ORIGINAL ARTICLE

The Treatment of Displaced Intra-articular Distal Radius Fractures in Elderly Patients

A Randomized Multi-center Study (ORCHID) of Open Reduction and Volar Locking Plate Fixation Versus Closed Reduction and Cast Immobilization

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Background: From 2000 to 2012, the annual incidence of inpatient treatment for distal radius fracture in Germany rose from 65 to 86 per 100 000 persons. It is unclear whether open reduction and volar angle-stable plate osteosynthesis (ORIF), a currently advocated treatment, yields a better functional outcome or quality of life than closed reposition and casting.

Methods: In the ORCHID multi-center trial, 185 patients aged 65 and older with an AO type C distal radial fracture were randomly assigned to ORIF or closed reposition and casting. Their health-related quality of life and hand/arm function were assessed 3 and 12 months afterward with the Short Form 36 (SF-36) questionnaire and the Disability of the Arm, Shoulder and Hand (DASH) questionnaire. The radiological findings, range of movement of the wrist, and EuroQol-5D (EQ-5D) scores were documented as well.

Results: Among the 149 patients in the intention-to-treat-analysis, there was no significant difference in SF-36 scores between the two treatment groups at one year (mean difference, 3.3 points in favor of ORIF; 95% confidence interval, –0.2 +6.8 points; p = 0.058). The DASH scores showed moderately strong, but clinically unimportant effects in favor of ORIF, and there was no difference in EQ-5D scores. ORIF led to better radiological results and wrist mobility at 3 months, with comparable results at 12 months. 37 of the patients initially allotted to nonsurgical treatment underwent secondary surgery due to significant loss of reduction.

Conclusion: The findings with respect to mobility, functionality, and quality of life at 12 months provide marginal and inconsistent evidence for the superiority of volar angle-stable plate osteosynthesis over closed reduction and casting in the treatment of intra-articular distal radius fractures. Primary nonsurgical management is also effective in suitable patients.

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Distal radius fracture is one of the most frequent human injuries. In persons aged 50 and over it is one of the typical fractures indicating underlying osteoporosis (1). The age-adjusted incidence in large population-based studies ranges from 73 to 202 per 100 000 in men and from 309 to 767 per 100 000 in women (2, 3). At the age of 60 years the residual lifetime risk of a distal radius fracture is 15% for women and 2% for men (3). In the year 2012 almost 84 000 persons received inpatient treatment for wrist fractures in Germany. In light of the current epidemic of osteoporosis, further growth of the incidence of distal radius fractures can be expected (4–6).

The published intervention studies paint an inconsistent picture and are inadequate for the establishment of clear standards of care. The relevant Cochrane Reviews have not been updated since 2008 (7, 8).

Treatment by closed reduction and cast immobilization can be carried out nationwide at low direct cost without admission to hospital, but permits no anatomical reconstruction of bone fragments and joint cartilage. Such reconstruction can be viewed as a necessary, albeit not sufficient, condition for the recovery of joint function. Clinical experience shows that both elderly patients' perception of age and their level of physical activity have undergone a dramatic transformation in recent years. The treatment of distal radius fractures therefore has to be oriented on the functional expectations of the individual patient. With regard to surgical treatment, volar locking plate fixation (open reduction and internal fixation, ORIF) has become the standard of care.

The authors of a systematic review published in 2011 (21 studies, 2093 patients) concluded that "the available data suggest that in patients over 60 the functional outcome of nonoperative therapy, despite the poorer radiological results, does not differ from that of surgical management" (9). The methods and clinical characteristics (e.g., inclusion criteria and interventions) of the individual studies varied so widely that further interpretation of the data was impossible.

The sole randomized trial to compare volar locking plate fixation with plaster cast treatment included 73 patients (mean age 77 years, proportion of intra-articular fractures 70%) (10). Three months after

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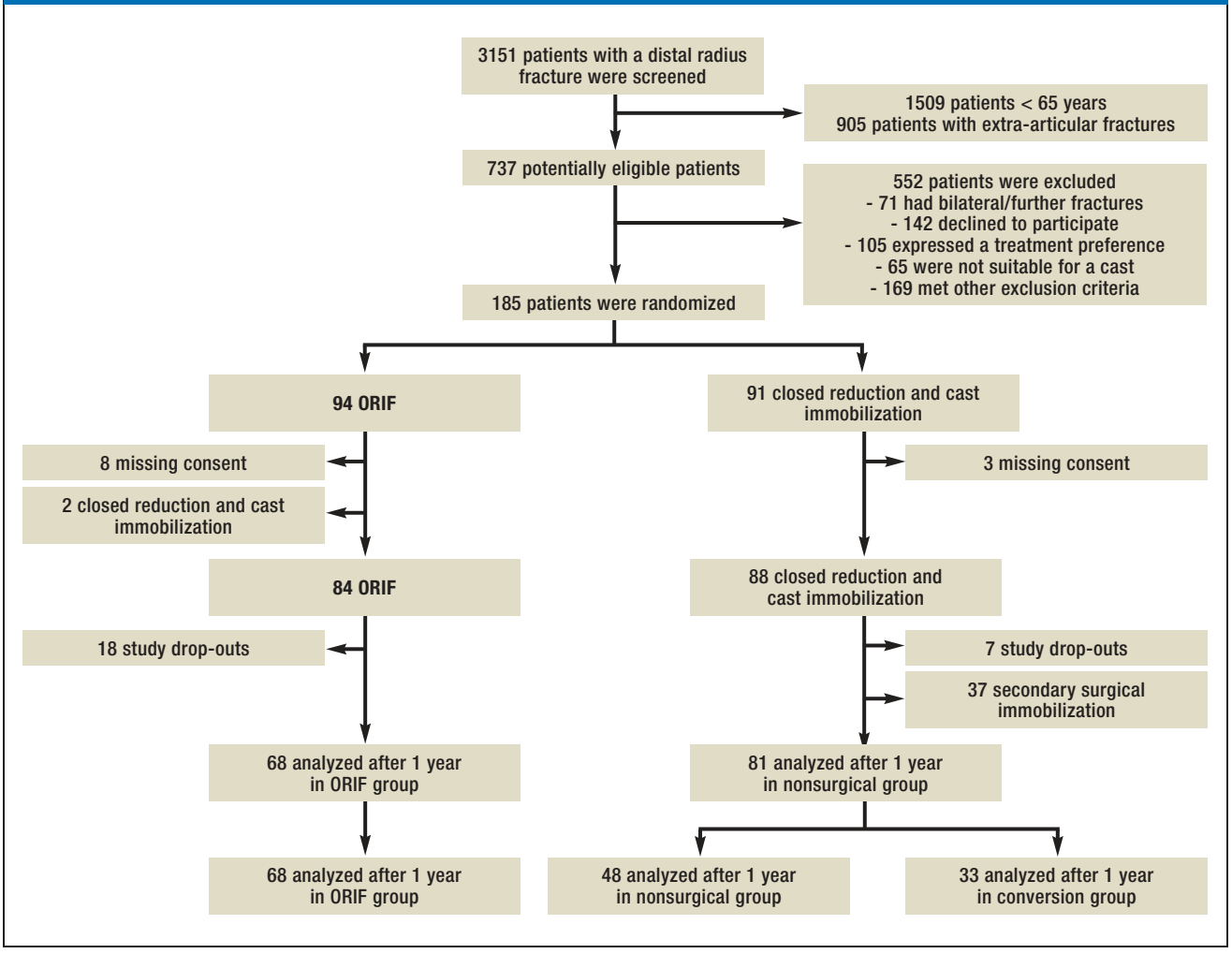
FIGURE 1



Study profile according to CONSORT requirements. ORIF, open reduction and volar locking plate fixation

operation there was a moderate advantage for surgical treatment. At 6 and 12 months, however, the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire revealed no significant differences (0.2 and 2.3 points) between the treatment groups. These results were in agreement with those of a previous retrospective study by the same research group (11, 12) and other studies (9, 13).

At present there is no clear answer to the simple question of whether, in multi-fragmentary intra-articular fractures (type C of the *Arbeitsgemeinschaft für Osteosynthese* [AO] classification), the benefits of anatomical reconstruction of the wrist joint by open reduction and volar locking plate fixation, coupled with swift attainment of functional stability, outweigh the disadvantages of higher costs and greater risk of complications in the long term.

On the assumption that in future the principal burden of disease will be caused by osteoporosis-related fractures in patients who wish to regain autonomy in looking after themselves and managing their household but are not engaged in sports or other strenuous physical activities, there is an urgent need for direct comparison between outpatient closed reduction with cast immobilization and inpatient volar locking plate fixation. This is also important with regard to strategic planning of inhospital care capacity in the coming years.

The pragmatic randomized multi-center ORCHID study (Open Reduction and Internal Fixation versus Cast Treatment of Highly Comminuted Intra-Articular Fractures of the Distal Radius) is intended to clarify whether open reduction with volar locking plate fixation is superior to nonsurgical treatment in respect of health-related quality of life and functional outcome in the scenario described.

Methods

Study goal

The ORCHID study was designed to answer the following question: "In patients ≥ 65 years with a complex fracture of the distal radius with articular in-

volvement, does open reduction with volar locking plate fixation result in a clinically relevant and statistically significant advantage in health-related quality of life and wrist function (SF-36 PCS) at 1 year after treatment compared to closed reduction and cast immobilization?".

Study design

The ORCHID study was carried out at 12 trauma centers in Germany between August 2008 and February 2012 (15). The study was registered at currentcontrolledtrials.com (ISRCTN 76120052). The protocol was approved by the ethics committees of all 12 centers and all patients consented to participate. Data management, auditing, and biometric evaluation took place at independent institutions. The study was done by the German Research Foundation (*Deutsche Forschungsgemeinschaft*, DFG 1105/6–1) in the framework of the "Klinische Studien" ("Clinical Trials") program. The DFG halted the study prematurely and against the wishes of the professional surgical associations because the recruitment rate was much lower than projected.

Inclusion and exclusion criteria

Men and women over 65 years of age with a radiologically confirmed, closed, unstable intra-articular fracture of the distal radius according to the AO criteria (fracture types 23-C1 to C3) *(eFigure 1)* were eligible for inclusion (14). Trauma surgeons at the participating centers verified the inclusion criteria *(eTable 1)* and informed eligible patients about the background and importance of the trial as well as the procedures that would be involved. Random, center-stratified block assignment on a 1:1 basis was achieved by means of the online resource www.randomizer.at.

Interventions

All fractures were initially treated with closed reduction and immobilization in a dorsoradial plaster cast. Patients in the nonsurgical group were treated with a closed forearm cast for 6 weeks, followed by physiotherapy according to local standards. The protocol permitted conversion to secondary surgical treatment in the case of significant loss of reduction or pronounced joint incongruence.

Patients in the ORIF group were treated primarily or after soft-tissue conditioning by open reduction with volar locking plate fixation via the volar Henry approach. The protocol permitted the use of implants from any manufacturer according to local standards and depending on availability. These patients were prescribed physiotherapy according to the standards of the individual center 2 weeks after surgery.

Follow-up

The protocol stipulated six study visits (V1 to V6). These comprised the initial interview and verification of eligibility (V1), the intervention (V2), and follow-ups (V3 to V6), including the final examination after 12 months *(eTable 2)*.

TABLE 1

Baseline characteristics of the patients

Variable	ORIF	Nonsurgical
n	86	88
Mean age, years	75.3 ± 6.7	74.4 ± 7.1
Women	77 (90 %)	76 (86 %)
Mean body mass index	25.6 ± 4.0	25.0 ± 4.0
Dominant right hand	76 (89 %)	84 (97 %)
Right hand affected	42 (49 %)	37 (42 %)
Fall event during previous 5 years	37 (46 %)	33 (38 %)
No use of walking aids	80 (93 %)	79 (90 %)
Fractures during previous 5 years*1	19 (23 %)	14 (17 %)
Mean EQ-5D*2		
Utility index	0.90 ± 0.17	0.90 ± 0.19
VAS score	76.2 ± 14.8	76.0 ± 16.7
ASA classification*3		
1	11 (13 %)	16 (18 %)
2	51 (59 %)	46 (52 %)
3	24 (28 %)	26 (30 %)
AO fracture type*4		
23-C1	36 (42 %)	40 (46 %)
23-C2	35 (41 %)	35 (40 %)
23-C3	15 (17 %)	13 (15 %)

The ± values are standard deviations

*1 Other osteoporotic fractures (e.g., vertebrae, proximal humerus, femur, pelvic girdle)

*2 Estimated EQ-5D score before the fracture event

*3 American Society of Anesthesiologists (ASA 1 = healthy patient, ASA 2 = mild general impairment/disease, ASA 3 = severe systemic impairment/disease

*4 The first digit of the alphanumeric AO classification specifies lower arm fracture, the second digit indicates distal location, the letter C signifies an intra-articular, multi-fragmentary fracture, and the final digit describes the extent of damage to the joint.

ORIF, open reduction and volar locking plate fixation; VAS score, points on the visual analog scale

Primary endpoint

The choice of all endpoints was based on the results of a systematic search of the literature and on repeated meetings between the study coordinators and representatives of the participating centers and professional associations. Emphasis was placed on patient-centered parameters. It was assumed that in older patients a distal radius fracture not only restricts the function of the affected wrist or the upper extremity as a whole, but also results in a temporary or even long-term impairment of physical performance. Therefore a generic instrument for measurement of health-related quality of life and the physical domain was preferred to a wrist specific outcome score. The mean difference in total physical score on the Short Form-36 health questionnaire (SF-36 PCS) at 1 year after randomization was selected as primary endpoint (16). This questionnaire is currently the most widely used and most robust instrument for measuring health-related quality of life.

TABLE 2

Primary and secondary endpoint analysis after 3 and 12 months (ITT population)

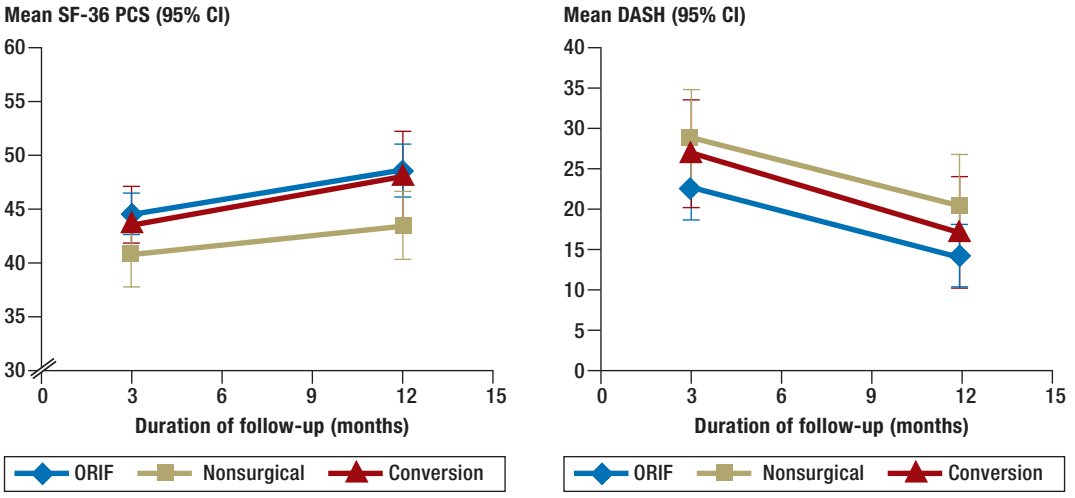
Variable	ORIF	Nonsurgical	Mean difference (95% CI)	*d*	p
3 months					
Patient-centered results, n	73	82			
SF-36-PCS	44.5 ± 8.4	42.0 ± 10.6	2.5 (−0.5 to 5.5)	0.16	0.096
SF-36-MCS	53.7 ± 8.7	54.0 ± 10.1	–0.3 (−3.3 to 2.7)	0.16	0.807
DASH	22.7 ± 16.7	28.2 ± 20.5	−5.5 (−11.4 to 0.4)	0.36	0.071
EQ-5D VAS	69.8 ± 16.0	70.9 ± 15.0	–1.1 (−6.0 to 3.8)	0.07	0.657
EQ-5D utility index	0.90 ± 0.14	0.87 ± 0.18	0.03 (−0.02 to 0.08)	0.19	0.190
Radiological results, n	71	78			
Radial inclination (degrees)	20.3 ± 4.5	17.7 ± 6.3	2.6 (0.9 to 4.3)	0.46	0.005
Palmar inclination (degrees)*[1]	5.1 ± 6.7	–3.7 ± 12.9	8.8 (5.5 to 12.1)	0.15	< 0.001
Ulnar advancement, mm*[2]	0.4 ± 1.6	1.6 ± 2.3	–1.2 (−1.8 to –0.6)	1.10	< 0.001
ROM difference, degrees*[3], n	71	82			
Extension	11.9 ± 13.7	18.2 ± 13.0	–6.3 (−10.6 to –2.0)	0.46	0.004
Flexion	13.3 ± 18.1	22.5 ± 16.5	–9.2 (−14.7 to –3.7)	0.52	0.001
Ulnar abduction	5.3 ± 10.6	10.7 ± 8.9	–5.4 (−8.5 to –2.3)	0.54	< 0.001
Radial abduction	5.1 ± 7.5	8.0 ± 6.9	–2.9 (−5.2 to –0.6)	0.39	0.013
Supination	8.0 ± 14.3	9.7 ± 15.1	–1.7 (−6.4 to 3.0)	0.12	0.471
Pronation	6.5 ± 10.4	10.2 ± 15.7	–3.7 (−7.9 to 0.5)	0.39	0.090
12 months					
Patient-centered results, n	68	81			
SF-36 PCS	48.6 ± 10.4	45.3 ± 11.3	3.3 (−0.2 to 6.8)	0.30	0.058
SF-36 MCS	53.8 ± 7.6	53.6 ± 9.1	0.2 (−2.5 to 2.9)	0.02	0.902
DASH	14.0 ± 16.1	19.0 ± 21.3	–5.0 (−11.0 to 1.0)	0.26	0.102
EQ-5D VAS	76.9 ± 13.9	73.9 ± 16.8	3.0 (−1.9 to 7.9)	0.19	0.248
EQ-5D utility index	0.89 ± 0.21	0.89 ± 0.18	0.00 (−0.06 to 0.06)	≈ 0	0.508
Independence n-/n (%)	63/72 (87.5)	65/82 (79.3)	8.2 % (−3.4 to 19.9 %)		0.363
ROM difference, degrees*[3], n					
Extension	7.5 ± 11.7	7.5 ± 10.0	0.0 (−3.9 to 3.9)	≈ 0	0.982
Flexion	8.2 ± 11.9	11.5 ± 12.8	–3.3 (−7.6 to 1.0)	0.26	0.143
Ulnar abduction	4.4 ± 7.5	5.9 ± 8.0	–1.5 (−4.2 to 1.2)	0.19	0.290
Radial abduction	3.9 ± 6.3	3.0 ± 5.7	0.9 (−1.2 to 3.0)	0.15	0.433
Supination	2.5 ± 5.9	3.2 ± 8.3	–0.7 (−3.2 to 1.8)	0.09	0.603
Pronation	2.8 ± 5.6	2.6 ± 9.4	0.2 (−2.5 to 2.9)	0.03	0.892

The ± values are standard deviations.
d = Effect strength according to Cohen (mean difference divided by pooled standard deviation).
*[1] Positive values show a palmar, negative values a dorsal inclination of the base of the radius
*[2] Positive values indicate a prominent ulna, negative values a prominent radius
*[3] Difference in range of motion (ROM) between the fractured side and the unaffected side, measured using a goniometer and the neutral null method
ORIF, open reduction and volar locking plate fixation; SF-36 PCS, Short Form (36) health questionnaire; SF-36 MCS, summed score of the SF-36; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; EQ-5D VAS; EQ-5D visual analog scale; 95% CI, 95% confidence interval

Secondary endpoints

The 30-item Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire was used as specific instrument to measure the organ-related impairment of wrist joint function after 3 and 12 months (17). The DASH scores range from 0 to 100, with lower scores indicating better function. The EuroQol 5D (EQ-5D) questionnaire served to quantify health states ("utility indices") and measure global health on a visual analog scale (VAS) (18). Wrist joint mobility in all degrees of

FIGURE 2



Physical components of health-related quality of life. Left: SF-36 PCS; right: Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. ORIF, open reduction and volar locking plate fixation; SF-36, Short Form (36) health questionnaire

freedom (i.e., extension, flexion, radial and ulnar abduction, supination, and pronation) was assessed 3 and 12 months after injury according to the neutral null method. Radiographic and/or computer tomography examinations to document reduction or any dislocation and evaluate bony consolidation were performed according to local standards as ordered by the treating physician. All patients underwent standardized radiographic assessment of wrist joint anatomy *(eFigure 2)*.

Adverse events

All adverse events and severe adverse events were registered and evaluated for their causal relationship to the intervention performed. An independent Data Safety Monitoring Board (DSMB) was regularly informed of the adverse events and severe adverse events that occurred.

Biostatistics

The number of cases required was decided on the basis of the International Quality of Life Assessment (IQOLA) Project (16). On the SF-36 PCS a difference of 2.5 points with standard deviation of 10.0 was defined as clinically relevant. To demonstrate this difference with acceptance of a two-sided error type $\alpha = 5\%$ and an error type $\beta = 20\%$, data from at least 252 patients per group were needed.

The primary analysis was oriented on the intention-to-treat (ITT) principle; all patients were analyzed according to their random treatment assignment. Evaluation adhered strictly to the steps laid down in the statistical analysis plan (SAP).

Results were expressed as mean differences with 95% confidence intervals (CI). The effect strength *d* was calculated as mean difference/pooled standard deviation, with values of 0.2, 0.5, and 0.8 classified as slight, moderate and strong respectively (19).

Confirmatory evaluation of the primary endpoint in the ITT population was conducted by means of covariance analysis (ANCOVA). Age, treatment group, sex and center were taken into consideration as determining factors. All other endpoints were analyzed exploratively with the statistics software packages SAS 9.1 and Stata 11.0, taking account of distributions and the quality and completeness of the data.

Results

The study profile complies with the Consolidated Standards for Reporting Trials (CONSORT) *(Figure 1)*. *Table 1* shows the basic demographic profile of the patients, which was comparable in the two groups.

The 12-month follow-up included 68 of the 86 members (79%) of the ORIF group and 81 of the 88 patients (92%) in the nonsurgical group. Thirty-seven study participants (41%) who were primarily allocated to cast treatment were reassigned to secondary surgical treatment due to loss of reduction within 2 weeks; these patients formed the conversion group. Patients with C3 fractures had a 2.1 times higher relative risk (95% CI 1.1 to 3.8) of a conversion to secondary surgery compared to those with C1 or C2 fractures.

The ITT analysis showed a trend towards more favorable SF-36 PCS scores in the surgical than in the nonsurgical group (48.6 vs 45.3 points, $p = 0.058$) *(Table 2)*. However, the observed mean difference of 3.3 points (95% CI –0.2 to 6.8) was above the level of 2.5 ± 10, a priori defined as clinically relevant difference. Exploratory analysis according to the treatment actually performed (as treated) showed comparable SF-36 PCS scores for the ORIF and conversion groups *(Figure 2 left, eTable 3)*.

The DASH score after 12 months showed the same picture *(Figure 2 right, Table 2, eTable 3)*. The observed mean difference of 5.0 (95% CI 1.0 to 11.0) was

TABLE 3

Severe adverse events (SAE), in relation to the ITT population

	ORIF	Nonsurgical
n	84	90
SAE with causal association with intervention		
Reduction loss necessitating revision	0	37
Malposition of implant necessitating revision	4	2
Rupture of extensor tendons	1	1
Rupture of flexor tendons*1	0	1
Wound healing disorder	1	0
Wound infection	0	0
Nerve lesion*2	0	3
Carpal tunnel syndrome	1	2
CRPS*3	0	1
Skin pressure mark*4	0	1
Pseudarthrosis	0	0
SAE without causal association		
Death*5	4	1
Further fractures*6	1	2
Others*7	7	2

*1 Isolated observation, nonsurgical management
*2 All neurological complications occurred after conversion in the surgical arm (two lesions of sensory radial nerve branches, one median nerve hypoesthesia).
*3 Complex regional pain syndrome type 1
*4 No specific consequence
*5 No association with the intervention
*6 Proximal femur fracture (n = 1), proximal humerus fracture (n = 1), vertebral fracture (n = 1)
*7 Musculoskeletal (n = 3), gastrointestinal (n = 2), neurological (n = 2), syncope (n = 1), pneumonia (n = 1)

below the minimal clinically important difference (MCID) of 10.0 points for the DASH (17). Three months after treatment both the radiological reconstruction results and the ranges of motion in the affected wrist were much better in the surgical group than in the patients with cast stabilization. This was not accompanied, however, by significantly better SF-36 PCS or DASH results *(Table 2)*. Bony consolidation of the fracture occurred in all patients regardless of the treatment performed. Neither the patients' assessment of benefit nor the global assessment of quality of life in the EQ-5D differed between the treatment concepts *(Figure 4)*. A total of 72 severe adverse events were registered during the study period, 19 in the group treated by open reduction and volar locking plate fixation and 53 in the nonsurgical group *(Table 3)*. The latter was dominated by loss of reduction in the cast.

Discussion

Despite its early termination, the ORCHID study is the largest multi-center randomized study to date to compare surgical and nonsurgical treatment of AO type C fractures of the distal radius in patients ≥ 65 years. One year after the fracture event, none of the preselected statistical procedures and test criteria showed a clear benefit of surgical over nonsurgical treatment with regard to function or health-related quality of life in the available sample. The much better mobility in the affected wrist joint 3 months after surgical treatment compared with nonsurgical treatment was not accompanied by higher scores for function and quality of life and the advantage was no longer present at the final follow-up. In the surgical arm there were no wound infections and the incidence of tendon-related complications was below that reported in recent publications (9, 13). Exploratory analysis showed functional 1-year results in the conversion group comparable to those in the primary surgical group.

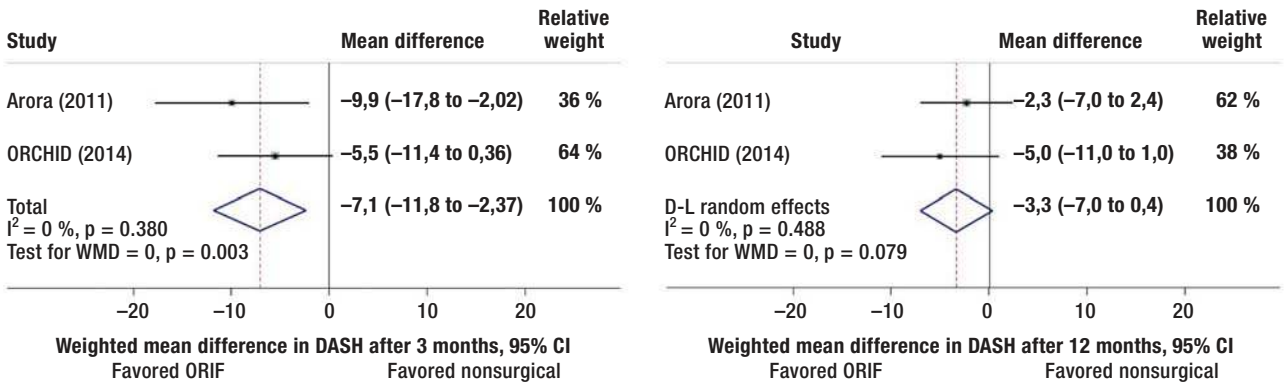
The high conversion rate of 41% underlines trauma surgeons' doubts about whether nonsurgical treatment can even be recommended for complex intra-articular fractures. The conversion rate was strongly associated with the severity of the fracture. The protocol permitted repeat reduction and continuation of nonsurgical treatment in the case of radiologically unfavorable positioning of the fragments, but this option was rarely selected. For wrist fractures initially treated by application of a plaster cast that show no relevant displacement within 2 weeks, continued cast immobilization achieves good results with regard to function and quality of life at 1-year follow-up.

The very high conversion rate was nevertheless unexpected and conflicted with the ITT principle. Furthermore, interpretation of the outcome is hampered by the slow recruitment and the resultant availability of only one third of the planned sample for primary endpoint analysis. However, the results are of considerable relevance for medical care provision. The ORCHID study shows clearly that treating physicians tend to make an early decision to switch to the clinically established open reduction and volar locking plate fixation, a procedure that can meanwhile be viewed as the standard surgical procedure. This may lead to the consequence that surgeons may not be familiar enough with the standard casting techniques.

The ORCHID study set out with the intention of portraying the influence of two opposed concepts for the treatment of one of the most frequent osteoporosis-related fractures with the aid of patient-centered indicators of the health-related quality of life. It attempted to accommodate the interests of all parties (clinicians, methodologists, professional associations, public funding agencies, resource providers, and patients). The scores used had been shown to be valid, for example, in evaluation of the outcome after treatment of lower leg fractures (20). In addition, the SF-36 and EQ-5D tools are indispensable in health economics analyses. The ORCHID study confirmed the results of previous trials by showing that radiological results do not necessarily correlate with clinical outcome parameters (7–9, 11).

Pooling the DASH score results of the ORCHID study with those of the randomized controlled trial by Arora et al. (10), the random-effects model yields mean weighted differences of 7.1 points (95% CI 2.4 to 11.8,

FIGURE 3



Pooled results of the available randomized trials. Left: DASH scores after 3 months; right: DASH scores after 12 months. ORIF, open reduction and volar locking plate fixation; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; WMD, mean weighted difference; 95% CI, 95% confidence interval

p = 0.003) after 3 months and 3.3 points (95% CI –0.4 to 7.0, p = 0.079) after 12 months in favor of surgical treatment. These differences are compatible with chance but lie below the relevant difference of the instrument *(Figure 3)*.

Interestingly, the recently published multi-center DRAFFT study from Great Britain, analyzing the efficacy of volar locking plate fixation versus percutaneous K-wire stabilization in 461 patients, shows an identical difference of 3.2 points (95% CI –0.1 to 6.5) in the DASH score after 12 months in favor of open reduction and volar locking plate fixation (21).

Summary

Ratings of wrist joint function and health-related quality of life in patients ≥ 65 years treated for AO type C fractures of the distal radius tend to be higher after open reduction and volar locking plate fixation than after cast immobilization alone, although the difference is not statistically significant. Patients managed initially by cast immobilization but then switched to surgical treatment owing to loss of reduction within 2 weeks achieve 12-month results practically identical with those of primary surgical care. Should the epidemiological trend towards increasing incidence of osteoporosis-related fractures exhaust the available resources of operating room availability and in-hospital care, primary nonsurgical management continues to offer a valid treatment option in elderly patients even in the era of locking plate fixation.

Acknowledgments
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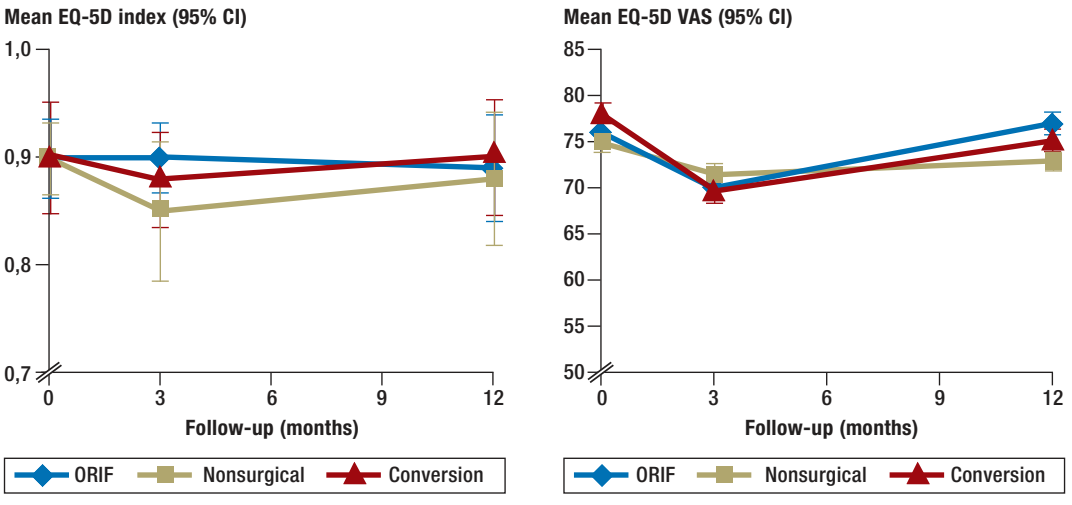
FIGURE 4

Results of the EQ-5D survey



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Conflict of interest statement
PD Dr. Stengel has received payments for consultation, reimbursement of congress attendance fees, and honoraria for preparation of scientific meetings from Biomet, Stryker, and the AO Foundation. He has received reimbursement of travel or accommodation costs from Biomet, Stryker, the AO Foundation, the German Trauma Society (*Deutsche Gesellschaft für Unfallchirurgie e.V.*, DGU), and the German Social Accident Insurance (*Deutsche Gesetzliche Unfallversicherung*, DGU).

PD Dr. Bartl, Dr. Bruckner, and Prof. Gebhard declare that no conflict of interest exists.

KEY MESSAGES

- The ORCHID study was a pragmatic randomized controlled multi-center trial comparing open reduction and volar locking plate fixation (ORIF) with closed reduction and cast immobilization in patients ≥ 65 years treated for multi-fragmentary intra-articular fractures of the distal radius (AO type C).
- One year after treatment the SF-36 PCS revealed a moderate effect strength of 0.30 in favor of ORIF. This was higher than expected but could still have been due to coincidence.
- The DASH score at 3 and 12 months yielded effect strengths of 0.36 and 0.26 in favor of ORIF, but these lay below the relevant difference of the instrument. The EQ-5D score showed no difference between the interventions at any time.
- Radiological criteria and wrist joint mobility showed a clear advantage of ORIF over nonsurgical treatment after 3 months, but this was not accompanied by higher subjective ratings of quality of life or hand and arm function.

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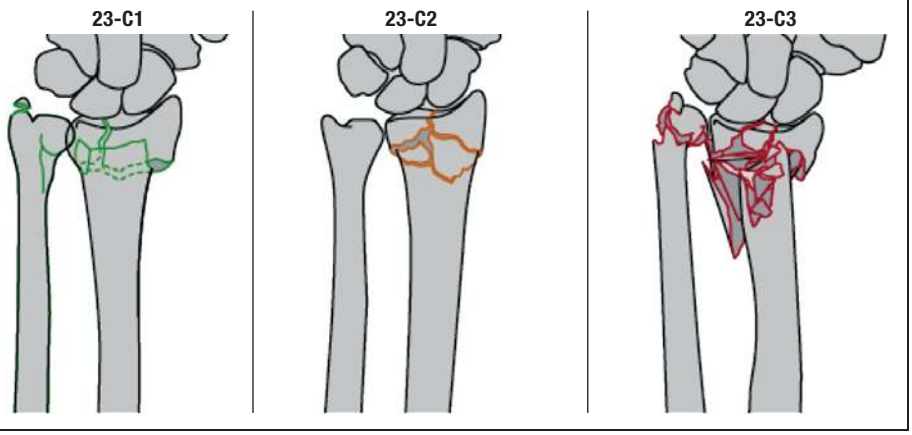
ORIGINAL ARTICLE

The Treatment of Displaced Intra-articular Distal Radius Fractures in Elderly Patients

A Randomized Multi-center Study (ORCHID) of Open Reduction and Volar Locking Plate Fixation Versus Closed Reduction and Cast Immobilization

Christoph Bartl*, Dirk Stengel*. Thomas Bruckner, Florian Gebhard and the ORCHID Study Group

eFIGURE 1



AO classification of intra-articular distal radius fractures. In the AO system the letter C signifies an intra-articular fracture. The suffixes 1 to 3 indicate increasing extent of fracture severity with increasing intra-articular involvement (extent of joint surface damage, number of fragments, extent of metaphyseal comminution zone) (14).
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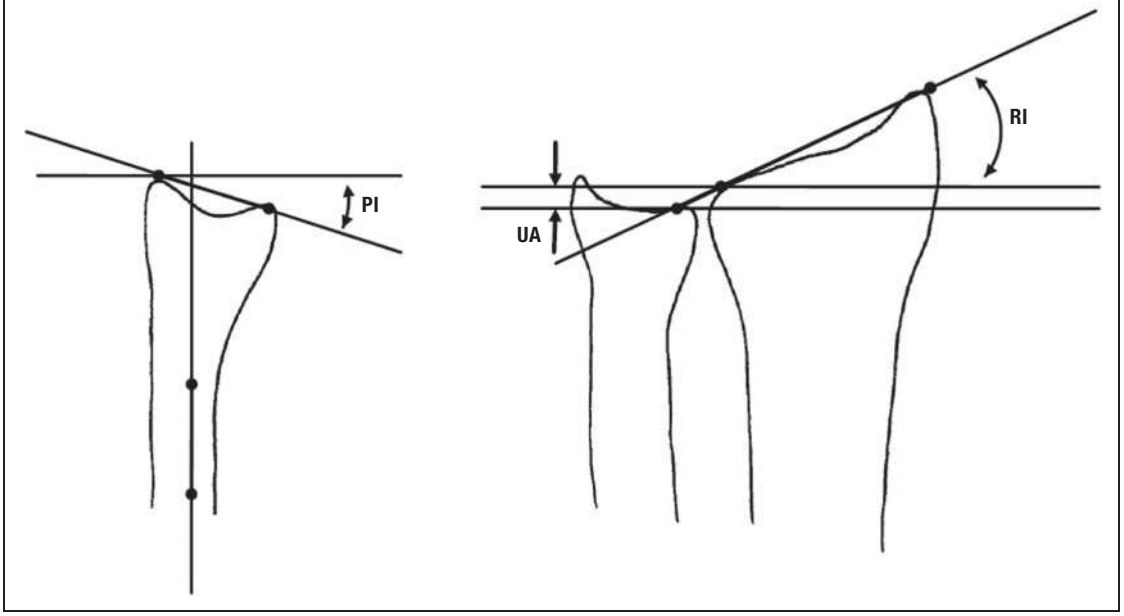
eFIGURE 2



Radiological measurement of wrist joint anatomy

Palmar inclination (PI): Angle between a perpendicular to the longitudinal axis of the radius and the line between the dorsal and volar margins of the joint. A positive value corresponds to palmar inclination, a negative value to dorsal inclination.

Ulnar variance (UV): Measure of the relative length of the ulna and the radius at the wrist joint. UA (in mm) is the distance between two lines perpendicular to the axis of the radius, one at the level of the ulnar joint surface, the other at the level of the sigmoid notch of the radius. In the majority of the population UV is 0, i.e., the joint surfaces are at the same level. Ulnar variance with a prominent ulna is given with a plus sign.

Radial inclination (RI): Angle between the radial joint surface line (a line between the styloid process of the radius and the ulnar corner of the lunate fossa) and a perpendicular to the longitudinal axis of the radius

eTABLE 1

Inclusion criteria and exclusion criteria

Inclusion criteria	Exclusion criteria
Women and men at least 65 years old with an isolated, unilateral, closed intra-articular fracture of the distal radius (AO-23 C1, C2, C3)	Patients with fractures that, in the opinion of the responsible surgeon, could not be treated adequately with a cast
Interval of no more than 1 week from injury to randomization	Patient's preference for one of the treatment options
No specific pretreatment (e.g., K-wire, external fixation, closed reduction)	Extra-articular fractures
Capacity to understand the goal of the study and the necessity for randomization to a particular treatment group	Open fractures
Written consent to take part in the study	Pathological fractures
	Patients not suitable for general anesthesia (e.g., ASA score > 3)
	Presence of a limiting dementia or neuropsychological disease with cognitive impairments
	Body mass index > 35
	Inability or unwillingness to take part in the study visits

eTABLE 2

Study visits

Documentation	Screening	Intervention	Day 1	2 weeks	3 months	1 year
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
History	X					
Physical examination	X		X	X	X	X
Radiographic examination	X		X	X	X	*1
Complications, AE, SAE		X	X	X	X	X
Short-Form 36 (SF-36)					X	X
EuroQol (EQ-5D)			X*2		X	X
Disabilities of the Arm, Shoulder and Hand (DASH)					X	X
Life circumstances (e.g., autonomy)			X*2			X

*1 Radiography was performed at visit 6 if clinically indicated
*2 The initial EQ-5D score and life circumstances were recorded at visit 3 following adequate pain treatment, to avoid a negative effect of the acute trauma situation
AE, adverse event; SAE severe adverse event

eTABLE 3

Endpoints after 3 and 12 months (explorative analysis)*1

Variables	Plate fixation	Conversion group	Cast treatment	p value
3 months				
Patient-centered scores, n	72	33	50	
SF-36 PCS*2	44.6 ± 8.4	43.6 ± 10.3	40.8 ± 10.7	0.091
SF-36 MCS*2	53.7 ± 8.7	53.7 ± 8.7	54.2 ± 10.8	0.963
DASH*3	22.7 ± 16.7	26.9 ± 19.7	28.8 ± 21.0	0.206
EQ-5D index*4	0.90 ± 0.14	0.88 ± 0.16	0.85 ± 0.19	0.355
EQ-5D VAS*4	70.0 ± 16.0	69.7 ± 13.8	71.5 ± 15.7	0.818
ROM difference*5, n	72	32	50	
Dorsal extension [°]	11.9 ± 13.7	21.7 ± 11.0	16.0 ± 13.8	0.003
Palmar flexion [°]	13.3 ± 18.1	24.6 ± 15.8	21.2 ± 16.9	0.004
Supination [°]	8.0 ± 14.3	6.6 ± 9.9	11.8 ± 17.4	0.229
Pronation [°]	6.5 ± 10.4	7.2 ± 11.3	12.1 ± 17.8	0.072
Radial abduction [°]	5.1 ± 7.5	9.4 ± 6.3	7.2 ± 7.1	0.018
Ulnar abduction [°]	5.3 ± 10.6	11.9 ± 9.4	10.0 ± 8.6	0.002
X-ray measurement, n	71	32	46	
Palmar inclination [°]*6	5.1 ± 6.7	5.5 ± 5.8	–10.2 ± 12.9	< 0.001
Radial inclination [°]	20.3 ± 4.5	19.3 ± 4.9	16.7 ± 7.1	0.003
Ulnar variance, mm*7	0.4 ± 1.6	0.7 ± 1.9	2.2 ± 2.3	< 0.001
12 months				
Patient-centered scores, n	68	33	48	
SF-36 PCS*2	48.6 ± 10.4	48.1 ± 11.9	43.5 ± 10.6	0.039
SF-36 MCS*2	53.8 ± 7.6	52.9 ± 8.3	54.1 ± 9.6	0.826
DASH*3	14.0 ± 16.1	17.1 ± 20.2	20.4 ± 22.2	0.210
EQ-5D index*4	0.89 ± 0.21	0.90 ± 0.19	0.88 ± 0.18	0.539
EQ-5D VAS*4	76.9 ± 13.9	75.2 ± 18.6	73.0 ± 15.5	0.429
Living autonomously n/n (%)	62 / 71 (87.3)	31 / 37 (88.6)	35 / 48 (72.9)	0.151
ROM difference*5. n	57	30	39	
Dorsal extension [°]	7.5 ± 11.7	7.6 ± 10.1	7.4 ± 10.1	0.998
Palmar flexion [°]	8.2 ± 11.9	10.5 ± 12.0	12.3 ± 13.5	0.291
Supination [°]	2.5 ± 5.9	1.6 ± 3.3	4.4 ± 10.5	0.257
Pronation [°]	2.8 ± 5.6	1.4 ± 3.0	3.5 ± 12.1	0.557
Radial abduction [°]	3.9 ± 6.3	3.6 ± 6.3	2.6 ± 5.4	0.569
Ulnar abduction [°]	4.4 ± 7.5	7.4 ± 6.9	4.7 ± 8.6	0.210

*1 The ± values are standard deviations
*2 SF-36 scores range from 0 to 100, with higher scores corresponding to better quality of life
*3 DASH scores range from 0 to 100, with higher scores corresponding to a poorer result
*4 EQ-5D index scores range from –0.1 to 1.0, with higher scores corresponding to a better quality of life. EQ-5D VAS scores range from 0 to 100, with higher scores corresponding to a better result
*5 Difference in the range of motion (ROM) between the fractured side and the contralateral side in degrees (°), measured with a goniometer relative to the neutral position
*6 Positive values indicate palmar inclination and negative values show dorsal inclination of the distal radius.
*7 Positive values indicate ulnar advancement and negative values show advancement of the distal radius.