Is casting of displaced paediatric distal forearm fractures non-inferior to reduction under general anaesthesia? The CASTING trial.

Study protocol for a pragmatic, randomized, controlled non-inferiority multicentre trial

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Background

Paediatric distal forearm fractures (DFFs) are common and account for 25-30% of all fractures in children (1,2). In Denmark, the incidence among 4-10 year old children is approximately 900/100,000 persons, corresponding to 3,500-4000 injuries per year (3), of which nearly half are treated surgically (4). The most common treatment of displaced paediatric DFFs is closed reduction under general anaesthesia with or without pin fixation (or in rare cases plate and screw fixation), followed by immobilization in a cast (5). However, surgery may have detrimental effects, such as fear, anxiety and complications related to surgery. Children's bones, and in particular the metaphysis and epiphysis, have a unique ability to heal and remodel throughout the growth period (6), making a non-surgical approach a possible alternative.

Numerous studies, including small cohort studies, randomized controlled trials (RCTs) and case series, have found pin fixation advantageous in achieving anatomic reduction and avoiding re-displacement (7–13). However, it is unknown whether patient-reported outcomes benefit from anatomic reduction and stabilization, as most studies use only radiographic or objective measures such as range of motion (ROM). During the last 20 years, only four studies (one case-control study (14), one prospective cohort study (15), and two retrospective case series (16,17)) have been

published, investigating non-surgical treatment of displaced DFFs in prepubertal children; they do however agree that displaced DFFs might heal well without reduction, and that most fractures will remodel almost to the anatomical position with no functional impairment within a year or two.

To the best of our knowledge, there are no published RCTs comparing non-surgical treatment to surgical treatment, and no studies reporting outcomes from the patient's perspective.

Aim
To compare the patient reported outcome measures assessing function, health-related quality of life, and pain after non-surgical versus surgical treatment of displaced distal forearm fractures in 4-10 year old children.

Methods

Design
A pragmatic, randomized, controlled non-inferiority multicentre trial with two parallel groups allocated 1:1 by block randomization. Primary outcome is patient-reported function after 1 year. The trial will be conducted at four Danish university hospitals (Køge, Aarhus, Aalborg and Odense). The Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) Statement will be followed (Table 1).

Table 1 Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) diagram

	STUDY PERIOD						
	Enrolment	Allocation	Post allocation				Close-out
TIMEPOINT	Pre-randomization	Randomization	Day of intervention	4 weeks	3 months	6 months	12 months
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTION:							
Casting			•———————————•				
Surgery + Casting			•———————————•				
ASSESSMENTS:							
Radiograph of injured wrist	X			X		X	X
Photograph of both wrists	X			X	X	X	X
Cast ± pin removal				X			
QuickDASH					X	X	X
EQ-5D-Y					X	X	X
WBS					X	X	X

Participants

We will include children aged 4-10 years with a displaced fracture of the distal metaphyseal radius with or without concomitant ulna fracture (ICD DS52.5 (distal radius) and DS52.6 (distal radius and ulna)), and where the on-call orthopaedic surgeon finds indication for surgical intervention.

For definition of the metaphysis we will use the AO-classification for children (figure 1) where the metaphysis is defined by a square based on the width of radius and ulna at the level of the radial epiphysis on AP projections. Thus, the proximal line define the border between the metaphysis and diaphysis (18).
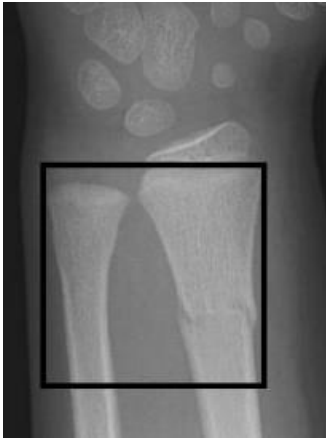
Figure 1 AO-classification of the metaphysis. URD: Ulna-radius-distance.

Inclusion criteria

- Children 4-10 years of age with open physes
- Fractures in the distal metaphyseal radius (with or without concomitant ulna fracture), including extra articular physeal fractures (SH I-II)
    - Overriding fractures
    - Angulated fractures of 20-40°
- The on-call surgeon finds reduction under anaesthesia with or without fixation indicated

Exclusion criteria

- Open fractures
- Nerve or vascular damage
- All intraarticular fractures including SH III-V
- Ulnar physeal fractures
- Polytrauma
- Concomitant ipsi- or contralateral upper extremity fractures (except distal ulna fracture)
- Pathologic fractures
- The injury is >7 days old
- Other conditions that may affect bone healing

Recruitment and informed consent

Recruitment

Patients will be recruited from Emergency and Orthopaedic Departments at the recruiting hospitals. Before recruitment begins, the principal investigator (PI) will ensure that the same written and oral information is available at all sites.

When a patient meets the inclusion criteria, the patient is screened for eligibility. The surgeon will briefly introduce the ongoing project and ask the parents/guardians to meet in the outpatient clinic the following day, where the local investigator will provide both oral and written information about the project. The parents/guardians will be informed that they have the right to bring a friend or family member to the oral information meeting.

Informed consent

When the child and the parents/guardians meet in the outpatient clinic, the local investigator will provide both oral and written information including trial participant's rights and a consent form. The information will be adapted to the child's ability to understand the project and its importance for them. After a reflection period, they will be asked for written consent.

Randomization and concealment of allocation

We will use Research Electronic Data Capture (REDCap), a computerized irreversible randomization application, to allocate patients into one of the two treatment groups.

The randomization sequence will be computer-generated in REDCap by block randomization (60 blocks with shifting block sizes of 2, 4 and 6 in each block).

Concealment will be assured by irreversible randomization before allocation takes place. A REDCap functionality will ensure that only patients who fulfil all inclusion criteria and does not meet any of the exclusion criteria can be randomized. From this point, any deviation from the allocation will be regarded as either cross-over or drop-out.

Interventions

As standard procedure a temporary cast will be applied in the emergency room. Offering any type of analgesia prior to casting will be up to the treating doctor. After proxy consent have been obtained, the child will be randomly allocated to one of the two following treatment options:

1. Non-surgical treatment (study intervention): No reduction. Cast optimization if considered necessary.
2. Surgical treatment (comparator): Reduction under general anaesthesia with or without additional pin (or plate) fixation of surgeons' choice followed by cast immobilization.

The cast will be removed after 4 weeks if radiological signs of healing (callus formation or bone bridges). The casting will be prolonged another 2 weeks if uncertainty of healing. If the initial cast was an above elbow cast, it will be changed to a below elbow cast at this point.

Follow-up

According to the pragmatic design of the study, the treating surgeon decides whether a control visit by 1 week for children undergoing surgery is preferred. Regardless of the treatment allocation, all patients will visit the outpatient clinic by 4 weeks for radiographs of the injured arm, photographs of both arms, and cast and pin removal. In accordance with the pragmatic design, children in the surgical group will, during the first 4 weeks, be consulted by different surgeons in the outpatient clinic. Children in the non-surgical group will be consulted by the local investigator. Hereafter, all participants will be consulted by the local investigator. The following visits will be at 3, 6 and 12 months for completion of questionnaires and photographs, and by 6 and 12 months also radiographs. The questionnaires are completed before the consultation and handed to a third party not otherwise involved in the patient or study, who will review the questionnaires to find incomplete answers and thereby minimize the risk of missing data. Radiographs of the injured arm will be evaluated by a blinded person to discover early physeal closure and to monitor the remodelling process. Furthermore, photographs of both arms will be taken by the local investigator to compare the clinical appearance.

Outcome measures

Outcome measures will be collected 4 weeks and 3, 6 and 12 months post-treatment. All questionnaires will be completed in the waiting room prior to clinical assessments and handed to a staff member not involved in the study, who will screen the questionnaires for incomplete item responses.

Primary outcome measure

QuickDASH

The primary outcome will be patient reported functional outcome, QuickDASH at 12 months post-treatment. The QuickDASH (19) is a shortened version of The 30-item Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure (20). The DASH was designed to help report the disability experienced by people with upper-limb disorders and also to monitor changes in symptoms and function over time.

Instead of 30 items, the QuickDASH uses 11 items corresponding to different activities of daily living and symptoms. Like the DASH, the QuickDASH also has two four-item optional modules that are scored separately. The QuickDASH can be used instead of the full DASH with comparable psychometric properties (21).

The patient (with help by parents if the patient is too young to self-report) rates each item according to the perceived degree of severity using a 5-point Likert Scale. Then, the overall score is transformed to a score between 0 and 100 (0 = no disability, 100 = maximum disability) according to the algorithm [(sum of responses N/N)-1]*25, where N is equal to the number of responses. At least 10 of the 11 items must be completed for a score to be calculated.

The QuickDASH has been validated among adults with distal radius fractures (22), as well as children aged 8-18 years with any upper extremity injury (23).

Secondary outcome measures

Secondary outcomes will include:

- QuickDASH (3 and 6 months)
- Health-Related Quality of Life (HRQoL) using EQ-5D-Y (3, 6 and 12 months) (24,25), and
- Pain by Wong-Baker Faces Pain Scale (WBS) (3,6 and 12 months) (26).

EQ-5D-Y

The EQ-5D-Y is a free, child-friendly version of the widely used EQ-5D generic measure of HRQoL. It consists of two parts. The first part (the descriptive system) assesses health in five dimensions (Mobility; Looking After Myself; Doing Usual Activities; Having Pain or Discomfort; Feeling Worried, Sad or Unhappy), each of which have three levels of response. This part of the EQ-5D-Y questionnaire provides a description of the respondent's health, generating a health state profile. The second part of the questionnaire, the EQ VAS, consists of a visual analogue scale (VAS) on which the respondent rates their perceived health from 0 (the worst imaginable health) to 100 (the best imaginable health). Instructions to respondents are included in the questionnaire. For evaluating purposes, we have defined an MCID of 10 EQ VAS points and SD=20, based on a study including children aged 3-6 years either healthy or with acute or chronic illness (27).

Wong-Baker Faces Pain Rating Scale

The Wong-Baker Faces Pain Rating Scale (WBS) was created in 1983 to help children effectively communicate about their pain. It is a free, widely used self-reported tool to assess pain using a series of six facial expressions to illustrate the degree of pain intensity. A numerical value is assigned to each face, from 0 (no hurt) to 10 (hurts worst), thus each face equates 2 points. It has been validated among children above the age of 3 with sickle-cell anaemia and HIV infection as well as children undergoing venepuncture and minor surgery (28). The WBS has an MCID of one face (2 points) (26).

Explorative outcomes

Radiographs

The remodelling process will be evaluated by the axial alignment of radius on antero-posterior (AP) and lateral radiographs taken at 6 and 12 months. Angular malalignment in metaphyseal and physeal fractures is determined as the angle formed by the intersection of two lines parallel to the axis of the radius proximal and distal to the fracture site or growth plate. Physeal arrest will be recognized by the presence of focal bone density bridging across the normally lucent physis.

Photographs

We will take photographs (AP and lateral views) at time of injury, 4 weeks, 3, 6 and 12 months visits to observe the cosmetic progress,.

No systematic measurements will be made on radiographs or photographs, but they may support our primary and secondary outcomes and used for didactic purposes.

Adverse events

According to WHO, a serious adverse event (SAE) is any untoward occurrence that

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization, or
- Results in persistent or significant disability /incapacity.

In the context of this trial, we expect no fatal or life-threatening adverse events. Compartment syndrome is considered a serious adverse event, but we have found no compartment syndromes in the available literature. Table 2 summarizes serious and mild adverse events listed according to their frequency and seriousness (for further details, see Appendix 1).

Table 2 Potential mild and serious adverse events. See Appendix 1.

	SERIOUS	MILD
SURGERY	Re-displacement after closed reduction alone requiring secondary surgery (18%, range 9-25%)[7,8,10–13] Re-displacement after pin fixation requiring secondary surgery (5%, range 0-8%)[7–9,13] Deep infection (0.5%, range 0-1.5%)[4,29,30] Osteotomy (0.2%, range 0-5.4%)[4,31]	Superficial pin infections (7.4%, range 0-34%)[4,8,12–14,29,32–34] Transient neuropraxia (2.6%, range 1.6-6.3%)[8,32] Scar tissue (3.7%, range 2.5-8.3%)[4,7,9,33] Subcutaneous pin migration (12%, range 11.5-12.5%)[8,32] Loosening of pin (2.7%)[33]
CASTING	Osteotomy (0.5%, range 0.4-0.6%)[31]	
BOTH GROUPS		Cast problems including skin abrasions, split for swelling, cast break or loosening (21%, range 3-29%)[35–37] Transient neuropraxia (2.6%, range 1.5-5.6%)[8,32,35]

The local investigators will monitor all adverse and unexpected events at predefined intervals to ascertain safety of the interventions. The PI will collect and evaluate all vents from the involved hospitals in order to classify their severity and relatedness to the treatment. All SEAs related to the treatment will be reported to The Research Ethics Committee for Region Zealand within 7 days from the time of the event.

Blinding

It is not possible to blind the surgeon, the patient, or the parents/guardians to the treatment allocation. PROM scores and radiographs will be evaluated by persons, who are blinded to treatment allocation and who are not otherwise involved in the study. Data analysis will be performed by an external biostatistician blinded to treatment allocation.

Sample size calculation

The QuickDASH was developed on adults, but has been used in several studies on different upper extremity fractures in children. However, these studies report only total QuickDASH scores (mean (SD)) and p-values, but do not reflect on whether these differences are clinically relevant (23,38–41).

The same studies report absolute differences between groups or individuals, but do not reflect on whether these differences are clinically relevant. We have identified four studies on adults using anchor-based approach to determine the MCID (42–45). Mintken et al. (45) reported an MCID of 8 on 101 adults with shoulder pain. Sorensen et al. (43) reported an MCID of 14 on 48 adults with non-operatively treated atraumatic hand and forearm conditions. Franchignoni et al. (42) reported an MCID of 15.91 on 266 adults with upper-limb musculoskeletal disorders, referred to in- and outpatient physiotherapy. In a similar population did Polson et al. (44) reported an MCID of 19 on 35 adults with a musculoskeletal condition to the upper extremity referred to physiotherapy. From these findings, we define an MCID of 15, and since no MCID has been defined among children, we have assumed it to be roughly comparable to adults.

To estimate a Standard Deviation (SD) for the QuickDASH in children, we have identified SD from 5.8-19.30 in studies on children with upper extremity fractures. We assume that these populations are the most comparable to that in our study. Quatman-Yates et al. (23) reported an SD of 19.30 in 149 children from Cincinnati and Columbus, Ohio, aged 8-12 years referred for outpatient rehabilitation following upper extremity injury. Ernat et al. (41) assessed 752 patients from Dallas, Texas, aged 2-13 years with supracondylar humerus fractures and the relationship between fracture classification and QuickDASH after a follow-up period of approximately 3 months (range 1-13 months). They reported SD's of 11.6 and 16.4 in Gartland II and III, respectively. Eguia et al. (40) did a cross-sectional survey 4.4 years (range 2-10 years) post-operatively on 508 children from Baltimore, Maryland, aged 3-8 years by the time of injury with a supracondylar humerus fracture treated with either crossed or lateral pinning. They reported SD's of 5.8 and 8.8 in the crossed and lateral pinning group, respectively. Roper et al. (39) did a cross-sectional study 5 years post-injury on 30 children from Houston, Texas, <18 years of age with a closed or open Monteggia fracture and reported SD for closed injury of 6.1 and for open injury of 8.8. Overall, there seems to be a

tendency for the SD to narrow over time. We assume these populations to be roughly comparable to that in our study, hence the SD be somewhere between 11.6-16.4 by 3 months (with a range up to approximately 1 year) and 5.8-8.8 by 4.4 years. From these assumptions, we estimate the SD to be 15, since our primary outcome at 12 months is closer to 3 months than 4.4 years.

A non-inferiority margin (NIM) of 15 QuickDASH points and standard deviation (SD) of 15 points, a significance level (α) of 0.025 and 80% power, will result in a sample size of 32 patients (16 in each group) (46). Allowing for 20% dropouts, the total sample size required is 40 patients (20 in each group).

Hypotheses

We hypothesize that non-surgical treatment is non-inferior to surgical treatment.

- H_0: A one-year postoperative QuickDASH score for patients receiving non-surgical treatment is inferior to that of patients receiving surgical treatment by at least NIM (d) = 15 points ($\mu_{casting}$ - $\mu_{surgery}$ ≥ d).

- H_A: A one-year postoperative QuickDASH score for patients receiving non-surgical treatment is not inferior to that of patients receiving surgical treatment by less than NIM (d) = 15 ($\mu_{casting}$ - $\mu_{surgery}$ < d).

Statistical analysis

Data analysis will be conducted by an external biostatistician. We will use descriptive statistics to report demographic data.

Continuous variables will be reported by mean or median, depending on the distribution, and will be compared using t-test for normal distributed variables, and Mann-Whitney U test for non-normal distributed variables. Categorical variables will be reported by numbers and percentage, and will be compared using Pearson's Chi-square test.

Significance is set as P-value <0.05.

Primary outcome analysis

The primary endpoints will be reported as mean QuickDASH scores on a continuous scale between 0-100, and will be analysed by the per protocol (PP) population and repeated, for sensitivity reasons, for the intention-to-treat (ITT) population. Non-inferiority will be assumed only if both analyses show non-inferiority.

The between-group difference in mean QuickDASH score by 12 months is compared using mixed-effects linear models (LMM).

Non-inferiority will be concluded if the lower end of the confidence interval is less than the NIM of 15 QuickDASH points.

Secondary outcome analysis

The between-group difference in mean QuickDASH score by 3 and 6 months will be compared as above. The between-group difference regarding HRQoL (EQ VAS) will be analysed by 3, 6 and 12 months. Mean EQ VAS scores from a continuous scale between 0-100, will be analysed using LMM. The between-group difference regarding pain (WBS) will also be analysed by 3, 6 and 12 months. Mean WBS scores between 0-10 points (from 6 answer options corresponding 0, 2, 4, 6, 8 and 10 points, respectively) will likewise be analysed using LMM.

For the EQ-5D-Y descriptive system, a health profile will be generated for each patient. Summary statistics will be derived, including numbers and proportions of patients reporting each level of severity in each EQ-5D-Y dimension (Mobility; Looking After Myself; Doing Usual Activities; Having Pain or Discomfort; Feeling Worried, Sad or Unhappy) in each visit.

Observed and patient-reported adverse events (see Table 2) will be reported with descriptive statistics where patients are grouped according to what treatment they received.

An interim analysis is planned when 22 (11 in each arm) patients have had their 6 months follow-up.

Missing data

LMM will also be used to deal with missing values due to dropout (e.g. if the patients does not show up), assuming the dropout mechanism is missing at random (MAR). We distinguish between item-wise missing (more than one, but not all, answers in a questionnaire are missing) and case-wise missing (all answers in a questionnaire are missing). Case-wise missing will be addressed using LMM as mentioned above. Incomplete questionnaires with item-wise missing will be assumed to be missing at random (MAR) and will be addressed by the multiple imputation, if the number of questionnaires excluded due to missing items exceeds 5%.

Information from medical records

Parents/guardians will be informed that their consent allow the local investigators to collect the following data throughout the study period:

- Personal information: Name, social security number (CPR), age, gender, height, weight
- Contact information: Address, email, phone number
- Medical information: dominant arm, mechanism of injury, type of injury(ies), comorbidities, medication list, previous upper extremity surgery, radiographs, CAVE, type of treatment both acute and long-term (including surgery code and/or cast type, e.g. high or low, splint or circular), complications to treatment) as well as information related specifically to the study (including QuickDASH score, EQ-5D-Y score, Wong Baker Faces Pain Scale score, photographs of patients' wrists).

Data management

Approval has been obtained from The Data Protection Agency of Region Zealand (REG-099-2022) before trial commencement. Compliance with The General Data Protection Regulation (GDPR) and the Danish Data Protection Act will be ensured at all times. A data processing agreement has been signed with all recruiting centres. All completed paper forms will be stored in locked file cabinets with limited access before and after they are entered in REDCap. Electronic participant information will be stored on a secured study-specific drive owned/managed by the PI. All data will be fully anonymized before publication.

Funding

The PI has initiated and designed the experiment in collaboration with Stig Brorson and Peter Buxbom without external funding. The study will be carried out without commercial funding. We will apply for non-commercial funding.

The trial is currently supported by the following:

- Region Zealand with 150.000 DKK for the PhD enrolment fee at Copenhagen University and a 20.000 DKK annuum covering expenses for conference participation, publication fee for open access publication and relevant material for the PhD student's conduct of research.
- Region Zealand Research Fund with 250.000 DKK for salary for the PI

Non-funded salary for the PI is covered by a deficiency guarantee provided by the clinical department of the PI. Other costs for treatment and follow-up will be covered by the Department of Orthopaedic Surgery, Zealand University Hospital Køge and the collaborating clinical departments.

Financial compensation or other benefits to subjects

Participants will not be financially compensated for their participation in the project.

Dissemination

The trial protocol is preregistered at www.clinicaltrials.gov (ID: NCT05736068). All results from the study – both positive, negative, and inconclusive – will be published in a relevant, international, scientific peer-reviewed journal. The PI will ensure publication with authorship following the guidelines of the International Committee of Medical Journal Editors (ICMJE) as well as the CONSORT guidelines for the reporting of parallel group randomized trials. Results will be presented at relevant national and international conferences, e.g. the Danish Orthopaedic Association. A website, www.thecastingtrial.com, is linked to the study; all relevant material and results will be available here.

Expected clinical impact

The goal of this trial is to prevent future patients comparable to those included in the study from undergoing redundant surgery.

Ethics

Today, most children with displaced distal forearm fractures are treated surgically under general anaesthesia with closed reduction and pin fixation. Besides the fact that surgery and anaesthesia can be stressful for the child and family, there are risks associated with surgery. These include infection, damage to the surrounding vessels, tendons and nerves, and scar tissue formation. Re-displacements are common (up to 50%), and re-operations with re-reduction with or without pin fixation may be necessary in up to half of these cases (8,12). Following pin fixation, a subsequent procedure (though most often without anaesthesia) is needed to remove the pins again. The child undergoing surgery will be exposed to a relatively large amount of radiation (almost three-fold higher than children being treated non-surgically) due to the use of fluoroscopy in the operating room (47,48).

In less than 0.6% of cases, a later corrective surgery will be needed if the bone remains misaligned, regardless of surgical or non-surgical treatment (31). However, this is particularly rare in the population included in this study, as children of this age still have a great remodelling potential.

Each child in this RCT will have a 50% chance of avoiding surgery and the associated inconveniences and potential complications. In return, some children may experience some forearm deformity which we expect is mainly a cosmetic issue and has minimal or no impact on the function. If the results of this study demonstrate non-inferiority of non-surgical treatment compared to surgical treatment, it opens up the possibility of treating up to 1800 children per year non-surgically.

In summary, we believe that the disadvantages associated with perhaps having a temporarily misaligned forearm, are outweighed by the benefits of avoiding surgery.

Radiation exposure

In Denmark, the background radiation is approximately 4 mSv/year, of which 1 mSv is from medical diagnostics (49). According to The International Commission on Radiological Protection (ICRP), the effective radiation dose limit to a person is 1 mSv/year (50). The approximate effective radiation dose per radiograph of an upper extremity is <0.001mSv (51). Each examination consists of an anteroposterior and lateral projection. In the case of unsatisfying imaging, it may be necessary to take 1-2 additional radiographs, resulting in maximum 4 images per examination.

During the standard treatment protocol outside this study, patients are usually having radiographs taken for the diagnostics in the emergency room, after initial casting, by 7 days control, and by 4 weeks control in relation to removal of cast and/or pins. In rare cases, an additional 6 weeks control may be necessary in case of delayed healing. Thus, the total amount of radiographs could accumulate up to 20 radiographs, which corresponds to a total radiation exposure of 0.02mSv.

In this study, all patients will have radiographs taken for diagnostics in the emergency room, after initial casting, by 4 weeks (and at 6 weeks in case of delayed healing), and by 6 and 12 months. Thus, the total amount of radiographs could accumulate to 24, corresponding a total radiation exposure of 0.024mSv.

Regardless of whether the children are included in the study or not, those undergoing surgery will be exposed to additional radiation due to intraoperative fluoroscopy. During the surgical procedures fluoroscopy is used to evaluate the closed reduction and pin fixation, and there is large variation in the use of fluoroscopy depending on the procedure and the experience of the surgeon (52). The average exposure of fluoroscopy during hand and wrists procedures has been estimated to 0.03-0.05mSv (47,48). Using these values, the total radiation exposure to children undergoing surgery is approximately 0.07mSv, which is almost three-fold higher than children being treated non-surgically. However, in both cases the radiation exposure is still far from the limits of tolerance. Since all children in our study would normally undergo surgery, and since half of the included children will instead be treated non-surgically, participation in our study may result in less or the same radiation exposure than children outside the study.

Trial insurance

Insurance of the trial is covered by The Danish Patients Compensation Fund (Patienterstatningen).

Appendix 1. Adverse events

Surgery, serious adverse events:

Re-displacement after closed reduction alone requiring secondary surgery: 137/768 ≈ 18%, range 9-25%

Reference	Number of closed reductions, n	Number of re-displacements requiring secondary procedure, n (%)
McLauchlan et al., 2002 (7)	33	6 (18.2%)
Colaris et al., 2013 (8)	67	17 (25.4%)
McQuinn & Jaarsma, 2012 (11)	155	14 (9.0%)
Wendling-Keim et al., 2015 (13)	263	38 (14.4%)
Proctor et al., 1993 (10)	67	16 (23.9%)
Zamzam & Khoshhal, 2005 (12)	183	46 (25.1%)
Total	**768**	**137**

Re-displacement after pin fixation: 6/130 ≈ 5%, range 0-8%

Reference	Number of pin fixations, n	Number of re-displacements requiring secondary procedure, n (%)
McLauchlan et al., 2002 (7)	32	0
Colaris et al., 2013 (8)	61	5 (8.2%)
Gibbons et al., 1994 (9)	12	0
Wendling-Keim et al., 2015 (13)	25	1 (4%)
Total	**130**	**6**

Subcutaneous pin migrations: 9/77 ≈ 12%, range 11.5-12.5%

Reference	Number of pin fixations, n	Number of buried wires, n (%)
Miller et al., 2005 (32)	16	2 (12.5%)
Colaris et al., 2013 (8)	61	7 (11.5%)
Total	**77**	**9**

Loosening of pin (2.7%):

Marson et al., 2021 (15): Total number pin fixations: 37. Number of loosening: 1 ≈ 2.7%

Deep infection: 2/412 ≈ 0.5%, range 0-1.5%

Reference	Number of pin fixations, n	Number of deep infections, n (%)
Botte et al., 1992 (29)	137	2 (1.5%)
Stahl & Schwartz, 2001 (30)	236	0
Laaksonen et al., 2022 (4)	39	0
Total	**412**	**2**

Osteotomy: 5/2,103 ≈ 0.2%, range 0-5.4%

Reference	Number of patients, n	Number of osteotomies, n (%)
Selles et al., 2020 (31)	2,027[1]	3 (0.15%)
Laaksonen et al., 2022 (4)	37 closed reductions	2[2] (5.4%)
	39 pin fixations	0
Total	**2,103**	**5**

[1] All paediatric patients with distal radius fractures, not specified how many had surgical and non-surgical treatment. Of the 2,027 patients, 13 had osteotomies, of which 3 had primarily pin fixation.

[2] Patients were 12 and 14 years by the time of primary treatment, hence they had a greater risk of permanent deformity.

Surgery, mild adverse events:

Superficial pin infections: 30/405 ≈ 7.4%, range 0-34%

Reference	Number of pin fixations, n	Number of superficial infections, n (%)
Colaris et al., 2013 (8)	61	2 (3.3%)
Miller et al., 2005 (32)	16	2 (12.5%)
Wendling-Keim et al., 2015 (13)	25	1 (4%)
Zamzam et al., 2005 (12)	46	3 (6.5%)
Marson et al., 2021 (15)	40	0
Hargreaves et al., 2004 (34)	29	10 (34%)
Botte et al., 1992 (29)	137	8 (5.8%)
Laaksonen et al., 2021 (14)	12	2 (16.6%)
Laaksonen et al., 2022 (4)	39	2 (5.1%)
Total	**405**	**30**

Transient neuropraxia: 2/77 ≈ 2.6%, range 1.6-6.3%

Reference	Number of pin fixations, n	Number of neuropraxia, n (%)
Colaris et al., 2013 (8)	61	1 (1.6%)
Miller et al., 2005 (32)	16	1 (6.3%)
Total	**77**	**2**

Scar tissue: 7/187 ≈ 3.7%, range 2.5-8.3%)

Reference	Number of pin fixations, n	Number of scarring, n (%)
Laaksonen et al., 2022 (4)	100^{1}	3 (3%)

McLauchlan et al., 2002 (7)	35	2 (5.7%)
Gibbons et al., 1994 (9)	12	1 (8.3%)
Marson et al., 2021 (15)	40	1 (2.5%)
Total	**187**	**7**

[1] Guardians of children who had pin fixation was asked about their treatment satisfaction. Three reported dissatisfaction with scarring.

Cast, serious adverse events:

Osteotomy: 14/2,884 ≈ 0.5, range 0.4-0.6%

Reference	Number of patients, n	Number of osteotomies, n (%)
Selles et al., 2020 (31)	2,027[1]	9 (0.4%)
Sundhedsplatformen	857[2]	<5 (0.6%)
Total	**2,884**	**14**

[1] All paediatric patients with distal radius fractures, not specified how many had surgical and non-surgical treatment. Of the 2,027 patients, 13 had osteotomies, of which 9 had primarily cast immobilization.

[2] By making an anonymous extraction from the electronic medical record system (Sundhedsplatformen) from the period 01.01.2018-31.12.2021, there were 857 children between 4-10 years with ICD10-diagnosis DS52.5 or DS52.6. Of these, less than 5 had a later osteotomy. Unfortunately, it was not possible to separate in those who were treated surgically and non-surgically.

Both groups, mild adverse events:

Cast problems including skin abrasions, split for swelling, cast breakage, or loosening: 53/253 ≈ 21%, range 3-28.4%)

Reference	Number of patients, n	Number of cast problems, n (%)

Skin abrasions		
Colaris et al., 2012 (35)	66	2 (3%)
Split for swelling		
Bohm et al., 2006 (36)	102	6 (5.9%)
Paneru et al., 2010 (37)	85	3 (3.5%)
Cast break or loosening		
Bohm et al., 2006 (36)	102	29 (28.4%)
Paneru et al., 2010 (37)	85	12 (14.1%)
Total	**253**	**52**

Transient neuropraxia: 4/151 ≈ 2.6%, range 1.5-5.6%

Reference	Number of castings, n	Number of neuropraxia, n (%)
Colaris et al., 2013 (8)	67	1 (1.5%)
Colaris et al., 2012 (35)	66	2 (3%)
Miller et al., 2005 (32)	18	1 (5.6%)
Total	**151**	**4**

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