm, t = 2.2, df = 31, p = 0.032, gap 1.5 versus 0.1 mm, t = 3.7, df = 33, p = 0.001) (Table 3). However, none of the measurement changes exceeded error magnitudes. SL distance at 6 weeks and follow-up exceeded the normal range of <2.0 mm with respectively 0.2 and 0.1 mm.

Injured versus uninjured wrist

When comparing the radiological measurements of the injured to the uninjured wrist at follow up, dorsal angulation was statistically significantly more pronounced in the injured wrist (-1.3° versus -5.1° , t = 5.0, df = 72, p < 0.001) (Table 4). This measurement change did not exceed the reported error magnitude of 6-8°.

Table 2. Patient characteristics.

	Total population (N = 73)
Age at time of the injury (years)	
Mean (SD)	33.5 (9.2)
Follow up (months)	
Median (IQR)	62.0 (53.0; 84.5)
	N (%)
Gender	
Male	41 (56.2)
Female	32 (43.8)
Energy trauma	
Low energy	20 (27.4)
High energy	45 (61.6)
Unknown	8 (11.0)
AO/OTA Classification	
Α	14 (19.2)
В	30 (41.1)
C	29 (39.7)
Dominant hand injured	37 (50.7)
Left sided dominancy	2 (5.4)
Right sided dominancy	30 (81.1)
Ambidexter	5 (13.5)
Treatment	
Cast	33 (45.2)
Closed reduction/cast	12 (16.4)
Surgical	28 (38.4)

N: number of patients; SD: standard deviation; IQR: interguartile range; AO/OTA: Arbeitsgemeinschaft fur Osteosynthesefragen/Orthopedic Trauma Association classification.

CROs

All aROM measurements of the injured wrist were statistically significantly lower in comparison to the uninjured wrist at follow up (respectively flexion/extension 141.3° versus 152.5°, t = -7.5, df = 72; ulnar/radial deviation 58.1° versus 649.9°, t = -5.9, df = 72; pro/supination 146.7 versus 152.0°, t = -3.4, df = 72, all p < 0.001) (Table 5). With regard to flexion/extension the difference of 11.2° exceeded the reported MIC of 5.0-7.1°.

Grip strength of the injured wrist was statistically significantly lower in comparison to the uninjured wrist at follow up (respectively 43.5 kg versus 46.1 kg, t = -3.8, df = 72, p < 0.001) (Table 5). The grip strength difference of 2.6 kg between the injured and uninjured wrist did not exceed the reported MIC of 6.5 kg.

PROs

When comparing PROs with outcomes as reported for healthy controls, the differences for PRWE subscales pain (8), function (10) and total PRWE score (13) all exceeded the reported MICs. The difference between DASH scores did not exceed the reported MIC of 10.83 (Table 6).

Associations between radiological measurements, CROs and PROs

The results of the univariable regression analyses are presented in Tables 7 and 8. Multivariable regression analyses revealed that step-off was statistically significantly associated with diminished flexion/extension as well as ulnar/radial deviation (respectively B = -36.8, p = 0.006 and B = -17.9, p = 0.013, respectively) (Table 9). Multivariable analyses revealed that shorter radial length was associated with diminished grip strength, sustained grip strength and key pinch strength measurements (B = 2.8, B = 2.1, and B = 0.5, all p < 0.001, respectively) (Table 9).

Only SF36 physical component score and mental component score were entered in the multivariable regression analyses (Table 10). SF36 mental component score was associated with step-off (B = -15.4, p = 0.008).

Discussion

Multiple radiological measurements changed statistically significantly over time. However, none of the measurement changes exceeded reported magnitude errors. As such, clinical relevancy could not be revealed.

All aROM measurements were statistically significantly diminished in the injured wrist compared to the uninjured wrist. Since MIC is only reported for flexion/extension, this finding appeared to be clinically relevant. Although grip strength was statistically

Table 3. Radiological measurements at baseline, 6 weeks and follow up.

		Baseline	6 weeks	Follow-up	Baseline ve	rsus 6 weeks	6 Weeks	versus follow-up
Radiological measurements	N	Mean (SD)	Mean (SD)	Mean (SD)	Mean difference (SD)	p-value (95% CI of mean difference)	Mean difference (SD)	<i>p</i> -value (95% CI of mean difference)
Ulnar variance (mm)	48	0.4 (2.0)	0.5 (1.8)	1.1 (1.9)	-0.7 (1.2)	-0.7 (1.2)	-0.7 (1.2)	<0.001 (-1.1; -0.4)*
Radial length (mm)	47	12.2 (2.5)	12.8 (2.0)	12.7 (2.1)	−.7 (1.2)	0.817 (-0.6; 0.5)	0.2 (1.3)	0.897 (-3; 0.4)
Radial inclination (°)	49	23.7 (4.1)	24.4 (3.9)	25.2 (3.9)	0.2 (1.3)	0.113 (-1.4; 0.2)	-0.9(2.8)	0.028 (-1.7; -0.1)*
Dorsal angulation (°)	46	-0.6 (7.3)	-0.2 (7.9)	-0.2 (7.3)	-0.9(2.8)	0.288 (-2.1; 0.6)	0.0 (5.2)	0.978 (-1.5; 1.5)
SL distance (mm)	34	2.2 (0.5)	2.2 (0.4)	2.1 (0.4)	0.0 (5.2)	0.627 (-2.1; 1.3)	0.1 (0.4)	0.114 (-0.0; 0.3)
DRUJ distance (mm)	43	2.0 (0.7)	2.4 (0.8)	2.4 (0.8)	0.1 (0.4)	0.660 (-0.2; 0.1)	-0.0(0.7)	0.843 (0.2; 0.2)
Step-off (mm)	37	0.6 (1.2)	0.5 (1.0)	0.1 (0.4)	-0.0 (0.7)	0.024 (-0.6; -0.0)*	0.3 (0.9)	0.032 (0.0; 0.7)*
Gap (mm)	43	1.7 (1.6)	1.7 (1.8)	0.5 (1.4)	0.3 (0.9)	0.845 (-0.3; 0.3)	1.0 (1.6)	0.001 (0.5; 1.6)*

Results of paired samples T test.

N: number of patients; SD: standard deviation; 95% Cl: 95% confidence interval; *significant difference; SL: scapholunate ligament; DRUJ: distal radioulnar Joint° degrees; mm: millimeters.

Table 4. Radiological measurements of the inured and uninjured wrist at follow-up.

Radiological measurements	N	Follow up injured wrist Mean (SD)	Follow-up uninjured wrist Mean (SD)	Mean difference (SD)	Significance <i>p</i> -value (95% CI of mean difference)
Ulnar variance (mm)	73	0.9 (1.8)	0.4 (1.6)	0.4 (1.9)	0.063 (-0.0; 0.9)
Radial length (mm)	73	13.0 (2.1)	13.2 (2.1)	-0.2 (2.1)	0.318 (-0.7; 0.2)
Radial inclination (°)	73	25.5 (3.6)	26.4 (3.8)	-0.9 (4.2)	0.079 (-1.9; -0.1)
Dorsal angulation (°)	73	-1.3 (6.6)	-5.1 (4.1)	3.8 (6.5)	<0.001 (2.3; 5.3)*
SL distance (mm)	45	2.1 (0.4)	2.0 (0.4)	0.1 (0.5)	0.099 (-0.0; 0.3)
DRUJ distance (mm)	72	2.4 (0.8)	2.3 (0.8)	0.1 (0.7)	0.224 (-0.1; 0.3)

Results of paired samples T test.

N: number of patients; SD; standard deviation; 95% CI: 95% confidence interval; *significant difference; SL: scapholunate ligament: DRUJ: distal radioulnar Joint; °degrees; mm: millimeter.

Table 5. CROs derived from injured and uninjured wrist at follow-up.

	Follow up ir	njured wrist	Follow-up un	injured wrist		Significance
aROM (N = 73)	Mean	SD	Mean	SD	Mean difference (SD)	<i>p</i> -value (95% CI of mean difference)
Flexion/extension (°)	141.3	18.2	152.5	13.4	-11.2 (12.6)	<0.001* (14.1; -8.2)
Ulnar/radial deviation (°)	58.1	10.7	64.9	11.3	-6.9 (9.9)	<0.001* (-9.2; -4.6)
Pro/supination (°)	146.7	13.0	152.0	10.9	−5.3 (11.0)	<0.001* (-7.9; -2.8)
Grip strength (N = 73)						
Grip strength (kg)	43.5	13.2	46.1	12.7	-2.6 (6.0)	<0.001* (-4.0; -1.2)
Sustained grip strength (kg)	24.6	10.9	25.0	9.6	-0.4 (6.4)	0.574 (-1.9; 1.1)
Key pinch strength (kg)	8.5	2.8	8.7	2.5	-0.1 (2.0)	0.547 (-0.6; 0.3)

Results of paired samples T test.

CROs: clinician reported outcomes; N: number of patients; SD: standard deviation; 95% CI: 95% confidence interval; *significant difference; odegrees; kg: kilogram; MCD: minimal detectable change; MCID: minimal clinically important difference.

Table 6. PROs at follow up compared to measurements of healthy controls.

PROs	All patients (N $=$ 73) Mean (SD)	Healthy controls [50] (N = 22) Mean (SD)	Difference	MIC
DASH	9 (12)	· ,	6	10.8 [29]
	9 (12)	3 (6)	0	10.6 [29]
PRWE				
Pain	9 (11)	1 (2)	8	1.5 [31]
Function	10 (15)	0 (1)	10	10
Total	14 (17)	1 (3)	13	11.5
MHQ	84 (16)	98 (3)	14	
SF36				
Physical functioning	92 (12)	93 (15)	1	
Social functioning	90 (19)	95 (12)	5	
Role model physical problem	86 (28)	88 (30)	2	
Role model emotional problem	90 (27)	95 (21)	5	
Mental health	83 (13)	89 (11)	6	
Vitality	71 (18)	82 (15)	11	
Pain	81 (19)	90 (14)	9	
General health experience	73 (18)	78 (14)	5	
Health change	52 (20)	51 (14)	1	

Results of paired samples T test.

PROs: patient reported outcomes; DASH; disability of arm, shoulder and hand questionnaire; PRWE: patient reported wrist evaluation; MHQ: Michigan Hand Questionnaire; SF36: Short Form36; SDC: smallest detectable change; MIC: minimal important change.

significantly lower in the injured wrist, the difference was not clinically relevant. The differences between patients with DRFs and healthy controls for PRWE subscales pain, function and total PRWE score all exceeded the reported MICs, suggesting a clinically relevant diminished score for non-osteoporotic patients following a DRF. Associations between radiological measurements and outcomes were found for step-off and diminished flexion/extension as well as ulnar/radial deviation and SF 36 mental component score. Radial length was associated with all grip strength measurements.

The evolution of radiological measurements in perspective

Ulnar variation, radial length, radial inclination and dorsal angulation were within normal ranges as presented in literature at all follow-up moments [4-9]. Neidenbach et al. stated that most changes of radiological measurements occur in the first 6 weeks following injury [34]. Although this seems to be logical, our study did not show many signs of radiological changes in the first 6 weeks following initial treatment after a DRF. Although these authors stated that no changes in radiological measurements occur between 6 weeks and 1 year follow-up, our study did suggest that ulnar variance and radial inclination increased and stepoff and gaps diminished during 5 years following a DRF[34]. When ulnar variance and radial inclination increase, but radial length does not increase, a compression (and relative shortening) of the ulnar side of the distal radius must be present. Rikli and Regazzoni described this anatomical area in 1996 as the intermediate column [60,61]. It consists of the lunate facet and the sigmoid notch and is responsible for >50% of the axial compressive forces that are transmitted across the wrist during normal activity [62]. Brink and Rikli acknowledge the importance of the intermediate column and describe the volar and dorsal "key corner" of

Table 7. Univariable regression analyses of radiological measurements and CROs.

					aROM				
		Flexion/extension			Ilnar/radial deviatio	n		Pro/supination	
Radiological factors	В	95% CI	р	В	95% CI	р	В	95% CI	р
Ulnar variance (mm)	0.050	-2.2; 2.4	0.966	-0.714	-2.1; 0.6	0.298	-0.523	-2.2; 1.1	0.532
R Radial length (mm)	-0.034	-2.0; 2.0	0.973	-0.459	−1.6; 0.7	0.440	-0.720	−2.1; 0.7	0.318
Radial inclination (°)	0.856	-0.3; 2.0	0.153*	-0.052	-0.8; 0.7	0.882	-0.250	-1.1; 0.6	0.562
Dorsal angulation (°)	0.078	-0.6; 0.7	0.812	0.167	-0.3; 0.6	0.475	0.167	-0.3; 0.6	0.475
SL distance (mm)	-5.853	-17.0; 5.3	0.296	4.281	-3.2; 11.7	0.254	10.490	2.2; 18.8	0.014*
DRUJ distance (mm)	-0.051	-5.6; 5.4	0.985	-3.468	-6.6; -0.3	0.030*	0.130	-3.8; 4.1	0.947
Step-off (mm)	-12.9	-27.9; 2.2	0.092*	-6.759	-14.6; 1.1	0.089*	1.105	− 8.4 ; 10.6	0.816
Gap (mm)	-5.154	−9.3 ; −1.0	0.016*	-3.070	-5.3; -0.8	0.008*	-5.149	-7.8; -2.5	<0.001*

					Strength measuren	nents			
		Grip strength	1		Sustained grip stre	ngth		Key pinch streng	gth
Radiological factors	В	95% CI	p	В	95% CI	p	В	95% CI	р
Ulnar variance (mm)	0.7	-1.0; 2.4	0.384	0.4	-0.9; 1.8	0.549	-0.1	-0.4; 0.3	0.768
Radial length (mm)	2.8	1.5; 4.1	< 0.001*	2.1	1.0; 3.2	< 0.001*	0.5	0.2; 0.7	< 0.001*
Radial inclination (°)	0.4	-1.5; 1.3	0.361	0.3	-0.4; 1.0	0.458	0.1	-0.1; 0.2	0.266
Dorsal angulation (°)	0.2	-0.3; 0.6	0.486	0.1	-0.3; 0.5	0.767	0.0	-0.1; 0.1	0.362
SL distance (mm)	5.0	-4.1; 14.2	0.273	2.1	-5.9; 10.2	0.600	0.5	-1.1; 2.0	0.530
DRUJ distance (mm)	2.0	-2.0; 5.9	0.324	1.7	−1.4 ; 5.1	0.279	-0.1	-0.8; 0.6	0.783
Step-off (mm)	0.2	−9.8; 10.2	0.968	-0.5	-8.6; 7.6	0.903	-1.2	-3.1; 0.7	0.218
Gap (mm)	1.2	-1.8; 4.2	0.440	0.5	−1.9; 2.8	0.711	-0.2	-0.8; 0.4	0.563

aROM: active range of motion; B: regression coefficient; 95% CI: 95% confidence interval, p: p-value; *significant difference; SL: scapholunate ligament; DRUJ: distal radioulnar joint; mm: millimeter.

the intermediate column [61]. They state that control with reduction and stable fixation of this "key corner" should be the first step of the operative strategy after a DRF, because insufficient treatment may result in carpal subluxation [61]. Our results suggest that the intermediate column is likely to be compressed after 6 weeks following a DRF, which may result in shortening. We agree with Brink and Rikli that care should be taken to pursue anatomical reduction and stable fixation of the intermediate column. However, when comparing the differences in measurements in our study to reported magnitude error by Watson et al., all findings were within the 95% confidence interval of expected normal ranges [10]. This suggests that the evolution of these radiological measurements over time might be regarded as measurement error and might not yield a clinically relevant change.

SL distance in our study exceeded the normal value of < 2.0 mm with only 0.1-0.2 mm and was not statistically significantly different in comparison to measurements of the uninjured wrist [47]. In addition to proper physical examination, it has been reported that diagnosing concomitant ligamentous injury on static radiographs is challenging, as only Geissler type IV lesions are represented by a distance between scaphoid and lunate >2 mm due to a complete SL tear [19,47,63-65]. Prevalences up to 98% of associated ligamentous injury with DRFs, mostly SL ligament injuries, have been described [65,66]. Fortunately, most often these injuries do not need surgical repair when treating DRFs, because very rarely the SL injury significantly affects carpal stability and outcome [19,63]. Measurements regarding SL distance in our study were small and most likely do not represent ligamentous injury with significant impact on outcome.

DRUJ distance increased statistically significantly from 2.0 to 2.4 mm between baseline and 6 weeks, but this distance did not differ significantly from the uninjured wrist. In literature it has been described that DRUJ instability is suspected when a difference is present between DRUJ distance on PA radiographs of the injured compared to the uninjured wrist. In addition, when on a lateral radiographs a distance is measured exceeding 4-5 mm between the dorsal cortexes of the distal radius and ulna, this is also a suggestion for DRUJ instability [49]. We therefore conclude that in our study DRUJ instability was most likely not present.

Residual articular incongruence in perspective

Surprisingly, our results showed that step-off and gap diminished significantly between 6 weeks and follow-up, although these differences were within earlier mentioned magnitude error [10]. Conflicting results regarding reliability of measuring gaps and step-offs following distal radius fractures have been reported. It has been reported that observers, independent of skill level, may measure step-off and gaps accurately to 0.62 ± 53 mm (95% CI 0.59-0.65) [67]. Intraclass correlation coefficient scores showed "substantial" (0.78) to "almost perfect" (0.81) inter- and intraobserver agreement [67]. In contrast, other studies reported low intra- and inter-reliability ICC values [10,18]. Watson et al. showed that measurement error lies within 1-2 mm, indicating that clinicians cannot measure differences <1 mm [10]. They therefore questioned the reliability of using these radiographic measurements to guide treatment decisions regarding conservative or operative management. To our knowledge, no literature on the decrease of articular incongruence over time in adult patients is available. Bone healing is a complex event that involves coordination of two complex forces: anabolism or tissue formation and catabolism or remodelling under influence of axial, translational and rotational forces [68,69]. Possibly remodelling processes have diminished the articular incongruence.

Outcomes in perspective

Flexion/extension seems to be a clinically relevant measurement in non-osteoporotic patients following DRFs, because our findings seemed to exceed MIC references [27]. As reported by our research group and others, it is well known that fractures healed with a step-off $\geq 2 \, \text{mm}$ are associated with development of PA, which may affect CROs and PROs [12-14,16,17,32,70]. Multiple studies report on better CROs following plate fixation with better anatomical realignment of articular congruence in comparison to conservative treatment or external fixators [71-73]. Unfortunately,

able 8. Univariable regression analyses for radiological measurements and PROs

ميوبير المرايم والمرام		DASH						PRWE						MHQ				SF 36	9		
nadiological factors					Pain			Function			Total					Phys	Physical componen	nent	Men	Mental component	ent
Subscales	В	95% CI	d	В	12% CI	р	В	12% CI	þ	В	95% CI	р	В	95% CI	р	В	95% CI	р	В	95% CI	р
Ulnar variance (mm)	0.9	-0.6; 2.3	0.238	1:1	-0.3; 2.4 0.113*	0.113*	1.8	-0.1; 3.6	*090.0	2.0	-0.1; 4.1	*890.0	-0.4	-2.4; 1.7	0.741	0.3	-1.8; 2.4	0.781	1.3	-0.7; 3.3	*007
Radial length (mm)	-0.2).2 -1.5; 1.1	0.760	-0.1	-1.2; 1.1 0.914	0.914	-0.8	-2.4;0.8	0.339	-0.5	-2.3;1.4	0.625	1.	-0.7; 2.8	0.230	0.1	-1.7; 1.9	0.933	0.5	-1.3; 2.3	.597
Radial inclination (°)	0.2	-0.6;1.0	0.596	I	0.1 -0.8; 0.6 0.807	0.807	-0.2	-1.2; 0.7	0.624	-0.2	-1.3;0.9	0.700	0.3	-0.7; 1.3	0.569	-0.5	-1.6;0.5	0.327	-0.3	-1.4;0.8	.569
Dorsal angulation (°)	0.0	-0.4;0.4	0.943	-0.1	-0.5;0.3	0.668	0.1	-0.4;0.6	0.680	-0.1	-0.6;0.6	0.927	-0.2	-0.8;0.4	0.455	-0.1	-0.6;0.5	0.830	0.1	-0.5;0.7	.773
SL distance (mm)	0.9	-6.6;8.4	0.809	2.3	-5.0;9.7	0.528	1.8	-9.2;12.9	0.742	3.2	-8.9;15.4	0.594	-4.7	-15.8;6.5	0.404	-10.1	-20.9;0.6	0.063*	-7.2	-17.2; 2.8	.155*
DRUJ distance (mm)	-0.7	-4.2;2.8	0.686	0.7	-2.5; 3.9 0.658	0.658	-2.4	-6.8;2.0	0.280	-0.5	-5.6;4.6	0.841	2.5	-2.2; 7.3	0.289	3.2	-1.6;8.0	0.193*	2.4	-2.5;7.2	.335
Step-off (mm)	1:1	-8.8;11.0	0.817	0.3	-8.7; 9.2 0.956	0.956	-1.3	-14.3;11.8	0.849	-0.2	-14.8; 14.4	0.977	-7.7	-21.6;6.2	0.272	-5.8	-19.1;7.5	0.383	-9.5	-22.1;3.1	.138*
Gap (mm)	1.3	-1.6; 4.2	0.376		0.2 -2.5; 2.8 0.902	0.902	8.0	-3.1;4.6	0.699	9.0	-3.7;4.9	0.784	-2.0	-6.1; 2.1	0.330	-0.3	-4.2; 3.5	0.872	-0.5	-4.2; 3.1	.772
PROs: patient reported outcomes; DASH: disability of arm, shoulder, hand questionnaire; PRWE: patient rated wrist evaluation; MHQ: Michigan Hand outcomes Questionnaire: SF-36: Short Form 36; B: regression	d outco	mes; DASH	: disabili	ity of an	m, shoulder	r, hand q	uestionn	aire; PRWE:	patient 1	rated wri	st evaluation	η; MHQ: Λ	<u> </u>	Hand outc	omes Qu	estionna	ire: SF-36: S	hort Forr	n 36; B:	regression	coeffi-
cient; 95% Cl: 95% confidence interval; p : p -value; * $p < 0.200$; SL: scapholunate	onfidenc	e interval; μ	v: p-valu	> d* ; *	0.200; SL: si	capholuna		nent; DRUJ: ι	distal rad	lioulnar .	igament; DRUJ: distal radioulnar Joint; mm: mil	nillimeter.									

Table 9. Multivariable regression analyses of radiological measurements and CROs.

Dependent	Explanatory variables	B (SE)	<i>p</i> -Value	95% CI
Flexion/extension	Step-off	-36.8 (12.8)	0.006*	-62.6; -11.1
Tiexion/extension	Constant	143.3 (2.5)	<0.001*	138.3; 148.4
Ulnar/radial deviation	Step-off	-17.9 (7.0)	0.013*	-32.0; -3.9
	Constant	58.9 (1.4)	< 0.001*	56.2; 61.7
Pro/supination	Constant	59.1 (1.6)	< 0.001*	55.8; 62.5
Grip strength	Radial length	2.8 (.7)	< 0.001*	1.5; 4.1
	Constant	7.2 (8.6)	0.403	−9.9 ; 24.4
Sustained grip	Radial length	2.1 (.6)	<0.001*	1.0; 3.2
strength	Constant	-2.9(7.2)	0.681	-17.4; 11.4
Key pinch strength	Radial length	.5 (.1)	<0.001*	0.2; 0.7
	Constant	2.4 (1.6)	0.135	-0.8; 5.5

CROs: clinician reported outcome; B: regression coefficient: SE: standard error; 95% CI: 95% confidence interval; *significant difference.

Table 10. Multivariable linear regression analysis for radiological measurements

Dependent	Explanatory variables	B (SE)	<i>p</i> -Value	95% CI
SF 36 physical	SL distance	-10.1 (5.3)	0.063	-20.9; 0.6
component	Constant	105.4 (11.6)	< 0.001*	82.2; 128.6
SF 36 mental	Step-off	-15.4(5.5)	0.008*	-26.6; -4.2
component	Constant	86.8 (2.0)	< 0.001*	82.8; 90.7

PROs: patient reported outcomes; SF36: Short Form 36; B: regression coefficient: SE: standard error; 95% CI: 95% confidence interval; *significant difference; SL: scapholunate ligament.

no MICs for ulnar/radial deviation and pro/supination are reported in literature. Therefore, further research is mandatory to determine MIC references to evaluate the clinical relevance of CROs. We conclude that patients with a DRF should be informed that lasting limitations in flexion/extension might be expected.

Although in our study a statistically significant difference in grip strength between the injured and uninjured wrist was found, this result did not exceed the reported MIC [28]. This suggests that no clinically relevant impact on grip strength is expected following DRFs. As such, grip strength seems to be merely a reflection of overall strength and the physical condition of a chain of muscles in the upper limb [74].

In our study, the MIC of the DASH was not exceeded, but MICs of PRWE subscales pain, function and total score were [29,31]. For the MHQ, no discriminative ability is present as captured in MIC following DRFs, because of the ceiling effect of the MHQ with high scores at 3 months follow up [30]. To our knowledge, no literature reported on MICs of the SF36 following DRFs so far. However, seemingly substantial differences between patients with DRFs and healthy controls on subscales MHQ general function, work, pain, satisfaction as total MHQ were found. In addition, for the SF36 subscales vitality and pain this seemed also to be true. More knowledge on reference MICs regarding PROs is mandatory to put these differences in clinical perspective. It is known that outcomes as measured with PROs and assessed using MICs can differ significantly between certain injuries or disorders and can therefore not be extrapolated [57]. In addition, slight variation exists in the psychometric properties of PROs measuring outcomes of different injuries or disorders, which can hamper comparability [55,75,76]. Waljee et al. and Goldhahn et al. have proposed a core set of parameters including aROM, grip strength, the PROs PRWE, DASH, MHQ, and the Patient Reported Outcome Measurement Information System (PROMIS®) upper extremity item banks to be included when reporting in literature on DRFs to improve comparability [77,78]. We believe that reporting on

aROM, grip strength and PROs with adequate MICs would improve interpretability of the clinical relevance of outcomes following DRFs in non-osteoporotic patients immensely.

Associations between radiological measurements and outcome in perspective

Step-offs were significantly associated with diminished flexion/ extension and ulnar/radial deviation. Several authors reported on the association between articular incongruency following DRFs and the association with development of posttraumatic arthritis (PA) at longer follow up duration [13,15,79-81]. The development of PA is related to several causes, such as increased stress on the articular surface following overcorrection of radial length, radiocarpal instability caused by ligamentous injuries or articular incongruency [12,82,83].

Radial length seems to be important to correct surgically, because radial shortening may result in diminished grip strength. However, this decreased grip strength may not be clinically noticeable for a patient, because measurements did not exceed reported MICs [28]. Note that several reports have associated radial shortening with diminished ROM and diminished grip strength measurements [32,38,84–86]. In contrast, a few others did not find such associations [34,35]. Radial shortening may cause an increased pressure in the DRUJ and a shift in the centre of pressure within the sigmoid notch and can cause diminished ROM and grip strength [87-89].

Articular incongruence of >1 mm may lead to lower SF36 scores [15] as is supported by our study in which the SF36 mental component score was significantly associated with residual stepoff. Unfortunately no MICs are reported for the SF36 and no sound conclusion can be drawn. It does illustrate the need for more knowledge on MICs following DRFs when reporting on outcome using PROs.

Strength and weaknesses

By reporting on a young non-osteoporotic population who sustained a DRF 4-11 years ago, we contribute to the knowledge on radiological measurements after a DRF and their associations with CROs and PROs. All measurements regarding CROs have been performed by one hand therapist for consistency. To eliminate interobserver bias, all measurements on radiographs were assessed by one specialized radiologist. It has to be acknowledged that, although all radiographs have been taken according to protocol, measurement accuracy can be influenced by the quality of the radiographs. Our response rate was low, presumably because our population was young and moved for study or work purposes and therefore many current addresses could not be retrieved. The included number of 73 patients might be insufficient to draw firm conclusions. However, in most studies describing populations after DRFs, the included number of patients did not exceed our cohort [11,72,90]. To our knowledge, no MIC values regarding the PROs MHQ and SF36 have been reported yet. Therefore we have compared the results of our cohort to a healthy young non-osteoporotic cohort of 22 participants. Care should be taken when drawing conclusions regarding comparisons with this healthy cohort, because the sample size is minimal. In addition, lack of consensus regarding the best methodology to determine the MIC exists. There are two main approaches; anchor-based methods in which an external criterion is used to define an important change (often patient-based judgement) and distribution-based methods, which use statistical measures as a value for MIC [76]. This could result in large variations in MIC values for CROs and PROs reported in literature [76]. Care should be taken to interpret MIC values and consensus should be reached on the preferred MIC methodology.

Conclusions

Radiological measurements following DRFs seem to evolve over time, but differences were small and are probably not clinically relevant. Range of motion, in particular flexion/extension, was clinically relevantly diminished in non-osteoporotic patients following a DRF, while grip strength was not. Residual articular incongruency seems to influence range of motion, where shortening of the radius might influence grip strength. The association between residual articular incongruency and patient reported outcomes needs further attention. Further research on MIC is mandatory, to enhance interpretation of clinically relevant outcomes after a DRF.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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