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TRAUMA SURGERY

The effect of local bone mineral density on the rate of mechanical failure after surgical treatment of distal radius fractures: a prospective multicentre cohort study including 249 patients

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Abstract
Introduction The aim of this prospective, multicentre study was to evaluate the influence of local bone mineral density (BMD) on the rate of mechanical failure after locking plate fixation of closed distal radius fractures.
Materials and methods Between June 2007 and April 2010, 230 women and 19 men with a mean age of 67 years were enrolled. Dual energy X-ray absorptiometry measurements for BMD of the contralateral distal radius were made at 6 weeks post-surgery. Follow-up evaluations at 6 weeks, 3 months and 1 year included wrist mobility and strength as well as standard radiographs. Any local bone/fracture or implant/surgery-related complications were documented. The Disability of the Arm, Shoulder, and Hand (DASH), Patient Rated Wrist Evaluation (PRWE), and EuroQol-5D scores were also recorded at the nominated time points.
Results Nine patients were reported with mechanical failure at an estimated risk of 3.6 %. The BMD measurements were generally low for the study population with no difference between patients with (0.561 g/cm^2) and without (0.626 g/cm^2) mechanical failure ($p = 0.148$). None of the patients achieved their pre-injury functional level and quality of life status after 1 year. 1-year DASH and PRWE scores as well as the difference in maximum grip strength of the affected wrist relative to the contralateral side were significantly higher for patients with mechanical failure ($p \leq 0.036$).
Conclusions Our study could not identify a clear association between bone mineral density status and the risk of mechanical failure. Although the risk for mechanical failure after treatment of distal radius fractures with palmar locking plates is low, these complications must be avoided to prevent negative impact on long-term patient functional and quality of life outcome.

Keywords Distal radius fracture · Radius fracture · Complications · Mechanical failure · Osteoporosis · Bone density

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Introduction

Distal radius fractures predominantly affect female patients over 50 years of age, and can be a predictor for subsequent fractures of the proximal femur or vertebra in the context of ageing and osteoporosis [1, 2].

Treatment of distal radius fractures with palmar locking plates has the potential to reliably retain reduction even in

patients with poor bone quality and a generally good clinical outcome has been documented [3–8]. However, a substantial number of complications including mechanical failure (MF; e.g. loss of reduction, screw and plate pull-out) are known [9–12].

It is assumed that poor local bone quality leads to a higher number of MF complications with internal fixation [13, 14], but this association has not yet been proven in a clinical setting. We hypothesised that a lower local bone mineral density (BMD) leads to a higher rate of postoperative MF in patients with distal radius fractures. Secondary outcomes focused on patient-rated evaluations of upper limb function and quality of life.

Materials and methods

Study design and patients

A prospective, multicentre cohort study with a 1-year follow-up was conducted to evaluate the outcome of BMD on the risk of MF in patients aged 50 years and older with a distal radius fracture treated operatively with a volar Locking Compression Plate (LCP) 2.4 mm (Synthes AG, Switzerland). The trial was registered at ClinicalTrials.gov (NCT01144208).

Between 2007 and 2010, 249 patients from ten participating centres (nine within Europe and one in Singapore, of which each centre had obtained institutional review board approval) treated with the implant of interest and meeting the inclusion criteria were enrolled. Patients aged between 50 and 90 years were included who suffered from a radiologically confirmed closed distal radius fracture and provided written informed consent before enrolment. The surgical procedure was intended to be performed within 7 days after the injury. Exclusion criteria included ulnar fractures (except an associated fracture of the ulnar styloid process), open fractures, a previous distal radius fracture on either side after the age of 25, concomitant contralateral radius fractures, and the time to surgery occurring after the 7-day inclusion period. Polytraumatized patients, those who had received radio- or chemotherapy prior to, during, or within the last year, those with active malignancy, and those with existing neuromuscular/rheumatic disease or psychiatric/metabolic disorders that would preclude accurate assessment were also excluded. Legally incompetent patients, prisoners, those undergoing regular systemic therapy with corticosteroids due to chronic disease, those with known drug or alcohol dependency, and those participating in other clinical trials of a drug or device were equally excluded.

Baseline evaluation

Patient demographics (i.e. gender, age, height, weight, limb dominance, concomitant medical disorders [15], and predisposing osteoporosis factors as well as existing injuries of the ipsilateral and contralateral arm) and baseline injury characteristics (i.e. accident type, fracture classification according to the Müller-AO Comprehensive Classification [16], and delay between accident and surgery) were documented during the inpatient period.

Patients were asked to recall their upper limb function as it was 1 week prior to the injury to determine a baseline Disability of the Arm, Shoulder, and Hand (DASH) score; a DASH score of 0 points indicates no disability, and a score of 100 reflects maximum disability [17, 18]. Patient self-assessments of wrist function in activities of daily living and general health status were also made using the Patient Rated Wrist Evaluation (PRWE) [19–21] and EuroQol-5D (EQ-5D) [22] questionnaires, respectively. High PRWE scores up to a maximum of 100 points indicate the greatest pain and disability. Patients' current health was assessed by combining responses of the five EQ-5D questionnaire items and comparing the overall response score to reference data to produce an EQ-5D index between 0 and 1; 0 represents the worst health status and 1 the best health status.

Standard anteroposterior and lateral radiographs were obtained upon admission, intraoperatively, and immediately postoperatively for each patient as well as at subsequent scheduled follow-up evaluations.

Dual energy X-ray absorptiometry (DXA) measurements of the contralateral healthy radius (distal 33 %) were made within the first 6 weeks post-surgery to determine local BMD. DXA measurements of axial skeleton reference sites (i.e. spine and femur) were also taken to evaluate local bone status.

Follow-up examinations

The study protocol included follow-up evaluations at 6 weeks, 3 months, and 1 year. Patient examinations included measurements of wrist and forearm mobility with a goniometer [23] and grip strength with a Jamar dynamometer (Sammons Preston Roylan, IL, USA) for both the affected and contralateral side. For the analysis of range of motion, absolute scores on the injured side as well as their relative values compared to the contralateral side were documented. For grip strength, the absolute (i.e. maximum) values for the injured side as well as the deviance from the maximum strength of the contralateral ("healthy") side were considered. Patient-rated outcomes were documented with the DASH, PRWE and EQ-5D questionnaires.

Any complications which occurred during the entire 1-year follow-up period were documented at the nominated follow-up visits. The classification of all reported adverse events, based on de-identified radiographs, was made at the end of the follow-up period by a review board comprising the principle investigator and an independent surgeon. MF complications were specifically defined as bone/fracture complications potentially associated with poor BMD including: loss of reduction defined as any change in intra-/extra-articular angles, radial/ulnar length or secondary fragment dislocation; malunion due to loss of reduction; fracture impaction; delayed healing; nonunion; refracture/secondary fracture, and implant/surgery complications (i.e. secondary screw perforation with loosening or back out; implant (plate or screw) loosening, failure or breakage; and radiolucency around the screw without screw loosening) [24].

Statistical analysis

All analyses were performed with Intercooled Stata version 11 (StataCorp LP, TX, USA). Baseline and follow-up parameters were described with use of standard descriptive statistics.

For the primary outcome analysis of BMD, patients were assigned to either the MF or no MF group based on the reviewed complication data. Patients in the MF group had experienced at least one MF during the first year following surgery.

Comparisons of BMD in the two groups were made using t tests supplemented with the Satterthwaite correction to account for variance differences between the MF and no MF groups. To compare outcome patterns over time, mixed linear models that include random effects to account for repeated measurements of the same patient were used for continuous outcomes; Wald tests were used for comparison. The comparison of frequencies for range of motion was performed by time point using the Fisher's exact test. The significance level was set at $p < 0.05$.

The final number of 249 patients was based on a sample size calculation made prior to commencing the study, which estimated a total of 244 patients required for study inclusion. This estimation included a power of 85 %, significance level of 5 %, and an expected ratio of 15:85 for the MF group versus the no MF group to test the null hypothesis that there is no difference in BMD within the first year post-surgery between the two groups; an additional 10 % was added to compensate for loss of power due to adjustment for imbalances between groups as well as 10 % loss to follow-up.

Patient demographics and baseline characteristics

Two hundred and forty-nine patients with an equal number of fractures were included in the study between June 2007 and April 2010, with the last patient's scheduled 1-year follow-up visit taking place on March 28, 2011. Until the 1-year visit 17 patients were lost to follow-up because they either could not be contacted or refused further examination, leaving 232 (93 %) patients.

The demographic data and baseline characteristics for the defined cohorts were similar (Table 1). The average age of the entire study population was 67 years, with a mean age of 71 for the MF group ($N = 9$) and 67 for patients without MF ($N = 240$).

No significant differences could be shown regarding existing injuries and predisposing osteoporosis factors (Fisher's exact/Mann-Whitney test; $p \geq 0.071$) (Table 2). The majority of patients had not experienced a previous low energy trauma before their current distal radius fracture [MF: 78 % (7/9) vs. no MF: 95 % (227/240)], were not undergoing corticosteroid therapy for longer than 3 months [MF: 89 % (8/9) vs. no MF: 99.6 % (238/239)] or osteoporosis therapy prior to injury [MF: 78 % (7/9) vs. no MF: 83 % (198/240)]. Furthermore, over 20 % of patients were smokers [MF: 22 % (2/9) vs. no MF: 23 % (54/240)], and around 89 % of the females had already reached menopause after a mean age of 50 years [MF: 83 % (5/6) vs. no MF: 95 % (213/224)], suggesting a lower predisposition to osteoporosis for most of the patients.

There were no significant differences between the patient subgroups based on the type of accident and injury details reported (Fisher's exact test; $p \geq 0.639$) (Table 3). Seventy-eight and 77 % of patients with and without MF, respectively, sustained their injury either at home or while walking or shopping, and mostly involved the right wrist [MF: 67 % (6/9) vs. no MF: 49 % (117/240)]. The majority of fractures were classified as AO Type 23C [MF: 56 % (5/

Table 1 Baseline patient demographics

Parameter	Mechanical failure ($N = 9$)	No mechanical failure ($N = 240$)
Age, years		
Mean (SD)	71 (9)	67 (9)
Median (range)	72 (54; 83)	67 (50; 88)
Gender, no. (%)		
Female	6 (67)	224 (93)
Male	3 (33)	16 (7)
Dexterity, no. (%)		
Right	8 (89)	207 (86)
Left	1 (11)	21 (9)
Ambidextrous	0 (0)	12 (5)
Body mass index (kg/m^2)		
Mean (SD)	22.9 (3.0)	24.2 (4.3)
Median (range)	22.5 (17.7; 26.4)	23.7 (15.8; 49.1)

SD standard deviation

Table 2 Predisposing osteoporosis status

Parameter	Mechanical failure ($N = 9$)	No mechanical failure ($N = 240$)	p value
Previous low energy trauma, no. (%)			
No	7 (78)	227 (95)	0.095[c]
Yes	2 (22)	13 (5)	
Corticosteroid therapy longer than 3 months, no. (%)[a]			
No	8 (89)	238 (99.6)	0.071[c]
Yes	1 (11)	1 (0.4)	
Current osteoporosis therapy, no. (%)			
No	7 (78)	198 (83)	0.662[c]
Yes	2 (22)	42 (17)	
Smoking status, no. (%)			
No	7 (78)	186 (77)	1.000[c]
Yes	2 (22)	54 (23)	
Onset of menopause, no. (%)[b]			
No	1 (17)	11 (5)	0.278[c]
Yes	5 (83)	213 (95)	
Age (years), median (min; max)	53 (49; 542)	50 (19; 60)	0.088[d]

[a] Including any corticosteroid therapy that was undertaken except during the last 3–6 months up to the time of the current injury/surgery; $n = 239$ for the no mechanical failure group due to a missing data point

[b] Applicable to female patients only ($n = 230$)

[c] Fisher's exact test

[d] Mann-Whitney test

Table 3 Injury and surgery characteristics

Parameter	Mechanical failure ($N = 9$)	No mechanical failure ($N = 240$)
Accident type, no. (%)[a]		
At home	2 (22)	72 (30)
While walking/shopping	5 (56)	112 (47)
Traffic accident	0 (0)	11 (5)
During sport activities	0 (0)	21 (9)
Other	2 (22)	21 (9)
Fracture side, no. (%)		
Right	6 (67)	117 (49)
Left	3 (33)	123 (51)
AO Classification, no. (%)		
23A	4 (44)	103 (43)
23B	0 (0)	14 (6)
23C	5 (56)	123 (51)
Delay to surgery (days)		
Mean (SD)	3.2 (2.4)	3.3 (2.4)
Duration of surgery (min)		
Mean (SD)	72.1 (13.8)	70.0 (25.7)
Type of surgeon, no. (%)		
Resident	1 (11)	92 (39)
Senior	6 (67)	123 (51)
Hand specialist	2 (22)	24 (10)

SD standard deviation

[a] $N = 237$ for the no mechanical failure group due to missing data points

9) vs. no MF: 51 % (123/240)]. Open reduction and internal fixation with a volar LCP 2.4 mm was done using the volar modified Henry approach between the radial artery and the flexor carpi radialis tendon for all patients. Only one patient without MF received graft augmentation. The delay between injury and surgery ranged from 0 to 7 days, with a mean of approximately 3 days (Table 3).

The mean baseline scores of DASH, PRWE and EQ-5D index for the study population were 3.8 points (range 0–43.3), 0.98 points (range 0–42.25), and 0.97 (range 0.50–1.00), respectively.

Results

Within the 1-year follow-up period, nine patients were reported with MF (Table 4); the estimated risk of developing at least one MF complication for the entire study population was 3.6 % (9/249; 95 % confidence interval, 1.7–6.8 %). Loss of reduction (2.8 %; 7/249) and implant loosening (1.6 %; 4/249) were most commonly reported. There were no patients with nonunion. Of the nine MF patients, six had experienced more than one MF complication.

In the MF group the dominant side was fractured seven times (78 %), whereas in 132 cases (55 %) of the non MF group the dominant side was broken.

The mean areal BMD at the contralateral radius was 0.624 g/cm^2 for the study population. The mean BMD determined for the contralateral radius was lower for MF patients (0.561 g/cm^2) compared to patients without MF (0.626 g/cm^2), but this difference was not significant (Satterthwaite corrected t test; $p = 0.148$). Local bone status measured at further reference sites of the axial skeleton (femur and spine) was also not significantly different between patients with and without MF.

The mean DASH score for the study population at 6 weeks was 34 points and decreased significantly to 18 and 11 points by the 3-month and 1-year time points, respectively (Wald test; $p < 0.001$); the final 1-year DASH score did not reach the recorded baseline DASH score. For patients with MF, the average 1-year DASH score was 20 points higher than the baseline score, whereas the no MF group had an average 1-year DASH score of 6.5 points above their pre-injury value (Wald test; $p = 0.015$).

Table 4 Mechanical failure complications

Type	No.
Mechanical failure bone/fracture complications	
Loss of reduction	7
Malunion due to loss of reduction	3
Fracture impaction	1
Delayed healing	2
Nonunion	0
Refracture/secondary fracture	1
Mechanical failure implant/surgery complications	
Secondary screw perforation = screw loosening/back out	2
Implant loosening (screw and plate)	4
Implant failure/breakage	1
Screw failure/breakage	2
Radiolucency around screw without screw loosening	0
Total no. of patients with at least one complication	9
Complication risk [% (95 % confidence interval)]	3.6 % (1.7; 6.8)

% = estimated risk of developing at least one complication based on the number of patients and not the number of complication events; calculated by dividing the number of patients experiencing at least one complication ($N = 9$) by the total number of patients in the treatment group (i.e. the safety patient population including those who were operated with volar LCP 2.4 mm; $N = 249$). If a patient experienced multiple complications under any complication class, the patient was only counted once

No. number of patients with at least one complication

The mean total PRWE score for the study population at 6 weeks was 45 points and decreased significantly to 21 and 9 points by the 3-month and 1-year time points, respectively (Wald test; $p < 0.001$); the final 1-year PRWE score did not reach the recorded baseline PRWE score. For MF patients, the average 1-year PRWE score was 32.7 points higher than the baseline score compared to the average 1-year PRWE score of 7.3 points above the pre-injury value for patients without MF (Wald test; $p = 0.001$).

The EQ-5D index was not significantly different between the MF and no MF groups: the average 1-year EQ-5D index was 0.11 points lower than the pre-injury value for MF patients and 0.03 points lower than baseline for patients without MF (Wald test; $p = 0.079$).

There was a significant difference between the proportions of patients with and without MF achieving final dorsal extension and forearm pronation equivalent to the "healthy" contralateral wrist (Fisher's exact test; $p \leq 0.030$); seven of the nine MF patients had complete range of motion evaluations, and none (0/7) achieved a 1-year dorsal extension status equivalent to their healthy side compared to 41 % (92/223) of patients without MF. In addition, only 29 % (2/7) of MF patients were reported with a 1-year forearm pronation status equalling their contralateral wrist compared to 74 % (166/223) of patients without MF.

The average grip strength achieved by MF patients at the 1-year follow-up was reduced by 8 kg relative to the contralateral hand; this was significantly worse than the average 3 kg reduction in grip strength from the "healthy side" for patients without MF (Wald test; $p = 0.036$).

Discussion

While the present study, including 249 distal radius fracture patients over 50 years of age treated with a volar LCP 2.4 mm, showed a higher BMD measurement of the contralateral wrist in patients without MF compared to those documented with a MF complication during the first year postoperatively, this difference was not within the magnitude of that considered in our hypothesis and was not statistically significant. Two main considerations must be acknowledged. Firstly, the outcome under investigation was rare. The sample size estimation of the current study was based upon a systematic literature search on the influence of osteoporosis on fracture fixation, which revealed a 16.8 % (95 % confidence interval, 15.1–18.6 %) risk of loss of reduction in a total sample of 1,764 patients with distal radius fractures [25]. Nevertheless within the entire length of follow-up, the number of reported MF complications was even much lower than anticipated (i.e. 4 %). As a result we ended up with unequal numbers of subjects per exposure group. Thus, since the results presented here derived from a limited number of MFs, the interpretation should be done with caution until larger studies provide confirmatory evidence about the effect of BMD in MF in patients with distal radius fractures. However these "unbalanced" numbers of subjects per exposure group are not rare in cohort studies. Cohort studies are observational in nature and thus reflect data of a real setting. Secondly, the distal radius DXA measurement for the entire study population was rather low and homogenous and thus, the differences we expected to observe with this study were practically not achievable.

In general, for our study population, the treatment of distal radius fractures with the volar LCP 2.4 mm was a safe procedure with a low MF rate, which is comparable to the rate of 5.3 % reported by Arora et al. [10] who documented six MF complications from a total of 114 patients. This positive finding is even more emphasised by the fact, that the mean areal BMD of the contralateral radius was low for the entire study population and therefore it has to be questioned, whether low BMD at fracture site leads to a

higher rate of postoperative MF in patients with distal radius fractures.

The 1-year DASH and PRWE scores of our study population were also in line with 1-year scores of a prospective randomised trial comparing the nonoperative treatment of distal radius fractures with volar LCP 2.4 mm fixation [26] as well as a retrospective review that compared the DASH-rated functional outcome of 90 wrist fracture patients after conservative versus operative treatment [27]. In our study population, MF complications seemed to have a considerable impact on postoperative DASH and PRWE scores, as the 1-year scores were significantly higher in the MF group. Interestingly, FitzPatrick et al. found that DASH scores after 1 year were significantly higher for patients with osteoporosis compared to those with osteopenia ($p = 0.01$). At the same time, patients with osteoporosis had a significant higher rate of major complications (such as refracture, loss of reduction, malunion and nonunion) in the afore mentioned study than patients without osteoporosis [28]. These findings correspond to our finding that MF patients had a slightly lower BMD than no MF patients, although this finding was not significant in our study. However, from our observations as well as those of Arora et al. [26], Egol et al. [27] and FitzPatrick et al. [28], we conclude that even after anatomical reconstruction of distal radius fractures, baseline DASH and PRWE are not fully achieved; MF needs to be avoided by any means, as it seems to have an additionally important negative impact on these scores. This conclusion is further strengthened by the loss of grip strength, which was significantly greater in patients with MF.

Finally, it might have an impact on the development of mechanical failures whether the dominant or non-dominant site is affected. Although there was an equal distribution of dexterity in both study groups, more mechanical failures of the dominant hand were observed. Eventhough not statistically significant, due to the small number of patients in the MF group, it might point out, that the dominant hand, if affected, is at higher risk for earlier inadequate postoperative stress and therefore at higher risk for mechanical failure.

The question remains as to which subgroup of patients older than 50 years requires surgery for their broken wrist. In a thoughtful commentary on the subject of distal radius fractures in the elderly, Cannada highlighted that decision making should remain focused on the individual [29]. Some elderly patients need an operation for their distal radius fracture to obtain a result that fulfils their functional demands independent of their local bone quality. Based on our study results, BMD could not be verified as an appropriate criterion for clinical decision making. Bone quality is one epiphenomenon of ageing, but there are other factors such as medical comorbidities, cognitive impairment, tendency to fall, which determine in what general state the patient is and defines his/her physical demands.

The study has its limitations. First it is not clear whether the DXA measurement of the contralateral distal radius within 6 weeks after surgery serves as a valuable BMD assessment of the fractured distal radius. Nevertheless, we believe that this measurement is a more appropriate estimate of local BMD of the fractured distal radius compared to measurements of the spine or femur; BMD can show substantial heterogeneity between clinically relevant bone sites [30]. Second, as discussed earlier already, the unbalanced number of subjects in the exposure groups. Nonetheless, the unbalanced number of subjects in the exposure groups reflects our observations of this large, prospective, observational cohort study, which is, in our view, a strength of this study.

In conclusion, this prospective multicentre study could not support the hypothesis that poor bone quality increases the risk of MF for patients over 50 years of age with distal radius fractures treated with a volar angle stable locking plate. In a large study population with a general low local BMD, we could show that treatment with the LCP 2.4 mm was associated with a low risk of MF, which per se is an important finding with clinical relevance. Notwithstanding, it has to be carefully considered whether a patient needs operative treatment and if so, MF should be avoided by any means as these complications have a clinically relevant, negative impact on the long-term outcome. It is still unclear which factors influence MF and the responsible surgeons should pay attention to this fact.

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Conflict of interest None.

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