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LIMPER trials: immediate mobilisation versus 2-week cast immobilisation after distal radius fracture treated with volar locking plate – a study protocol for a prospective, randomised, controlled trial

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ABSTRACT

Introduction Open reduction and internal fixation with volar locking plate has become the most common fixation method in the treatment of unstable distal radius fracture (DRF). There is, however, no consensus as to whether or for how long a wrist should be immobilised after operative treatment. To date, there have been relatively few studies that have evaluated the effect of immediate postoperative mobilisation on functional outcomes. The aim of postoperative rehabilitation is to obtain a good function and to reduce impairment, recovery time, socioeconomical costs and absence from work. Therefore, there is a need for studies that evaluate the optimal method of postoperative rehabilitation to optimise wrist function and return to work.

Methods and analysis This study is a prospective, randomised, controlled trial in which a total of 240 working-age patients who undergo volar plating for DRF will be randomly assigned to either an early mobilisation group or a postoperative 2-week casting group. The aim of the study will be to compare early postoperative outcomes between the study groups. The primary outcome will be patient-rated wrist evaluation at 2 months after operation. A coprimary outcome will be the total length of sick leave. Our follow-up period will be 1 year, and secondary outcomes will include pain, patient satisfaction, perceived ability to work and complications identified at different time points. We expect those patients who undergo immediate mobilisation will have at least as rapid a return to work and function as those patients who undergo postoperative immobilisation, indicating/meaning that there will be no need for postoperative casting.

Ethics and dissemination This study will be conducted according to the Standard Protocol Items: Recommendations for Interventional Trials statement. The Ethics committee of Tampere University Hospital has approved the protocol. Ethics committee approval number is R21111, and it is accepted on 7 September 2021. The results of this study will be submitted for publication in peer-reviewed journals.

Trial registration number NCT05150925.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ As our multicentre study will recruit 240 patients, it will be the largest Randomized controlled trial (RCT) to date that compares immediate postoperative mobilisation to postoperative casting in working-age patients with distal radius fracture treated with volar locking plate.
⇒ The co-primary outcome will be the total length of sick leave which has not been previously used as a main outcome.
⇒ The functional results of this study are applicable only to patients in working-age, since we excluded patients who are over 65 years old.

INTRODUCTION

Distal radius fractures (DRFs) are one of the most common fractures in adults. The incidence of DRFs is increasing in the older population, but also among individuals of a working age (18–65 years).[1–3] In young adults with good bone quality, these injuries typically occur from high-energy trauma, whereas older patients more commonly have low-energy accidents, such as falls from standing height. Displaced DRFs have been considered fractures with a dorsal tilt of more than 15°, radial shortening or an intra-articular step of more than 2 mm after closed reduction.[4–7] If any of the above criteria are met after closed reduction and casting, primary open reduction internal fixation with volar locking plate is usually performed in working-age patients with the aim of avoiding malunion and thereby decreasing disability.

A volar locking plate provides enough stability to allow early mobilisation, thereby avoiding the need for prolonged cast immobilisation. While postoperative

immobilisation is standard practice, there is no consensus on whether how long, if at all, a wrist should be immobilised after operatively treated DRF.[8 9] Previous studies have reported that postoperative immobilisation varies widely from 0 to 6 weeks after the volar plating of DRF.[8 10–13] However, relatively few studies specifically evaluate the impact of postoperative splinting/casting versus immediate mobilisation. The main problem with previous studies has been the relatively small sample sizes, which makes the comparison of these studies difficult.[10 11 14] Moreover, the literature does not provide evidence from controlled datasets of the differences in functional outcomes after 3 months from DRF operation with volar locking plate between the varying postoperative immobilisation periods.[12 13] Moreover systematic reviews on rehabilitation efforts after DRF in adults have shown that the effectiveness in various rehabilitation protocols is not sufficiently evidence based.[15 16]

Since DRF can potentially lead to impaired physical function, rehabilitation can play a vital role in reducing deterioration and recovery time as well as socioeconomical costs, such as limiting the time off work.[17] Any permanent loss of function can even lead to the inability to work, affecting personal coping. After primary intervention, DRFs are associated with the use of multiple resources, including operative interventions, outpatient visits and rehabilitation. Postoperative casting also uses expensive resources, such as time spent in the OR and visits to outpatient clinics for cast fixing or removal.[18] Moreover, the restoration of wrist function and the reduction of impairment is important considering that more than 50% of DRF patients are still of working age. A mean sick leave duration of 4–12 weeks has been reported, which means sick leave after DRF has an important socioeconomical role.[19–22] Further, a recent study has suggested that self-reported disability, pain, and disabilities of the arm, shoulder and hand outcome measure as early as 1-week postfracture are the strongest predictors of length of sick leave, regardless of whether the treatment is operative or non-operative.[21]

To our knowledge, only a few studies exist that have compared standard postoperative casting with immediate mobilisation.[8 10–12] The aim of this trial is to compare outcomes between working-age patients allocated to either immediate postoperative mobilisation or 2-week postoperative cast immobilisation after volar locking plate fixation of DRF. We expect patients in the immediate mobilisation group will have at least as rapid a return to work and function as those patients in the postoperative immobilisation group, meaning that there will be no need for postoperative casting. Immediate mobilisation will allow the effective use of scarce resources without compromising the results of volar plating in DRF with no differences in the numbers of complications 1 year after surgery.

OBJECTIVES

Coprimary objectives

This trial compares the patient-related wrist evaluation (PRWE) at the 2-month time point and the total postoperative length of sick leave between early mobilisation and 2-week casting after volar plating of DRF.

Secondary objectives

Secondary objectives are to compare pain, perceived ability to work, patient satisfaction and complications within a total of 1-year follow-up. We will also investigate the objectively measured physical upper extremity activity level from baseline to 4 weeks in patients in the immediate mobilisation group and from 2 to 4 weeks in patients in the casting group using the tri-axial (Axivity Ltd, Newcastle upon Tyne, UK) accelerometer.

Trial design

This ongoing trial is a prospective, 1:1 equivalence study. This study is a randomised, controlled, multicentre trial comparing immediate mobilisation versus 2-week cast immobilisation in working-age patients after DRF treated with open reduction and volar locking plate fixation.

METHODS

Study setting

The eligible study population will comprise patients aged 18–65 (<65th birthday) who are treated operatively with volar locking plate for DRF at the participating study centres. The participating study centres are Tampere University Hospital, Finland; Central Finland Central Hospital, Finland and South Carelia Central Hospital, Finland. We aim to have more centres participating this study. Patient recruitment started on 1 December 2021. The results of the study will be analysed after the last participating patient has reached 1-year follow-up period, which is expected to be at the end of 2025. This trial is a part of LIMPER (lower and upper limb injuries, diseases and postinjury rehabilitation and treatment) trials.

Eligibility criteria

Inclusion criteria

Patients eligible for the trial must comply with the following criteria at randomisation: intra-articular or extra-articular DRF, including Smith's and volar Barton's fracture with or without accompanying fractures of the processus styloideus ulnae, and who have been pragmatically chosen for operative treatment.

Exclusion criteria

- Refusal to participate in the study.
- Open fracture with a severity greater than Gustilo grade 1.
- Patients aged less than 18 or more than 65 years.
- Patient does not understand written or spoken guidance in local languages.
- Pathological fracture.

- Fractures that are operated on 3 weeks or more after the injury.
- Fracture assessed to need casting after operation: for example, severely comminuted fracture where the fracture morphology is assessed to need both the volar locking plate and postoperative casting.
- Previous fracture in the same wrist or forearm in the last 10 years that has led to impairment of function
- Ipsilateral fracture in upper extremity.
- Polytrauma.

Recruitment

Working-age patients with DRF who are scheduled for volar plating will be asked to participate in the study. Patients will be recruited at either preoperative visits to the outpatient clinic before surgery or on the ambulatory surgery ward the same day the surgery will be performed. The study participants will provide signed informed consent before the operation. Randomisation will be performed intraoperatively after the wound is sutured. Patients that refuse to participate, will be collected in screening log. Participants that are recruited, but are intraoperatively excluded for randomisation will be followed via questionnaires during the 1-year follow-up.

Intervention

All participants in this trial will be treated with open reduction and internal fixation using the volar locking plate system. The decision to operate will be at the discretion of the treating surgeon and the patient and will not be related to the trial. A standard technique with volar modified Henry approach will be used. Wounds will be sutured with absorbable intracutaneous sutures, and an adhesive tape will be placed over the sutured wound.

After the wound is closed, the participants will be randomised to either the immediate mobilisation group or the 2-week cast group. Participants allocated to the 2-week cast group will have a dorsal functional position plaster cast fitted in the operating room after surgery. The cast will be removed in a primary healthcare centre after 2 weeks. After cast removal, participants will be advised to perform a full range of active motion exercises without resistance for the following 2 weeks.

Participants allocated to the immediate mobilisation group will have a padded dressing that may be removed the next day. The participants in the immediate mobilisation group will be advised to perform a full range of active motion exercises without resistance starting from the first postoperative day.

Both groups will receive written aftercare and rehabilitation instructions. The detailed rehabilitation programme for both groups is presented in additional online supplemental materials 1 and 2 in Finnish, and online supplemental materials 3 and 4 in English. After 4 weeks, participants in both groups will meet a physiotherapist in a public health centre or an occupational health centre. The physiotherapist will supervise a full range of motion exercises with progressive weight bearing. After the first follow-up at 4 weeks, the exercise protocol will be the same in both groups. All participants will receive 4 weeks of sick leave from the operating unit after surgery. They will be advised to contact their occupational health centre if the sick leave needs extending or they are willing to return to work earlier.

The upper-limb physical activity of the participants will be measured using a tri-axial (Axivity Ltd) accelerometer. The participants will have an accelerometer sensor mounted on both upper arms with a wrist band. Patients in the immediate immobilisation group will be asked to wear the sensor immediately after surgery, whereas patients in the casting group will wear the sensor after cast removal at 2 weeks after surgery. The sensors will be given to patients in the 2-week casting group after surgery and told to wear them on their upper arms after removal of the cast. Notification will also be sent via Research Electronic Data Capture (REDCap) to ensure application of the Axivity sensors. All patients will return the sensors via post 4 weeks after surgery.

Patient and public involvement

Patients were not involved in the design, recruitment or conduct of this study. Patients will be informed by the results of the study after completion.

Outcomes

We chose the patient-reported outcome measure PRWE as the coprimary outcome since it is widely used and validated in upper extremity studies. Our coprimary outcome is total length of sick leave.

Baseline data

After enrolment, the following baseline data will be collected from the participants: date of birth, age, weight, height, handedness, relevant comorbidities, date of injury, mechanism of injury and fracture characteristics. Participant will be also asked to complete baseline questionnaires on their work status, education level, smoking, physical work exertion and perceived work capacity. Physical work exertion levels are measured on a scale of 1–5.[23] The exertion levels are presented in table 1. Wrist pain prior to injury will be assessed on a numerical rating scale. Participants will complete the PRWE questionnaire describing their wrist function prior to sustaining the fracture.

Primary outcome measures

The coprimary outcome measures of this study will be PRWE score and total length of the sick leave. The primary time point with PRWE will be at 2 months.

Patient-rated wrist evaluation

PRWE is a 15-item questionnaire designed to measure wrist pain and disability in activities of daily living. It is a reliable upper extremity outcome instrument, and has passed to several validation tests. The questionnaire consists of two subscales (pain and function) and the score ranges from 0 (no disability) to 100 (severe disability).[24–26]

Table 1 Physical work exertion level

Physical work exertion level		
1	Sedentary	Work mainly involves sitting, and the occasional lifting of objects weighing a maximum of 5 kg. From time to time might carry, for example, a paper folder or small tools. Walking can be part of the job but work mainly involves sitting
2	Light	Work may occasionally require the lifting of objects weighing a maximum of 10 kg and may require the regular lifting or carrying of objects weighing a maximum of 5 kg. Work can involve a lot of movement, such as walking or using limbs
3	Medium	Work occasionally requires lifting objects weighing a maximum of 25 kg and regularly carrying or lifting objects weighing a maximum of 12 kg
4	Heavy	Work occasionally requires lifting objects weighing a maximum of 50 kg and regularly carrying or lifting objects weighing a maximum of 25 kg
5	Very heavy	Work occasionally requires lifting objects weighing more than 50 kg or regularly carrying or lifting objects weighing more than 25 kg

Moreover, in 2015, Walenkamp *et al* reported that the minimal clinically important difference in the PRWE is 11 points.[25] The validity and reliability of the Finnish PRWE has been shown to be acceptable in patients with DRF.[26] The PRWE is measured at the 4-week, 2-month, 6-month and 12-month time points.

Total length of sick leave

The coprimary outcome of the study is the total length of the sick leave. The day of the return to work is included in the questionnaires sent to participants at different time points. Return to work will be measured as a yes/no question, and the exact date of the return to work is asked by electronic follow-up questionnaire in the follow-ups at the 4-week, 2-month, 6-month and 12-month time points. Patients are also asked, if they have been returned to work at part time or modified work. At 1-year follow-up, the full length of the sick leave for each participant will assessed using data from the Social Insurance Institution of Finland.

Secondary outcomes

Work capacity

Perceived working capacity will be assessed using electronic follow-up questionnaires at all follow-up time points: 4 weeks, 2 months, 6 months and 12 months. The participants will be asked to rate their working capacity on a numerical scale from 0 to 10, with '0' being not able to work at all and '10' being the ability to work at its best.

Pain

The Visual Analogue Scale (VAS) is a validated subjective measure for acute and chronic pain. VAS scores will be recorded by making a mark on an electronic 100 mm line that represents a continuum between 'no pain' and 'worst pain'. Patients will be asked to evaluate the perceived pain during last 7 days. VAS score will be measured at 4 weeks, 2 months, 6 months and 12 months.

Patient-acceptable symptom state

Patient satisfaction will be measured using the patient-acceptable symptom state. Patients will be asked to answer questions via electronic questionnaire at 2 months, 6 months and 12 months. The questionnaires will include the following questions: would you be willing to take the same treatment again if the treatment result was as it is now? (Yes/No). Considering all the different ways your injury is affecting you, if you would remain in this state, do you feel that your current state is satisfactory? (Yes/No).

Complications

At 1-year follow-up, patient data will be reviewed to detect any complications. Complications are defined as problems with wound healing, deep infections, hardware failure (loss of reduction, malunion), tendon complications (both extensor and flexor irritations or ruptures), nerve-related problems (paresthesia, Complex Regional Pain Syndrome (CRPS)) or reoperation (for any reason). Complications are divided into major and minor complications. Problems with wound healing are categorised as minor complications and will be assessed via electronic questionnaires. Major complications include loss of reduction and hardware failure during follow-up resulting in reoperation, permanent nerve damage and CRPS.

Activity level

We will also investigate objectively the physical upper extremity activity level measured from baseline to 4 weeks in patients in the immediate mobilisation group and from 2 to 4 weeks in patients in the 2-week casting group using the tri-axial accelerometer. The sensors will measure 24/7 activity and degree of movement. With this data, we will be able to compare activity levels between the two study groups and against healthy population.

Participant timeline

The time schedule for enrolment, interventions, and visits is presented in table 2. After written informed consent, study personnel will complete case report forms for baseline. Standard radiological parameters will be defined from baseline X-rays. These parameters include volar-dorsal angulation angle, radioulnar inclination angle, intra-articular step-off and intra-articular diastasis. According to normal follow-up procedure, all patients will

Table 2 Schedule of enrolment, interventions and assessments

	Enrolment	Allocation	Follow-up				
Timepoint	Baseline	Operation	2 weeks	4 weeks	2 months	6 months	12 months
Enrolment							
Eligibility screen	X						
Informed consent	X						
Randomisation		At the end of the operation					
Interventions							
Immediate immobilisation							
Postoperative casting			Cast removal				
Assessments							
Outpatient visit	X			Remote clinic			
Physiotherapist visit		X		X			
X-ray	X	X		X			
PRWE, return to work	X			X	X	X	X
Pain, complications	X			X	X	X	X
Tri-axial accelerometry	Immediate mobilisation group	———	———	———			
Tri-axial accelerometry	Casting group		———	———			

PRWE, patient-rated wrist evaluation.

undergo a follow-up at a virtual clinic 4 weeks after surgery. Before the visit, direct lateral and AP radiographs will be taken at local health centres and an orthopaedic surgeon will evaluate the X-rays and a virtual clinic appointment will then be carried out over the telephone electronical questionnaires, including PRWE and VAS, will be sent via REDCap before the follow-up appointment at the virtual clinic at 4 weeks.

Randomisation

The randomisation procedure will be set up in the REDCap randomisation tool. After recruitment and baseline measurements, a site principal investigator from each hospital will administer the online allocation procedure by entering patient data into the REDCap system, which will enable the randomisation tool. Allocation concealment will be ensured, as randomisation will not be performed and revealed before the patient has been included in the trial.

Randomisation will be performed by the researchers. Randomisation will be performed after the wound has been sutured, because earlier randomisation might influence the surgeons judgement, for example, in longer operating time. Thereafter, the allocation group will be revealed to the patient and the operating surgeon. Participants will be included in the immediate mobilisation group or the 2-week cast group in a 1:1 allocation as per computer-generated randomisation matrix with randomised block size and stratified by work physical exertion level (sedentary/light vs medium/heavy/very heavy), fracture articulateness (intra-articular or extra-articular) and age (older or younger than 55 years).

Blinding

Due to the nature of the intervention, patients cannot be blinded from the treatment allocation. After the first 4-week sick leave period, subsequent sick leaves will be issued by health professionals working outside our institution and not related to the study.

Data management and analysis

Data management

Each patient will be assigned a unique trial identification number (TIN) matched with the patient's personal identification number (ID). This is assigned when patient has signed informed consent, and TINs are consecutive and never reused. The research data will only be handled with a TIN throughout the trial. The research data will be saved on a database with an online patient management programme REDCap (https://www.project-redcap.org/), and secured by password. Only trial researchers will have access to the REDCap data located on a secure study server at Tampere University Hospital. The research data saved to the server will contain only pseudonymous TINs with a set of numbers acquired from the questionnaires, that is, each question will be answered with a number. This will ensure the pseudonymity of each patient and that the patient's identity will remain secret should server data be revealed to third parties.

All primary and secondary data will be acquired and stored on the study server. Data will be entered by the patient during the first visit via a tablet or by a researcher or study nurse when the questionnaires are returned by mail. During the follow-ups, patients will receive a link via email to the questionnaires. Patient-reported outcome data will be entered directly into the REDCap system by the patients using the 'required fields' option activated to ensure there are no missing items from the completed questionnaires. Researchers from each participating hospital will have access to the secure study server where the trial research data is stored. An information security committee has approved the server at Tampere University Hospital. At the end of the trial, each researcher will have access to the data for further analyses.

The copyright of the trial research data will be owned and created by the collaboration parties. The data will be shared freely among the collaboration parties. All participating researchers will have access to the data after the trial. Due to confidentiality and legal agreements, public data sharing will be restricted until primary analysis and publication have been completed. Under certain circumstances, for example, when a new member joins the collaboration, we will grant access to the data. All data will be stored for 5 years after the end of the trial.

Power analysis

The coprimary outcomes in our study are the PRWE, and the total length of sick leave. We set our sample size to 120 patients per group. First, in a Finnish study, the SD of the PRWE in working-age patients was reported to be 14.8 points. Assuming 90% power and a true mean difference of 0 points between groups, 120 patients per group means an equivalence margin of 6.3 points, which is well below the previously established minimal clinical important difference. The previous literature regarding sick leave after DRF is variable. Moreover, the SD for sick leave after DRF is rarely reported. One study reported SD of 9.7 weeks. This means that we would have 90% power for a 4.1-week equivalence margin. Sick leave is, however, very dispersed. In our pilot study, the IQR for sick leave was 42–76 days, which translates to an SD of only 3.6 weeks, assuming a normal distribution. This would mean higher precision in the estimates. Adjustment will be used in all analyses, thus increasing the efficiency of our analyses.

Statistical analysis

Primary analysis of the PRWE will be conducted using a repeated measures (linear) mixed model. Group allocation is the main exposure and age, gender, fracture articularity, and physical work exertion and study centre will be used as covariates. The patient will be used as a random factor. Score at time of assessment (primary outcome at 2 months) for continuous outcome variables, that is, PRWE, length of sick leave, will be included as a fixed factor. Treatment effect will be interpreted as the interaction between group allocation and the score at time of assessment. Analysis for sick leave will be conducted with linear regression, including the same covariates. Regression coefficient for group allocation is interpreted as the treatment effect. This will be done with estimated marginal means and reported with 95% CI. Binary outcomes will be analysed with logistic regression. Group allocation is the main exposure and above-mentioned covariates will be included in the model for adjustment. The main result will be the adjusted marginal proportion between the groups from this model. All analyses with the activity data will be exploratory and hypothesis-generating. R statistical software (The R Foundation for Statistical Computing, Vienna, Austria) will be used in the statistical analyses. We will have an exploratory analysis, where the result is adjusted with the delay from time from of the injury to the time to the operation.

ETHICS AND DISSEMINATION

Ethical approval

The Ethics Committee of Tampere University Hospital has approved the protocol. Ethics committee approval number is R21111, and it is accepted on 7 September 2021. Each recruiting centre will apply for local ethical approval. This study will be conducted according to the World Medical Association Declaration of Helsinki.

Consent

Informed consent will be obtained by the local recruiting study personnel in each participating centre. The consent form is written in Finnish. It is available in additional online supplemental material 5.

Confidentiality

The electronic databases will be maintained in secure storage at the coordinating centre for 5 years after completion of the study (after the last patient has reached the 1year follow-up time point).

Access to data

The primary investigator and study nurse hold the register of patients within the trial. At follow-ups, all patient data will be analysed by a statistician and the authors of the manuscript.

Dissemination policy

The results of this study will be submitted for publication in peer-reviewed journals.

Monitoring

Data monitoring

We will conduct the study without a data monitoring committee.

Harms

All the medical records of the participating patients will be carefully assessed, and all complications in both groups

will be reported when reporting the results of this trial. The harms will be divided into major and minor complications, as described in the Outcomes section.

Auditing

We will not conduct auditing between the participating centres during the trial.

DISCUSSION

During recent decades, there has been a trend towards operative fixation using volar plating in the treatment of displaced DRFs. However, no consensus exists regarding optimal postoperative casting to expedite return to function following the volar plate fixation of DRF. Moreover, there is insufficient evidence on the effectiveness of various rehabilitation protocols.

We assume high adherence to the allocated intervention. As patients have undergone a surgical operation and are of working age, it is unlikely that the patient would remove the cast postoperatively or acquire external support elsewhere. Adherence to accelerometer use may be inferior to that of the allocated intervention. Patients may feel the accelerometer unpleasant to wear and decide to remove it. However, this poses no threat to the validity of the study since accelerometer data are a secondary measurement. Thus, even with lower adherence to accelerometer use, we can still estimate activity differences reliably.

There will be an analysis of the functional outcome, PRWE, and we expect equally good function in both study groups. Further, we expect patients who underwent early mobilisation after volar plating for DRF to return to work as quickly as those patients who wore a cast. We also expect immediate mobilisation to be a safe method for the postoperative care of patients who undergo volar plating for DRF. Considering the number of operated DRFs annually, it is essential to use postoperative interventions that have proven efficacy and are cost-effective.

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Contributors LK, APL and AR developed the trial, LK being the principal investigator. LK drafted the manuscript and all the members (LK, APL, AR, TK, TL, VP, VMM, LH and MH) contributed to the writing of the protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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