NATIONAL CLINICAL GUIDELINE ON THE TREATMENT OF DISTAL RADIAL FRACTURES



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QUALITY OF EVIDENCE – THE FOUR LEVELS

Rating quality of evidence and grading strength of recommendations is done based on the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system. See also: <u>http://www.gradeworkinggroup.org</u> and <u>Appendix 9</u> and <u>Appendix 11</u>.

High $(\oplus \oplus \oplus \oplus)$

We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate (⊕⊕⊕O)

We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low $(\oplus \oplus \bigcirc \bigcirc)$

Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low (000)

We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

STRENGTH OF A RECOMMENDATION

Strong recommendation for $\uparrow\uparrow$

The Danish Health Authority (DHA) makes a strong recommendation for when the desirable consequences of an intervention are judged to clearly outweigh undesirable consequences.

Weak/conditional recommendation for \uparrow

The DHA makes a weak/conditional recommendation for when the desirable consequences of an intervention are judged to marginally outweigh undesirable consequences or when the available evidence cannot rule out a significant benefit of an existing practice if the adverse effects of the latter are judged to be few or absent.

Weak/conditional recommendation against ↓

The DHA makes a weak/conditional recommendation against when the undesirable consequences of an intervention are judged to outweigh desirable consequences and this is unsupported by strong evidence. This recommendation is also made in case of strong evidence of both beneficial and adverse effects when the balance between them is difficult to determine.

Strong recommendation against $\downarrow\downarrow$

The DHA makes a strong recommendation against in case of high-quality evidence showing that the undesirable consequences of an intervention clearly outweigh desirable consequences. The DHA also makes a strong recommendation against when the review of the evidence shows with great certainty that an intervention is useless.

Good practice $\sqrt{}$

Good practice based on professional consensus among the members of the working group that prepared the clinical guideline. The recommendation may be either for or against the intervention. A good practice recommendation is made when relevant evidence is not available.

For a detailed description, please see <u>Appendix 9</u>.

2 Key messages

Assessing and evaluating a surgery indication

- $\sqrt{}$ It is good practice to offer surgical treatment of a distal radial fracture to patients of any age if a conventional wrist X-ray examination, following eventual reduction of the fracture, reveals one or more of the following radiological parameters:
 - More than 10 degrees of dorsal angulation of the articular surface of the radial in a side view as compared to perpendicular to the longitudinal axis of the radial
 - Ulnar variance of more than 2 mm
 - Articular step-off of more than 2 mm
 - Incongruity of the distal radioulnar joint
- $\sqrt{}$ In case of well-reduced distal radial fractures with loss of substance/comminuted fracture of the dorsal cortex, it is good practice to monitor the patient closely or to consider primary surgery.
- $\sqrt{}$ It is good practice not to perform routine CT scan prior to distal radial fracture surgery.
- $\sqrt{}$ In case the assessment of a conventional X-ray examination creates doubt as regards choice of treatment method, supplementary CT scan is good practice.
- $\sqrt{}$ It is good practice to perform surgery at a time agreed with the patient and without undue fasting and waiting.

Strategy for surgical treatment

- $\sqrt{}$ When surgery is indicated, it is generally good practice to offer open reduction and internal fixation with a volar angular stable locking plate to patients of any age. If this method cannot be used, K-wire osteosynthesis may be considered as the primary choice rather than bridging external fixation.
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

This key message regarding strategy for surgical treatment is based on a comparison in pairs of the evidence for the most frequently used treatment methods: K-wires, bridging external fixation, volar angular stable locking plate and conservative treatment in the form of closed reduction and immobilisation bandage.

K-wires vs. conservative treatment

↑ Consider use of K-wires rather than conservative treatment of distal radial fracture in patients of any age when surgery is indicated ($\oplus \oplus \bigcirc \bigcirc$).

Bridging external fixation vs. conservative treatment

↑ Consider use of bridging external fixation rather than conservative treatment of distal radial fracture in patients of any age when surgery is indicated $(\oplus \bigcirc \bigcirc \bigcirc \bigcirc)$.

Volar angular stable locking plate vs. conservative treatment

↑ Consider use of a volar angular stable locking plate rather than conservative treatment of distal radial fracture in patients of any age when surgery is indicated ($\oplus \bigcirc \bigcirc \bigcirc$).

Volar angular stable locking plate vs. bridging external fixation

↑ Consider use of a volar angular stable locking plate rather than bridging external fixation of distal radial fracture in patients of any age when surgery is indicated ($\oplus \oplus \bigcirc \bigcirc$).

Volar angular stable locking plate vs. K-wires

↑ Consider use of a volar angular stable locking plate rather than K-wires during distal radial fracture surgery in patients of any age when surgery is indicated ($\oplus \oplus \bigcirc \bigcirc$).

Rehabilitation

- ↑ Consider use of short-term cast or similar immobilising cast or similar immobilising bandage(less than 2 weeks) following insertion of a volar angular stable locking plate rather than long-term cast or similar immobilising bandage(more than 5 weeks) (⊕⊕○○).
- √ It is good practice not to prescribe rehabilitation supervised by an occupational therapist or a physiotherapist on a routine basis to patients with uncomplicated cases. This is due to finding no difference in the effect as compared to independent rehabilitation based on a written training plan following a single instruction ($\oplus \bigcirc \bigcirc \bigcirc$).
- $\sqrt{}$ As a minimum, it is good practice to offer guidance and practical instruction concerning self-rehabilitation following distal radial fracture to all patients regardless of the treatment method.

1. Introduction

1.1 Purpose

The purpose of the national clinical guideline on the treatment of distal radial fractures is to provide evidence-based national recommendations for the indication for conservative treatment vs. surgical treatment as well as recommendations for the type of treatment considered most efficient and beneficial for the patient and for rehabilitation following treatment. Attempts are made to clarify which patients will benefit from surgery and to list the appropriate clinical and radiological parameters on which to base the decision about the indication.

The national clinical guideline will hereby contribute to ensuring uniform high quality treatment of patients with distal radial fractures across regions, hospitals and municipalities.

1.2 Delimitation of the group of patients

The guideline concerns patients over the age of 18 with a distal radial fracture caused by a low energy trauma. Thus, the guideline does not contain recommendations for fractures caused by a high energy trauma – the most frequent cause in younger people.

The first part of the guideline concerns diagnostics and delimitation of the group of patients to whom additional treatment other than just application of a plaster cast should be offered. The second part of the guideline concerns selecting a treatment method for these patients. The final part concerns time of immobilisation and rehabilitation.

The guideline concerns fractures of AO classification type A2, A3 and AO C1-3. These types of fractures cover what was previously known as Colles-type distal radial fracture. The AO classification is used below, since it is most frequently used classification in a scientific context ^(1,2).

The guideline does not address treatment of:

- Isolated ulnar fracture (AO type A1)
- Smith's fracture and AO type B fractures (Chauffeur's fracture and Barton's fracture)
- Open fractures
- Fractures caused by a high energy trauma
- Patients with additional concomitant significant hand and wrist injuries

Wrist fractures are caused by falls, and osteoporotic individuals have an increased risk of fracture if they fall. Therefore, assessment for and treatment of underlying osteoporosis as well as prevention of new falls should be considered in this group of patients. However, this guideline does not shed light on the significance of osteoporosis and prevention of new falls in patients with fractures near the wrist. Both the Danish Endocrine Society ⁽³⁾ and the DHA ⁽⁴⁾ have prepared nationwide guidelines in this field.

1.3 Target group/users

The primary target group for this guideline are doctors specialising in orthopaedic surgery. Furthermore, the guideline is relevant for nurses and doctors receiving acute patients with distal radial fracture as well as all doctors, nurses, physiotherapists and occupational therapists providing and handling outpatient treatment and rehabilitation in a hospital setting or the primary care sector.

The guideline may also be relevant for patients or relatives wishing to find information on treatment of distal radial fracture.

1.4 Delimitation of the subject matter

The national clinical guideline contains instructions on how to handle selected and well-defined clinical issues (resulting from 'probing' the patient-care process). These issues were prioritised by the professional working group as the most important areas as regards clarification of the evidence concerning treatment of distal radial fractures.

Based on the above-mentioned delimitation, this guideline focuses on 10 selected areas distributed on 3 main subjects:

Assessing and evaluating a surgery indication:

1: Surgery indication in case of distal radial fracture based on radiological parameters.

2: The value of supplementary CT scan in case of distal radial fracture.

3: The benefits and harms of surgery earlier vs. later than 48 hours following the occurrence of a distal radial fracture.

Strategy for surgical treatment:

Selection of surgical method based on an overall assessment of a comparison in pairs of the effect and risk associated with the most frequently used treatment methods:

4: Conservative treatment with reduction and plaster/cast or similar immobilising bandages vs. K-wire surgery.

5: Conservative treatment with reduction and plaster/cast or similar immobilising bandages vs. surgery comprising bridging external fixation.

6: Conservative treatment with reduction and plaster/cast or similar immobilising bandages vs. surgery with open reduction and internal fixation with a volar angular stable locking plate.

7: Surgery comprising bridging external fixation vs. surgery with open reduction and internal fixation with volar angular stable locking plate.

8: K-wire surgery vs. surgery with open reduction and internal fixation with a volar angular stable locking plate.

For all comparisons, it is intended to clarify whether there are special circumstances for the group of patients with a low level of function, defined as permanent lack of ability to perform daily activities independently, and for patients over the age of 65.

Rehabilitation:

9: The effect and risk of short-term (less than 2 weeks) vs. long-term (more than 5 weeks) cast or similar immobilising bandage following surgery with the insertion of a volar angular stable locking plate.

10: The effect of independent rehabilitation (home programme) vs. rehabilitation supervised by a physiotherapist or an occupational therapist.

1.5 Perspective of the patient

When selecting the focused questions and outcomes, it was important to ensure that the critical effects of the intervention investigated are patient-related, i.e. effects expected to be deemed critical by most patients. Traditionally, assessment of the effect of the treatment of distal radial fractures has mainly been based on radiological parameters. These parameters are not among the outcomes included in this guideline, since, generally, they are poorly correlated to the function and quality of life experienced by the patients ⁽⁵⁾. The most frequently used patient-related outcomes (PROM – Patient Reported Outcome Measures) within this field are DASH score (Disabilities of the Arm, Shoulder and Hand score) and PRWE score (Patient Rated Wrist Evaluation score). Both measuring instruments have a score ranging from 0 to 100 with lower scores indicating a better result. The smallest clinically relevant difference is 10 for DASH and 14 for PRWE⁽⁶⁾.

The patient organisations of relevance for this guideline were represented in the established reference group. The names of the members of the reference group are included in <u>Appendix 12</u>.

1.6 Legal matters

The DHA's national clinical guidelines are systematically prepared statements based on relevant expert knowledge.

National clinical guidelines are aimed at facilitating decision-making for professionals concerning appropriate and good clinical healthcare services in specific situations. The national clinical guidelines are publicly available, and patients are also welcome to read the guidelines.

National clinical guidelines are classified as professional counselling, which implies that the DHA recommends that the guidelines be followed by relevant professionals. The national clinical guidelines are not legally binding, and the professional judgment in the specific clinical situation will always take priority when deciding about appropriate and correct clinical healthcare services.

A successful treatment outcome cannot be guaranteed, even if healthcare professionals follow the recommendations. In certain situations, a treatment

method with a lower strength of evidence may be preferable, because it is considered a better choice for the patient and by the patient.

2. Surgery indication in case of distal radial fracture

2.1 Focused question 1

Is there any evidence that one or more of the radiological parameters below, assessed during wrist X-ray examination, may be used as the basis for deciding on a reduction and/or surgery indication?

- More than 10 degrees of dorsal angulation of the articular surface of the radial in a side view measured perpendicular to the longitudinal axis of the radial.
- Ulnar variance of more than 3 mm*
- Intra-articular step-off or diastasis of more than 2 mm
- Incongruity of the distal radioulnar joint
- Loss of substance of the dorsal cortex

*The initial choice, ulnar variance of 3 mm, was made based on the 2009 AAOS guidelines $^{(7)}$.

2.2 Recommendation

- ✓ It is good practice to offer surgical treatment of a distal radial fracture to patients of any age when during a conventional wrist X-ray examination, following eventual reduction of the fracture, one or more of the following radiological parameters are found:
 - More than 10 degrees of dorsal angulation of the articular surface of the radial in a side view as compared to perpendicular to the longitudinal axis of the radial
 - Ulnar variance of more than 2 mm
 - Articular step-off of more than 2 mm
 - Incongruity of the distal radioulnar joint
- √ In case of well-reduced distal radial fractures with loss of substance/comminuted fracture of the dorsal cortex, it is good practice to monitor the patient closely or to consider primary surgery.

2.3 Practical advice and special patient considerations

The treatment of distal radial fractures should always be selected in consultation with the patient. The treating doctor provides guidance to the patient based on a risk assessment of benefits and risks of conservative vs. surgical treatment in consideration of the patient's wishes and needs. Not all patients need or want surgical treatment, even when surgery is indicated by the radiological parameters.

Caution should be exercised as regards the use of surgical intervention in patients with a low level of function assessed as permanent lack of ability to perform daily activities independently.

2.4 Background of the choice of question

Conventional wrist X-ray examination is the recognised method for diagnosing distal radial fracture. Along with an assessment of the patient's morbidity and overall functional capacity, the X-ray will in most cases be crucial when planning the further treatment, including deciding whether to offer a conservative treatment with or without reduction or surgery to the patient. There may be disagreement concerning the choice of radiological parameters, on which this assessment should be based.

There has thus been a desire to determine whether the radiological parameters stated indicate that the nature of a given fracture is such that lack of reduction and surgical stabilisation will most likely cause patient discomfort and impaired functional capacity as well as impaired quality of life in the long term.

The radiological parameters stated in the focused question were chosen based on the 2009 AAOS guidelines on distal radial fractures ⁽⁷⁾.

2.5 Literature

A review of the literature, including existing guidelines, systematic reviews and randomised controlled studies, did not identify evidence to answer the focused question. Therefore, an additional search for follow-up studies dated 1983 and onwards was performed. This search identified one prognostic study and four follow-up studies, of which three are using DASH as an outcome. Thus, a total of five studies were included to answer the focused question.

These are cohort studies, where the level of quality of evidence is generally low. However, the diversity of the studies makes an actual data synthesis impossible. Therefore, evidence rating of these studies was not carried out.

The prognostic study ⁽⁸⁾ followed a cohort of approx. 4,000 patients with distal radial fracture for 5.5 years. Based on X-rays, the authors developed a calculation model to predict the risk of early and late displacement, respectively, and the risk of malunion in case primary reduction is the only treatment performed. The study showed that more than 5-10 degrees of dorsal angulation measured perpendicular to the longitudinal axis of the radial, radial shortening of more than 0 mm (i.e. the distal articular surface of the ulna is longer than the radial) and comminuted fracture with loss of substance of the volar or dorsal cortex are all significant risk factors for fracture redisplacementand/or malunion. In this study, age was the strongest predictor for both fracture redisplacementand malunion irrespective of other factors.

Two follow-up studies ^(9,10) both followed two groups of patients with intraarticular fractures with articular surface depression and lack of articular surface congruity, respectively, at the time of healing. Both studies showed a significantly increased incidence of radiocarpal arthrosis. However, this was not correlated to changes in the functional gradings at 5.5 and 9 years, respectively.

In a third follow-up study⁽¹¹⁾, a group of patients was followed for 2.2 years. The patients had all been treated for displaced distal radial fracture with closed reduction or external fixation. The radiological parameters (the difference between the healthy and the fractured side) after the follow-up period were compared to the

patients' DASH score. This showed that the DASH score was significantly poorer in case of radial shortening (ulnar variance) of 2 mm or more and more than 15 degrees of dorsal angulation (as compared to the opposite hand).

In a fourth follow-up study ⁽¹²⁾, the effect of a treatment protocol for patients with distal radial fracture in southern Sweden was validated. In the protocol, the following algorithm was used as an indicator to offer surgery to patients: more than 10 degrees of dorsal angulation or ulnar variance of 2 mm or more and intraarticular step-off of more than 1 mm. Due to this algorithm, the patients were divided into three groups: Non-displaced fractures, which were treated with plaster; displaced fractures, which were reduced and plastered and were still in position at outpatient control after 7-10 days; and, finally, a group of patients who either initially or following outpatient control fell within the radiological algorithm stated and therefore were offered surgery (they were not all operated). For follow-up purposes, a DASH score was calculated for 360 patients after 12 months. The patients in the three groups had an almost identical DASH score mean of 15, 17 and 16, respectively. The patients were compared to a background population, which was matching in age and gender, for which the DASH score was 2.5. On that basis, the authors concluded that a protocol with the measurements stated as a surgery indicator was suitable for bringing all patients to the same level after a year. However, the study showed a tendency towards slightly poorer DASH scores among patients who experienced fracture redisplacementand were offered surgery late. The authors assumed that the finding may be explained by a generally cautious use of surgery in these elderly patients.

The results of the studies included thus point out:

- that there is evidence to recommend an upper limit of dorsal angulation of 5-10 degrees as measured perpendicular to the articular surface of the radial, since further angulation increases the risk of fracture redisplacement, malunion and poorer patient-related outcomes as measured by DASH,
- that articular step-off above a limit of 1-2 mm increases the risk of radiological arthrosis,
- that ulnar variance of 0-2 mm or more increases the risk of fracture collapse, malunion and poorer DASH score, and
- that dorsal loss of substance and comminuted fracture increases the risk of fracture redisplacementand malunion.

2.6 Working group considerations

Quality of the evidence	Only indirect evidence is available. Therefore, the evidence was not assessed.
Balance between	The X-ray examinations will contribute to clarify the
beneficial and adverse effects	indication for surgery. When surgery is relevant, it will most likely provide a better effect than no surgery. Furthermore, these X-ray examinations are not known to have caused any adverse effects.
Values and preferences	The patients' preferences are deemed consistent, since most patients would want the intervention based on the assumption that it will provide a better basis for selecting the right treatment and thus obtaining the best possible result.

2.7 Rationale for recommendation

It was not possible to identify evidence from randomised controlled studies describing the effect of decision-making based on the radiological parameters stated. Instead, the radiological parameters suggested emerged from completed cohort studies – studies which are only able to predict the likelihood of a given result (stability of the fracture) by means of regression analysis, as well as follow-up studies showing that patients with poorer radiological fracture positions than those stated will have a poorer DASH score at follow-up. One of the sources included suggests to decide for or against a surgery intervention based on a suitable mathematical model. The mathematical model has not been clinically validated.

Literature does not support a cut-off for ulnar variance of 3 mm. By contrast, the studies found report convincing data in favour of a cut-off value of 2 mm. Therefore, the working group selected an ulnar variance of 2 mm rather than the initially suggested 3 mm. The recommendations for dorsal angulation and articular step-off are 10 rather than 5 degrees and 2 mm rather than 1 mm, respectively. These measurements are recommended because they are the values included when searching for evidence for recommendations and also because the literature found does not clearly recommend lower cut-off values.

3 CT scan in case of distal radial fracture

3.1 Focused question 2

How is a surgery indication affected by supplementary CT scan following conventional wrist X-ray examination?

3.2 Recommendation

- $\sqrt{}$ It is good practice not to perform routine CT scan prior to distal radial fracture surgery.
- $\sqrt{}$ In case the assessment of a conventional X-ray examination creates doubt as regards choice of treatment method, supplementary CT scan is good practice.

3.3 Background of the choice of question

Wrist CT scans are more accurate than X-rays to determine the extent and complexity of especially intra-articular fractures. A few departments perform a CT scan as a standard procedure prior to surgery in case of intra-articular distal radial fracture.

There has thus been a desire to determine whether a pre-operative CT scan can add information that will influence on the choice of surgical method and technique, and whether the classification of the fracture will change as a result of supplementing a conventional X-ray examination of the wrist with a CT scan.

3.4 Literature

A review of the literature, including existing guidelines and systematic reviews, and an extended comprehensive search for randomised controlled studies and cohort studies dated 2003 and onwards did not identify studies suitable for use in answering the focused question. A comprehensive search for diagnostic studies and a cross reference search identified three studies ⁽¹³⁻¹⁵⁾ that indirectly shed light on the question. All three studies investigated whether the surgical methods used by the surgeons involved change depending on the diagnostic images available. The studies investigated whether switches occur from one treatment group to another (conservative treatment, K-wire, external fixation and ORIF with plate osteosynthesis). Potential occurrence of change of surgical technique within a given group was not investigated. Thus, a total of three cross-sectional studies were included to answer the focused question. These studies only assessed the effect indirectly by investigating the intrarater agreement between findings from a wrist X-ray examination and a CT scan, respectively.

These are cohort studies, for which the quality of the evidence is generally low. However, the diversity of the studies makes an actual data synthesis impossible. Therefore, evidence rating of these studies according to the GRADE method was not carried out. Two studies ^(13,15) investigated the interrater vs. intrarater agreement as regards diagnosing fracture patterns. However, they did not apply AO classification. The results of these two studies are not consistent.

All three studies do conclude that supplementary CT scan with multiplanar reconstructions and possibly 3D reconstruction maps more fracture details. This additional information causes some surgeons to change their indication for treatment in favour of open surgery.

3.5 Working group considerations

Quality of the evidence	Only indirect evidence is available. Therefore, the evidence was not assessed.
Balance between beneficial and adverse effects	There are no available known significant adverse effects of wrist CT scans ⁽¹⁶⁾ . A CT-scan may provide additional information as a supplement to X- ray examination in case of doubt about the type of fracture and treatment method.
Values and preferences	The patients' preferences are expected to be essentially consistent. Most patients will probably consider an additional examination acceptable if deemed necessary for diagnostics and surgery planning.
Other considerations	A supplementary CT scan entails additional costs and will only aid in selecting a treatment method in case of doubt about the type of fracture.

3.6 Rationale for recommendation

The available literature confirms that CT scan may be of importance as regards the choice of surgical method. Also, the examination is believed to cause no patient discomfort. The assessment therefore is that it may sometimes be appropriate to perform a supplementary CT scan of a distal radial fracture following X-ray evaluation if the latter creates doubt as regards the choice of treatment method. Due to the extra costs associated with performing a CT scan combined with the fact that it only adds value to the process of predicting the treatment method in case of doubt as regards the type of fracture, a CT scan is not recommended on a routine basis.

4 Surgery earlier or later than 48 hours following distal radial fracture

4.1 Focused question 3

What is the effect and what are the risks of surgery within the first 48 hours vs. more than 48 hours after deciding that surgery is indicated for a distal radial fracture?

4.2 Recommendation

$\sqrt{}$ It is good practice to perform surgery at a time agreed with the patient and without undue fasting and waiting.

The working group found no evidence which compares differences in effect and risks of surgery within the first 48 hours vs. after 48 hours.

4.3 Practical advice and special patient considerations

Surgery at an agreed time may preferably take place in the daytime, e.g. in an outpatient/day surgery setting, where the surgical experts are present and are able to allocate the time needed.

Patients with nerve pressure, dislocations and other similar and competitive disorders, which indicate emergency intervention, must be treated accordingly.

4.4 Background of the choice of question

In a number of Danish hospital departments, distal radial fracture surgery is often delayed several days rather than performing emergency surgery within the first 24 hours. The delay is often justified by lack of emergency surgery capacity or a desire to entrust the surgery to a more experienced surgeon. In some hospitals, the patients are handled in a 'sub-acute' outpatient/day surgery setting.

For a large number of patients with a reduced fracture, the decision for a surgery intervention is not made until during an outpatient control after 9-12 days – in case loss of reduction of the fracture is found during the control. (cf. <u>focused question</u> <u>1</u>).

Accordingly, there has been a desire to determine whether delayed surgery of a distal radial fracture (more than 48 hours after deciding that surgery is indicated) may impact negatively on patient-related outcomes or increase the incidence of complications.

4.5 Literature

A review of the literature, including existing guidelines and systematic reviews, and an extended comprehensive search for randomised controlled studies and follow-up studies dated 1983 and onwards did not identify studies that shed light on the question.

4.6 Working group considerations

Quality of the evidence	There is no evidence for the recommendation. This means that it is based on consensus among the members of the working group concerning good clinical practice.
Balance between beneficial and adverse effects	No evidence is available to shed light on the balance between beneficial and adverse effects. Planned waiting is found to be non-detrimental to the patient, provided he/she is well-informed about the process and is offered appropriate pain relief and cast or similar immobilising bandage during the waiting period.
Values and preferences	The patients' preferences are deemed inconsistent. Some patients would prefer scheduled surgery in case of sufficient pain relief. That would also leave time for providing information to the patients and having a dialogue on the preferred treatment. Other patients would prefer to have the surgery performed as soon as possible.

4.7 Rationale for recommendation

There is no evidence of a better functional outcome and fewer complications if distal radial fracture surgery is performed within 48 hours. Accordingly to the working group it is not necessary to perform distal radial fracture surgery as an emergency intervention. Planned surgery – as opposed to emergency surgery – allows for scheduling the surgery with an experienced surgeon and to thoroughly inform the patient about the treatment options and the upcoming treatment. A patient-care process involving emergency intervention will, in some cases, comprise several interrupted fasting periods and increase the patient's uncertainty.

5 Strategy for surgical treatment in case of distal radial fracture

5.1 Background

In order to be able to provide an overall recommendation regarding the choice of surgical treatment of distal radial fractures, the literature was reviewed and the evidence assessed for the four most frequently used treatment methods:

- Conservative treatment (reduction and immobilisation using plaster or a similar material)
- K-wire osteosynthesis (Kapandji or Willenegger technique)
- Bridging external fixation, when indicated supplemented with K-wires
- Open reduction and internal fixation with a volar angular stable locking plate.

The various methods were assessed against each other as per focused questions 4-8, and the results of these comparisons are provided in detail in section 5.4.

5.2 Recommendation as regards the choice of surgical method in case of distal radial fracture

- ✓ When surgery is indicated, it is generally good practice to offer open reduction and internal fixation with a volar angular stable locking plate to patients of any age. If this method cannot be used, K-wire osteosynthesis may be considered as the primary choice rather than bridging external fixation.
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

5.3 Rationale for recommendation

The recommendation is based on an assessment of the evidence for the four most frequently used treatment methods, a thorough balancing of beneficial effects against adverse effects, and the expected patient preferences when comparing the individual treatment methods. The quality of the evidence is generally low, but pointing in the same direction.

The patient-related outcomes for volar angular stable locking plate are significantly better after 3 months as compared to the three other methods. After 12 months, the difference between volar angular stable locking plate and the other treatment methods is reduced: There is no longer a significant difference in the patient-related outcomes when comparing volar angular stable locking plate and conservative treatment and K-wire osteosynthesis, respectively, whereas the difference between volar angular stable locking plate and external fixation remains significant. However, the difference in this comparison is only 8 in terms of DASH score, which is not considered clinically relevant. A difference on this scale should be at least 10 to be clinically relevant ⁽⁶⁾.

The patient-related outcomes for external fixation are significant and markedly poorer after 3 months as compared to conservative treatment. The patient preference for this method is generally deemed lower as compared to the other methods, since many patients consider the external device uncomfortable. The working group finds that most patients would prefer volar angular stable locking plate rather than the other treatment options, because it allows the patients to regain their daily skills faster.

Rejection of ORIF and volar angular stable locking plate may be due to the patient's desire to avoid surgery or to the surgeon's assessment that K-wire will be sufficient for a simple fracture. A very distal fracture may, in certain situations, be handled better with K-wires, and a very comminuted fracture may sometimes necessitate use of external fixation.

The adverse reactions from the four surgical methods are dissimilar due to the nature of the surgical interventions involved, including their extensiveness. A review of the adverse reactions reported in the studies included found a comparable incidence of serious adverse reactions for all four methods.

Treatment with the insertion of a volar angular stable locking plate increases the demands made on surgical skills. When used correctly, this method rarely causes serious adverse reactions.

5.4 Comparison of treatment methods

5.4.1 K-wire surgery vs. conservative treatment (focused question 4)

What is the effect and what are the risks of conservative treatment with reduction and plaster/cast or similar immobilising bandages vs. K-wire surgery (Kapandji or Willenegger technique)?

Do special circumstances apply to patients with a low level of function, defined as permanent lack of ability to perform daily activities independently, or to patients over the age of 65?

5.4.1.1 Recommendation

- ↑ Consider use of K-wires rather than conservative treatment of distal radial fracture in patients of any age when surgery is indicated (⊕⊕○○).
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

5.4.1.2 Practical advice and special patient considerations

K-wire osteosynthesis is a brief and relatively simple surgical intervention. However, in most cases reasonable bone quality is a prerequisite for this intervention.

5.4.1.3 Background of the choice of question

Previously, use of K-wire osteosynthesis was quite widespread for the treatment of unstable distal radial fractures, because it is a simple and relatively fast surgical operation. The number of patients operated using this technique has been decreasing in the past 3 to 4 years. In addition, it has been questioned whether it is suitable in elderly patients. Accordingly, there has been a desire to determine whether this surgery technique continues to be indicated, including whether special circumstances apply to patients over the age of 65 and patients with a low level of function, respectively.

In Denmark, the Kapandji technique and/or the Willenegger technique have been the most frequently used methods. Therefore, the evidence for the use of these methods vs. conservative treatment is elucidated.

5.4.1.4 Literature

The evidence basis for this focused question is a systematic Cochrane review of 2007⁽¹⁷⁾. Supplementary searches did not identify additional literature. The review included five studies ⁽¹⁸⁻²²⁾ which are all rather old and of a very varying nature as regards, e.g., patient population, cast or similar immobilising bandage technique and fracture type. The studies did not include patient-related outcomes such as DASH and PRWE, but various older grading systems based on a combination of pain, grip strength, radiological parameters and a few more function-related

questions. When assessing the quality of the evidence found, the working group attached greater importance to the studies which used grading systems that were later compared to and validated against DASH. The functional gradings used place the patients in the categories 'excellent', 'good', 'fair' or 'poor'⁽⁵⁾.

The Cochrane review contains a meta-analysis of the functional grading 'fair or poor' which does not take the follow-up period into account. In order to obtain an assessment of an effect that corresponds to the focused question asked, new meta-analyses of the functional grading 'fair or poor' for the follow-up periods 6 and 12 months were made. After 12 months, significantly fewer patients scored 'fair or poor' in the group of patients treated with K-wire as compared to the conservatively treated patients. Likewise, the VAS was significantly lower among the K-wire patients after 12 months.

The five studies did not all collect and register complications of the treatments systematically. The working group reviewed the studies systematically and extracted the complications reported. The review identified a predominance of serious complications in the form of malunion and need of surgery due to fracture redisplacement in the group of conservatively treated patients. A smaller number of the patients treated with K-wire also experience fracture redisplacement. However, the risk of re-operation is significantly lower in case of initial K-wire treatment.

The studies included patients aged 18-80 years. Only the study by Azzopardi⁽¹⁸⁾ included patients over 60 years of age exclusively. In this study, the SF-36 (physical score) had improved significantly after 1 year in patients treated with K-wire osteosynthesis.

5.4.1.5 Summary of Findings

Table 1: Focused question 4; K-wires vs. reduction and plaster (conservative treatment) in case of distal radial fracture

Population: Patients over the age of 18 with distal radial fracture cf. focused question 1 **Intervention:** K-wires

Comparison: Conservative treatment

Outcomes	Absolute effect*	(95% CI)		No. of	•	Comments
	Control group	Intervention group	e risk (95%	participan ts	the evidence	
			(33 /% CI)	(studies)	(GRADE)	
	Conservative treatment	K-wires				
SF-36 mental score SF-36. Scale from 0 to 100. Follow-up: Mean 12 months	mental score in	The mean SF-36 mental score in the intervention group was 51.0 (46.02 to 55.98)		54 (1 study ⁽¹⁸⁾)	⊕⊕⊝⊝ low ^{2,3}	No difference between the intervention group and the control group
SF-36 physical score SF-36. Scale from 0 to 100. Follow-up: Mean 12 months	physical score in			54 (1 study ⁽¹⁸⁾)	⊕⊕⊝⊝ low ^{2,3}	Use of K-wires is better than conservative treatment in the comparison
Functional grading: 'Fair or poor' 6 months Excellent, good, fair or poor Follow-up: Mean	253 per 1,000	193 per 1,000 (104 to 355)	RR 0.76 (0.41 to 1.4)	148 (2 studies ^(22,23))	⊕⊝⊝⊝ very low ^{2,4,5,6}	A relative risk of less than 1 means that conservative treatment is poorer.

6 months					However, since 1 is included in the 95% Cl, it means no significant effect
Functional grading: 'Fair or poor' 12 months Excellent, good, fair or poor Follow-up: Mean 12 months	452 per 1,000	140 per 1,000 (63 to 312)	RR 0.31 (0.14 to 0.69)	85 ⊕⊖⊝⊖ (2 studies very (^{20,24)}) low ^{2,4,5,6}	A relative risk of less than 1 means that conservative treatment is poorer. Since 1 is not included in the 95% Cl, it means significant effect
Pain VAS VAS. Scale from 0 to 10. Follow-up: Mean 12 months	The mean VAS score in the control group was 1.2	The mean VAS score in the intervention group was 0.7 (0.21 to 1.19)		54 ⊕⊕⊝⊝ (1 study ⁽¹⁸⁾ low ^{2.3})	Use of K-wires is better than conservative treatment in the comparison
Pain occasionally	200 per 1,000	100 per 1,000 (20 to 484)	RR 0.50 (0.1 to 2.42)	40 ⊕⊕⊝⊝ (1 study ⁽²⁰⁾ low ^{2,3})	A relative risk of less than 1 means that use of K-wires is better. However, since 1 is included in the 95% CI, it means no significant effect
Return to work Number of patients who had not returned to work Follow-up: Mean 12 months	333 per 1,000	77 per 1,000 (3 to 1,000)	RR 0.23 (0.01 to 3.97)	11 ⊕⊕⊝⊖ (1 study ⁽²⁰⁾ Iow ^{2,3})	A relative risk of less than 1 means that use of K-wires is better. However, since 1 is included in the 95% CI, it means no significant effect

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

 ² Lack of blinding
 ³ Wide confidence intervals and only 1 study
 ⁴ No 'intention to treat' analysis, patient attrition poorly described
 ⁵ The measurement method is not an actual patient-related outcome, but rather several comparable methods, which incorporate radiological parameters, the surgeon's assessment and function

- measurements. ⁶ Cast or similar immobilising bandage position with volar/ulnar wrist flexion is outdated

Quality of the evidence	The overall quality of the evidence is low.
	The literature found is rather old, and this is reflected in the studies. The evidence was downgraded due to risk of bias, lack of blinding and lack of analysis of patient attrition. Also, the evidence was downgraded due to indirectness resulting from lack of use of patient-related outcomes and an outdated cast or similar immobilising bandage position in the group of conservatively treated patients (volar/ulnar wrist flexion).
Balance between beneficial and adverse effects	Complications are not registered systematically in the old literature found.
	There are indications that conservatively treated patients have an increased risk of fracture redisplacement and malunion and that K-wire osteosynthesis provides a significantly better result in terms of functional outcome. Thus, beneficial and adverse effects both point in the direction of recommending K-wire osteosynthesis.
Values and preferences	Patient values and preferences for conservative treatment vs. K-wire surgery are expected to be individual. Some patients find the thought of outpatient removal of K-wires unpleasant. The reduced risk of long term complications is deemed to outweigh this.

5.4.1.6 Working group considerations

5.4.1.7 Rationale for recommendation

When comparing K-wire surgery to conservative treatment, it is assessed that most patients would prefer a brief surgical intervention with K-wire insertion to conservative treatment, because the prospect of a better final outcome and fewer complications outweighs the undesirable consequences of surgery.

5.4.2 Bridging external fixation vs. conservative treatment (focused question5)

What is the effect and what are the risks of conservative treatment with reduction and plaster/cast or similar immobilising bandages vs. surgical treatment comprising bridging external fixation with or without supplementary K-wires?

Do special circumstances apply to patients with a low level of function, defined as permanent lack of ability to perform daily activities independently, or to patients over the age of 65?

5.4.2.1 Recommendation

- ↑ Consider use of bridging external fixation rather than conservative treatment of distal radial fracture in patients of any age when surgery is indicated (⊕○○○).
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

5.4.2.2 Practical advice and special patient considerations

Treatment involving external fixation necessitates device care and maintenance. Often the patient will need some sort of help, e.g. from a home care nurse.

In the dialogue with the patient concerning selecting a treatment method, the patient should be informed that if external fixation is selected, the device may cause discomfort to him or her during the first 3-6 months. However, in the long term the patient may experience a better treatment effect.

Osteosynthesis with external fixation in most cases requires a reasonable bone quality.

5.4.2.3 Background of the choice of question

Until a few years ago, external fixation was the most frequently used surgical procedure in Denmark for the treatment of distal radial fracture. Bridging external fixation, in which the actual wrist is fixed, is used more frequently than non-bridging fixation in which the wrist can move freely. Most often, the fixation is supplemented by K-wires.

In spite of the decline in external fixation, it was considered important to review the evidence for this type of treatment vs. conservative treatment.

5.4.2.4 Literature

The evidence basis for this focused question is a systematic Cochrane $review^{(25)}$ of 2007 and two recent randomised clinical studies^(26,27).

The studies included in the Cochrane review are all older studies of a very varying nature as regards, e.g., patient population, cast or similar immobilising bandage technique and fracture type. The studies did not include patient-related outcomes such as DASH and PRWE, but various older grading systems based on a combination of pain, grip strength, radiological parameters and a few more function-related questions. When assessing the quality of the evidence found, the working group attached greater importance to the studies which used grading systems that were subsequently compared to and validated against DASH. The functional gradings used place the patients in the categories 'excellent', 'good', 'fair' or 'poor'⁽⁵⁾.

The Cochrane review contains a meta-analysis of the functional scoring which does not take the follow-up period into account. In order to obtain an assessment of an effect that corresponds to the focused question asked and to be able to use data from the two recent studies, a new meta-analysis for the variable Functional grading 'fair or poor' for the follow-up periods 3-6 months and 1-10 years was made.

The studies included did not all collect and register complications of the treatments systematically. Therefore, the working group reviewed the studies systematically and extracted the complications reported. The comparison of the complications did not identify any difference in the number of serious complications of the two treatment methods. There was an increased incidence of superficial pin infection/irritation in the group with external fixation. However, this did not affect the treatment result in the long term.

Age was not included as a variable. Therefore, no specific evidence is available for the 65+ age group. The 65+ age group was included in most of the studies.

The literature found shows a better result of conservative treatment for patientrelated outcomes after 3-6 months. This difference is most likely due to discomfort caused by the device in the early phase of the treatment. However, after a year the results are in favour of external fixation.

5.4.2.5 Summary of Findings

Table 2: Focused question 5; External fixation vs. reduction and plaster (conservative treatment) in case of distal radial fracture

Population: Patients over the age of 18 with distal radial fracture cf. focused question 1 **Intervention:** External fixation **Comparison:** Conservative treatment

Outcomes	, <i>, ,</i>		Relative risk		•	Comments
	Control group	Intervention group		participants (studies)	evidence (GRADE)	
	Conservative treatment	External fixation				
Functional grading: 'Fair or poor' 3-6 months Follow-up: 3-6 months	189 per 1,000	399 per 1,000 (238 to 670)	RR 2.11 (1.26 to 3.54)	(3 studies (27-	⊕⊖⊖⊖ very low ^{1,2,3}	A relative risk of greater than 1 means that external fixation is poorer than conservative treatment. Since 1 is not included in the 95% Cl, it means significant difference
Functional grading: 'Fair or poor' 1-10 years Follow-up: 1- 10 years	309 per 1,000	231 per 1,000 (176 to 302)	RR 0.75 (0.57 to 0.98)	(10 studios	⊕⊝⊝⊖ very low ^{1,2,3}	A relative risk of less than 1 means that external fixation is better than conservative treatment. Since 1 is not included in the 95% Cl, it means significant difference

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

¹ Lack of blinding

² Most often no 'intention to treat' analysis and lack of account of patients 'lost to follow-up'

³ The measurement methods used are not actual patient-related outcomes, but a measurement incorporating radiological assessments, the surgeon's assessment and a measurement of the patient's function level.

Quality of the evidence The overall quality of the evidence is very low. The literature found is mainly rather old, and this is reflected in the studies. The evidence was downgraded due to risk of bias, lack of blinding and lack of analysis of patient attrition. Also, the evidence was downgraded due to indirectness resulting from lack of use of patient-related outcomes and an outdated ⁽³⁹⁾ cast or similar immobilising bandageposition in the group of conservatively treated patients (volar/ulnar wrist flexion). Complications are not registered systematically in **Balance between** the literature found. beneficial and adverse effects However, the number and the severity of the complications are comparable between the two treatment groups. Superficial pin infection/irritation is not a serious complication and will not influence on the effect of the treatment in the long term. It may, however, cause undue worry for the patient and increase the resource consumption. Values and preferences The patients' preferences are expected to be inconsistent. Some patients would prefer treatment with external fixation, because it will most likely lead to better results in terms of returning to daily activities. Other patients would prefer treatment with plaster to avoid the discomfort caused by the device applied during the external fixation and potential worry as regards device care and maintenance. Other considerations Most often, patients with external fixation will need help for pin care from a home care nurse.

5.4.2.6 Working group considerations

5.4.2.7 Rationale for recommendation

When comparing conservative treatment to bridging external fixation, it is assessed that external fixation rather than conservative treatment should be offered to patients in whom surgery is relevant, because the prospect of a better final outcome outweighs the undesirable consequences of surgery and the discomfort from using the external fixation device during the first period of time. A suitable support function as regards device care is a prerequisite for this assessment.

5.4.3 Internal fixation with volar angular stable locking plate vs. conservative treatment (focused question 6)

What is the effect and what are the risks of conservative treatment with reduction and plaster vs. surgery with internal fixation and a volar angular stable locking plate?

Do special circumstances apply to patients with a low level of function, defined as permanent lack of ability to perform daily activities independently, or to patients over the age of 65?

5.4.3.1 Recommendation

- ↑ Consider use of a volar angular stable locking plate rather than conservative treatment of distal radial fracture in patients of any age when surgery is indicated (⊕○○○).
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

5.4.3.2 Practical advice and special patient considerations

Surgical treatment with the insertion of a volar angular stable locking plate allows for faster mobilisation (see PICO 9) as compared to conservative treatment. This may speak in favour of applying the method in patients with special needs such as patients with a walking frame.

Insertion of a volar angular stable locking plate requires correct insertion of osteosynthesis material and screws in order to reduce the risk of late complications in the form of tendon injuries ⁽⁴⁰⁾.

If postoperative X-ray control leads to a suspicion of sub-optimal location of the osteosynthesis material (too long screws or too distally located plate), the patients should be informed about this and offered follow-up control for assessment of the need for secondary removal of the osteosynthesis material.

Surgery scheduled for daytime hours (cf. recommendation according to PICO 3) is preferable in most cases, since this allows for scheduling the surgery with an experienced surgeon.

5.4.3.3 Background of the choice of question

The introduction volar angular stable locking plates has changed the surgical behaviour in many Danish hospital departments over the past 5-6 years. A benefit of this treatment is that the patients, due to major stability of the method, are allowed to start mobilising earlier. The method is more invasive than the previously more frequently used methods, K-wires and external fixation, and therefore requires a somewhat longer surgery time. In addition, it has been stated that the method increases the risk of both flexor and extensor tendon injuries in case the osteosynthesis material and the screws are not placed correctly.

There has been a trend towards offering this type of treatment to more, especially elderly, patients. Therefore, the working group considered it important to clarify

whether there is evidence for using volar angular stable locking plates vs. conservative treatment. In particular, we wanted to shed light on the situation for the 65+ age group of patients.

5.4.3.4 Literature

In spite of the increasing use of osteosynthesis with a volar angular stable locking plate in recent years, only one randomised controlled study, in which this method was compared to conservative treatment, was found in a search ⁽⁴¹⁾. The study comprised 73 patients older than 65. No literature was found describing the difference between the two treatment methods for younger patients. A number of studies exist, however, in which external fixation was compared to volar angular stable locking plate (see focused question 7). Based on the results of focused question 7, the assessment is that the results of the study in patients over the age of 65 can be extrapolated to the wide group of younger patients.

The study included only reported the complications related to the surgical method. Thus, complications related to plaster treatment were not registered systematically.

The study identified significant and clinically relevant differences in patient-related outcomes (PRWE and DASH) after 3 months in favour of plate insertion in these patients over the age of 65. After a year, there was a trend towards better effect of surgery with the insertion of a plate. However, it should be taken into account that the study only comprised 73 patients.

5.4.3.5 Summary of Findings

Table 3: Focused question 6; volar angular stable locking plate vs. reduction and plaster (conservative treatment) in case of distal radial fracture Population: Patients over the age of 18 with distal radial fracture cf. focused question 1 Intervention: volar angular stable locking plate Comparison: Reduction and plaster (conservative treatment) Outcomes Absolute effect* (95% CI) Relative No. of Quality Comments participants of the risk Control group Intervention group (95% (studies) evidence ÌΟ) (GRADE) Conservative volar angular stable locking plate treatment The mean PRWE PRWE The mean 73 $\Theta \Theta \Theta \Theta$ volar angular 73 (1 study ⁽⁴¹⁾) **very** (Patient-Rated PRWE score score after 3 months stable locking Wrist after 3 months in the intervention low plate is better Evaluation in the control than group was score). Scale 33.7 conservative group was 54.4 (23.3 to 44.2) from 0 to 100. treatment in the comparison, Follow-up: and the Mean 3 months difference is significant 73 (1 study ⁽⁴¹⁾) very low^{1,2,3} PRWE The mean PRWE The mean $\oplus \Theta \Theta \Theta$ volar angular (Patient-Rated PRWE score stable locking score after 1 year in Wrist after 1 year in the intervention group plate is better Evaluation the control was than score). Scale 12.8 conservative group was (5.2 to 20.4) treatment in the from 0 to 100. 14.6 Follow-up: comparison, Mean 1 year and the difference is not significant

DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 3 months	after 3 months	The mean DASH score after 3 months in the intervention group was 13.3 (8.5 to 18.1)	73 ⊕⊝⊝⊝ (1 study ⁽⁴¹⁾) very low ^{1,2,3}	volar angular stable locking plate is better than conservative treatment in the comparison, and the difference is significant
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 1 year	after 1 year in	The mean DASH score after 1 year in the intervention group was 5.7 (2.1 to 9.3)	73 ⊕⊝⊝⊝ (1 study ⁽⁴¹⁾) very low ^{1,3}	volar angular stable locking plate is better than conservative treatment in the comparison, and the difference is not significant
Pain at rest – 3 months VAS scale from 0 to 10. Follow-up: Mean 3 months	The mean VAS score at rest after 3 months in the control group was 0.3	The mean VAS score at rest after 3 months in the intervention group was 0.2 (0 to 0.4)	73 ⊕⊝⊝⊝ (1 study ⁽⁴¹⁾) very low ^{1,2,3}	No difference
	The mean VAS score at rest after 1 year in the control group was 0.1	The mean VAS score at rest after 1 year in the intervention group was 0.1 (0 to 0.2)	73 ⊕⊝⊝⊝ (1 study ⁽⁴¹⁾) very low ^{1,3}	No difference
Pain during activity – 3 months VAS scale from 0 to 10. Follow-up: Mean 3 months	score during activity after 3 months in the control group was 1.8	The mean VAS score during activity after 3 months in the intervention group was 1.4 (0.8 to 2.1)	73 ⊕⊝⊝⊝ (1 study ⁽⁴¹⁾) very low ^{1,3}	No difference
Pain during activity – 1 year VAS scale from 0 to 10. Follow-up: Mean 1 year	The mean VAS score during activity after 1 year in the control group was 0.6	during activity after 1 year in the intervention group was 0.7 (0.4 to 1)	73 ⊕⊖⊖⊖ (1 study ⁽⁴¹⁾) very low ^{1,3}	No difference

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval **RR:** Relative risk; ¹ Lack of blinding of study subject and healthcare professional and lack of data for withdrawn patients (no ITT analysis) ² Wide confidence intervals ³ Only one study is available

Quality of the evidence	The overall quality of the evidence is very low.
	The study included was carried out well. However, the evidence was downgraded due to risk of bias, lack of blinding and lack of analysis of patient attrition. Since only one study is available, the evidence was downgraded further due to risk of lack of accuracy.
Balance between	In terms of the functional score, the effect of a
beneficial and adverse	correctly inserted volar angular stable locking
effects	plate is better than that of conservative treatment.
	The complications were not registered consistently for the two treatment groups. However, when comparing the complications in this study to the complications reported for conservatively treated patients in questions 4 and 5, the amount and significance of the complications are deemed comparable.
Values and preferences	The patients' preferences are expected to be roughly consistent. It is expected that most patients would consider regaining their normal level of function fast a decisive factor in favour of surgery and that this would outweigh the undesirable consequences of surgery for many of them.

5.4.3.5 Working group considerations

5.4.3.6 Rationale for recommendation

When comparing conservative treatment with reduction and plaster to internal fixation with a volar angular stable locking plate, it was assessed that surgery with the insertion of a volar angular stable locking plate should be offered to patients in whom surgery is relevant. Treatment with the insertion of a volar angular stable locking plate allows the patients to return to their usual daily activities faster and shows significantly better patient-related outcomes after 3 months.

5.4.4 Bridging external fixation vs. volar angular stable locking plate (focused question 7)

What is the effect and what are the risks of surgery comprising bridging external fixation, possibly supplemented with K-wires, vs. open surgery with reduction and insertion of a volar angular stable locking plate?

Do special circumstances apply to patients with a low level of function, defined as permanent lack of ability to perform daily activities independently, or to patients over the age of 65?

5.4.4.1 Recommendation

- ↑ Consider use of a volar angular stable locking plate rather than bridging external fixation of distal radial fracture in patients of any age when surgery is indicated (⊕⊕○○).
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

5.4.4.2 Practical advice and special patient considerations

Surgical treatment with the insertion of a volar angular stable locking plate allows for faster mobilisation (see focused question 9) as compared to conservative treatment. This may speak in favour of applying the method in patients with special needs such as patients with a walking frame.

Insertion of a volar angular stable locking plate requires correct insertion of osteosynthesis material in order to reduce the risk of complications in the form of tendon injuries in the long term ⁽⁴⁰⁾.

If postoperative X-ray control leads to suspicion of sub-optimal location of the osteosynthesis material (too long screws or too distally located plate), the patients should be informed about this and offered follow-up control for assessment of the need for secondary removal of the osteosynthesis material.

Therefore, surgery scheduled for daytime hours is preferable in most cases, since this allows for scheduling the surgery with an experienced surgeon.

5.4.4.3 Background of the choice of question

The past 5 to 6 years have seen a shift in surgical methods from external fixation towards osteosynthesis with a volar angular stable locking plate. The topic has been the object of extensive discussion at professional meetings in the field of orthopaedic surgery. Accordingly, there has been a desire to compare the two methods in order to clarify which one of them is more beneficial for the patient as regards effects and risks.

5.4.4.4 Literature

The evidence basis for the recommendation is a systematic review ⁽⁴²⁾ comprising three studies ⁽⁴³⁻⁴⁵⁾ with a total of 174 patients, supplemented with a randomised controlled study ⁽⁴⁶⁾ with 94 patients.

The primary outcome in the systematic review was a patient-related outcome (DASH). A significant difference in the level of function in favour of volar angular stable locking plate was identified after both 3 and 12 months. However, after 12 months the difference was only 8 points, which is not considered clinically relevant (the smallest clinically relevant difference for DASH is 10 points⁽⁶⁾). In

the three studies included in the review, the population covered a broad age range from 19 to 87 years. The studies generally only included AO type A2-3 and C1-3. Three study subjects, however, had AO type B fractures, and that AO type is not included for the population defined in the guideline, but the working group finds that this does not significantly affect the transfer of the study results.

The randomised controlled study included assessed pain using a visual analogue scale (VAS) after both 3 and 12 months. The study did not detect any clinical or statistical difference.

In general, the number of complications was low for both treatments. The types of complications differed among the two treatments. Therefore, it makes no sense to test for significance at the level of individual complications. The working group assessed the seriousness of the complications against each other and found no difference between the two types of treatment.

The review of the literature did not identify evidence concerning treatment of patients with a very low level of function. Most often, these patients were excluded from the randomised studies.

The meta-analysis included comprised three studies, one of which excluded patients over the age of 70 years. The other studies comprised patients aged 19 to 87 years. In the randomised controlled study⁽⁴⁶⁾ included, patient ages ranged from 20 to 84 years. Based on the wide age dispersion in the studies included, the assessment is that the results can be extrapolated to the group of patients over the age of 65.

5.4.4.5 Summary of Findings

 Table 4: Focused question 7; External fixation vs. volar angular stable locking plate in case of distal radial fracture

Population: Patients over the age of 18 with distal radial fracture cf focused question 1 **Intervention:** volar angular stable locking plate **Comparison:** External fixation

Outcomes	Absolut	e effect* (95% CI)	Relative		Quality	Comments
	Control group	Intervention group	risk (95% CI)	participants (studies)	of the evidence (GRADE)	
		volar angular stable locking plate				
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 3 months		The mean DASH score in the intervention group was 15.58 lower (6.64 to 24.52)		174 (3 studies ⁽⁴²⁾)	⊕⊕⊝⊖ low ^{1,2}	volar angular stable locking plate is better than external fixation. The difference is significant
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 1 year		The mean DASH score in the intervention group was 8.00 lower (0.44 to 15.55)		174 (3 studies (⁴²⁾)	⊕⊕⊝⊝ low ^{1,2}	volar angular stable locking plate is better than external fixation. The difference is significant
Complications	256 per	196 per 1,000	OR 0.71	174	$\oplus \oplus \ominus \ominus$	An odds ratio

	_				4.0	
Total number of complications Follow-up: Mean 1 year	1,000	(105 to 334)	(0.34 to 1.46)	(3 studies ⁽⁴²⁾)	low ^{1,2}	of less than 1 means that volar angular stable locking plate is associated with fewer complications. Since 1 is included in the 95% Cl, it means no significant effect
Pain at rest – 3 months VAS (0 to 100) Follow-up: Mean 3 months		The mean VAS score at rest after 3 months in the intervention group was 3 lower (-8 to 2)		94 (1 study ⁽⁴⁶⁾)) low ^{2,3}	No difference
Pain during activity – 3 months VAS (0 to 100) Follow-up: Mean 3 months		The mean VAS score during activity after 3 months in the intervention group was 6 lower (-14 to 1)	_	93 (1 study ⁽⁴⁶⁾)	⊕⊕⊝⊝) low ^{2,3}	No difference
Pain at rest – 1 year VAS (0 to 100) Follow-up: Mean 1 year		The mean VAS score at rest after 1 year in the intervention group was 2 lower (-5 to 1)		104 (1 study ⁽⁴⁶⁾)) low ^{2,3}	No difference
Pain during activity – 1 year VAS (0 to 100) Follow-up: Mean 1 year	, the mass	The mean VAS score during activity after 1 year in the intervention group was 3 higher (-3 to 9)		104 (1 study ⁽⁴⁶⁾)) low ³	No difference

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

¹ Lack of blinding. Possibly attrition bias
 ² Wide confidence intervals.
 ³ Lack of blinding. Not block randomised according to AO groups

Quality of the evidence	The overall quality of the evidence is low.
	The meta-analysis and the supplementary randomised controlled study are of predominantly high quality and include a population which corresponds very much to the one comprised by the guideline. However, the evidence was downgraded due to lack of blinding and lack of analysis of patient attrition.
Balance between	The level of function (DASH) is significantly better
beneficial and adverse	in the group of patients treated with a volar angular
effects	stable locking plate, after both 3 and 12 months.
	However, the clinically relevant difference evens out over time.
	In the opinion of the working group, the severity of the complications in the two groups is comparable.
Values and preferences	The patients are expected to have fairly clear preferences, since most patients would prefer internal fixation with a volar angular stable locking plate. A volar angular stable locking plate enables an earlier start-up of a rehabilitation programme. In contrast, many patients will experience discomfort caused by the external fixation device in their normal daily life. Also, device care and maintenance may cause concern.
Other considerations	Most often, patients with external fixation will need help for pin care from a home care nurse.

5.4.4.6 Working group considerations

5.4.4.7 Rationale for recommendation

When comparing external fixation with bridging to internal fixation with a volar angular stable locking plate, the latter is recommended. The results for volar angular stable locking plate in terms of the patient-related outcomes are significantly better after both 3 and 12 months. It is assessed that most patients would select internal fixation with a volar angular stable locking plate because it allows for faster mobilisation rather than external fixation early in the process and the discomfort associated with the use thereof.

5.4.5 K-wires vs. open reduction and internal fixation with a volar angular stable locking plate (focused question 8)

What is the effect and what are the risks of K-wire surgery vs. open reduction and internal fixation with a volar angular stable locking plate?

Do special circumstances apply to patients with a low level of function, defined as permanent lack of ability to perform daily activities independently, or to patients over the age of 65?

5.4.5.1 Recommendation

- ↑ Consider use of a volar angular stable locking plate rather than Kwires during distal radial fracture surgery in patients of any age when surgery is indicated (⊕⊕○○).
- $\sqrt{}$ It is good practice to be cautious about the use of surgical intervention in patients of any age with a low level of function.

5.4.5.2 Practical advice and special patient considerations

Surgical treatment with the insertion of a volar angular stable locking plate allows for faster mobilisation (see focused question 9) as compared to K-wire surgery. This may speak in favour of osteosynthesis with a plate in patients with special needs such as patients with a walking frame.

K-wire osteosynthesis is a brief and simple surgical intervention. In most cases, use of this intervention requires a reasonable bone quality.

Insertion of a volar angular stable locking plate requires correct insertion of osteosynthesis material in order to reduce the risk of complications in the form of tendon injuries in the long term ⁽⁴⁰⁾.

If postoperative X-ray control leads to suspicion of sub-optimal location of the osteosynthesis material (too long screws or too distally located plate), the patients should be informed about this and offered follow-up control for assessment of the need for secondary removal of the osteosynthesis material.

Therefore, surgery scheduled for daytime hours (cf. recommendation according to focused question 3) is preferable in most cases, since this allows for scheduling the surgery with an experienced surgeon.

5.4.5.3 Background of the choice of question

In recent years, treatment with the insertion of a volar angular stable locking plate has become the preferred surgical method in a number of departments rather than K-wire osteosynthesis. Accordingly, there has been a desire to compare the two methods in order to clarify which one of them is more beneficial for the patient as regards effects and risks.

5.4.5.4 Literature

The evidence is based on five randomised controlled studies ⁽⁴⁷⁻⁵¹⁾. The working group did not identify systematic reviews of relevance for answering the focused question.

Based on the studies included, a meta-analysis was made of DASH after 3, 6 and 12 months, respectively. The authors of one of the studies ⁽⁵⁰⁾ contributed with supplementary data to enable these analyses. The populations and fracture delimitations of all five studies correspond to those set up in this guideline. Exact data for the meta-analysis were requested from the author of another study ⁽⁴⁷⁾, but no data were received. Therefore, this study was not included in the meta-analysis. It is described separately below.

After 3 and 6 months, the DASH score was significantly better in patients treated with a volar plate. After 3 months, the difference in mean DASH score was 9.29. However, the difference must be at least 10 to be clinically relevant, so 9.29 is close to being clinically relevant, but too low ⁽⁶⁾. The results after 12 months showed a tendency towards better mean DASH score in favour of the use of a volar plate, but the difference was not significant.

In general, the number of serious complications was low for both groups. However, the incidences of fracture redisplacement and re-operation or deep infection were higher in patients operated using K-wires.

A small number of patients treated with a volar plate will require removal of the plate in subsequent elective surgery.

Only one study ⁽⁴⁷⁾ looked exclusively at the group of patients over the age of 65. This relatively small study in 40 patients found the same DASH and PWRE scores in the two treatment groups after both 3 and 12 months. However, the study identified a significantly faster return to the usual daily activities for patients treated with a volar plate.

None of the studies looked at patients with an impaired level of function separately. In general, the studies did not investigate parameters other than DASH, which is why the number of data in the SoF table is low.

5.4.5.5 Summary of Findings

Table 5: Focused question 8; volar angular stable locking plate vs. K-wire surgery in case of distal radial fracture

Population: Patients over the age of 18 with distal radial fracture cf. focused question 1 **Intervention:** volar angular stable locking plate Comparison: K-wires

Outcomes	Absolute effe	ect* (95% CI)	Relative		Quality	Comments
	Control group	Intervention group	risk (95% Cl)	participants (studies)	of the evidence (GRADE)	
	K-wires	volar angular stable locking plate				
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 3 months		The mean DASH score after 3 months in the intervention group was 9.29 lower (-13.21 to -5.38)		236 (4 studies ^(48- 51))	⊕⊕⊝⊝ Iow¹	volar angular stable locking plate locking plate is better than K-wires. The difference is significant
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 6 months		The mean DASH score after 6 months in the intervention group was 6.68 lower (-10.15 to -3.21)		159 (2 studies ^(49,50))	⊕⊕⊝⊝ low¹	volar angular stable locking plate is better than K-wires. The difference is significant
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow-up: Mean 1 year		The mean DASH score after 1 year in the intervention group was 3.04 lower (-9.96 to 3.87)		76 (2 studies (^{48,51)})	⊕⊝⊝⊝ very low ^{1,2}	volar angular stable locking plate is better than K-wires. The difference is not significant

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

¹ Lack of blinding and no 'intention to treat' analysis
 ² Wide confidence interval

Quality of the evidence	The overall quality of the evidence is low.
	The evidence was downgraded due to lack of blinding and lack of analysis of patient attrition. The parameter 'return to work' was only reported in one study. Therefore, the associated evidence was downgraded further due to the risk of lack of accuracy.
Balance between	The incidence of serious complications was low for
beneficial and adverse	both treatments, but higher in patients treated with
effects	K-wires.
circets	K-wites.
	Surgical treatment with the insertion of a volar fixed-
	angle plate is associated with a better patient-related
	outcome and a faster effect.
	outcome and a faster effect.
Values and preferences	The patients' preferences are expected to be
L.	essentially consistent. A volar angular stable
	locking plate enables an earlier start-up of a
	rehabilitation programme, which is expected to be
	given a high priority by most patients.
Other considerations	The difference in DASH score is close to being
	clinically relevant after 3 months, but too low (9
	points). Thereafter, the difference between the two
	groups is only 6 and later 3 points.
	groups is only 0 and fator 5 points.

5.4.5.6 Working group considerations

5.4.5.7 Rationale for recommendation

When comparing K-wire surgery to treatment with the insertion of a volar angular stable locking plate, the effect of the latter is significantly better, but the difference is not considered to be of clinical relevancy. However, K-wire osteosynthesis is associated with a slightly higher incidence of serious complications. This, as well as the faster mobilisation and return to the usual daily activities enabled by osteosynthesis with volar angular stable locking plate, result in a recommendation to offer this treatment to the patients.

6 Cast or similar immobilising bandage time after insertion of a volar angular stable locking plate

6.1 Focused question 9

What is the effect of short-term (less than 2 weeks) vs. long-term (more than 5 weeks) cast or similar immobilising bandage following surgery with the insertion of volar angular stable locking plate?

6.2 Recommendation

↑ Consider use of short-term cast or similar immobilising bandage(less than 2 weeks) following insertion of a volar angular stable locking plate rather than long-term cast or similar immobilising bandage(more than 5 weeks) (⊕⊕○○).

6.3 Practical advice and special patient considerations

In case of identifying instability of scapholunate or distal radioulnar joints by fluoroscopy ⁽⁵²⁾ after completion of the surgery, the issue should be handled according to local guidelines, possibly including consulting with a hand surgeon.

6.4 Background of the choice of question

Patients treated with K-wires or plaster/cast or similar immobilising bandageafter reduction and patients treated with external fixation are typically immobilised for a minimum of 5 weeks. Treatment involving volar angular stable locking plates is often combined with a less restrictive regimen, where the patients are allowed to start mobilising and training after approx. 2 weeks. Concerns have been expressed as to whether this early mobilisation may lead to inadequate healing of the soft tissue and carpal bone injuries which may accompany distal radial fractures, but are rarely diagnosed acutely⁽⁵³⁾.

There has therefore been a desire to determine whether soft tissue and carpal bone injuries will heal well in case of early patient mobilisation.

6.5 Literature

The evidence is based on a single randomised clinical study ⁽⁵⁴⁾. In this study, patients were randomised to two groups. In both groups, surgery was followed by application of a conventional plaster cast for 2 weeks. After this period, one group was instructed to take off a removable cast or similar immobilising bandage daily and to do movement exercises, whereas the other group was not given a training programme and was only instructed to take off the cast or similar immobilising bandage before taking a shower. However, there was no follow-up as to whether the patients had followed the instructions.

There were no differences in the patient-related outcomes, range of movement, grip strength or X-ray findings, between the two groups.

The longest follow-up period in the study was 6 months, which is less than the desired period of 12 months.

One patient with an early start of mobilisation and seven patients with a late start of mobilisation had AO group B fractures. These AO type B fractures are not included in this guideline. However, the study was included, since it was shown that these patients with AO type B fractures who had undergone surgery with the insertion of a volar angular stable locking plate did not perform poorer vs. patients with AO type C fractures⁽⁵⁵⁾.

The literature found did not elucidate directly any undiagnosed associated carpal injuries heal poorer in case of early mobilisation leading to problems in the long term. It did show, however, that there were no differences between the two groups as regards patient-related outcomes (DASH score) and pain.

Summary of Findings 6.6

Table 6: Focused question 9; Early mobilisation (within 14 days) vs. late mobilisation (after 5 weeks) following distal radial fracture treated with a volar angular stable locking plate

Population: Patients over the age of 18 with distal radial fracture cf. focused question 1, who had undergone surgery with the insertion of a volar angular stable locking plate Intervention: Early mobilisation (within 14 days) Comparison: Late mobilisation (after 5 weeks)

Outcomes	Absolute effect* (9	95% CI)				Comments
	Control group	Intervention group	risk (95% Cl)	participants (studies)	of the evidence (GRADE)	
	Late mobilisation (after 5 weeks)	Early mobilisation (within 14 days)				
Pain – 3 months VAS scale from 0 to 10. Follow-up: Mean 3 months		The mean VAS score after 3 months in the intervention group was 2.4 (1.7 to 3.2)		56 (1 study ⁽⁵⁴⁾)	⊕⊕⊝⊝ low ^{1,2}	No difference
Pain – 6 months VAS scale from 0 to 10. Follow-up: Mean 6 months		The mean VAS score after 6 months in the intervention group was 1.5 (0.7 to 2.3)	-	54 (1 study ⁽⁵⁴⁾)	⊕⊕⊝⊖ low ^{1,2,3}	No difference
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow- up: Mean 3 months	months in the control group was 17	The mean DASH score after 3 months in the intervention group was 19 (13 to 25)		56 (1 study ⁽⁵⁴⁾)	⊕⊕⊝⊖ low ^{1,2,3}	No difference
DASH (Disabilities of the Arm, Shoulder and Hand score). Scale from 0 to 100. Follow- up: Mean 6 months	months in the control group was 8.1	The mean DASH score after 6 months in the intervention group was 8.5 (2.6 to 14)		54 (1 study ⁽⁵⁴⁾)	⊕⊖⊝ very low ^{1,2,3,4}	No difference

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

¹ Eight patients had AO B type fractures and therefore did not match our population

² Only one randomised study concerning this topic is available

³ A follow-up period of 6 months is significantly different from 12 months which was the desired follow-up period in the PICO question

Wide confidence intervals

6.7 Working group considerations

Quality of the evidence	The overall quality of the evidence is low.				
	The evidence was downgraded due to differences in fracture types and the relatively short follow-up period (6 months). Since only one study is available, the quality of the evidence was downgraded due to risk of lack of accuracy.				
Balance between	There were no measurable beneficial effects of short-				
beneficial and adverse	term cast or similar immobilising bandage and no				
effects	adverse effects either.				
Values and preferences	The patients' preferences are expected to be roughly consistent in favour of early cast or similar immobilising bandage removal. Early cast or similar immobilising bandage removal allows for an earlier start-up of exercises and will also facilitate the daily personal hygiene.				

6.8 Rationale for recommendation

When formulating the recommendation, the working group put a significant emphasis on patient values and preferences, because it was assessed that most patients would prefer early cast or similar immobilising bandage removal and startup of mobilisation after 2 weeks rather than waiting for 5 weeks.

7 Independent vs. supervised rehabilitation following distal radial fracture

7.1 Focused question 10

What is the effect of independent rehabilitation based on a written training plan following a single instruction from a healthcare professional vs. rehabilitation supervised by a physiotherapist or an occupational therapist more than once?

7.2 Recommendation

- ✓ It is good practice not to prescribe rehabilitation supervised by an occupational therapist or a physiotherapist on a routine basis to patients with uncomplicated cases. This is due to finding no difference in the effect as compared to independent rehabilitation based on a written training plan following a single instruction ⊕⊖⊖⊖.
- ✓ As a minimum, it is good practice to offer guidance and practical instruction concerning self-rehabilitation following distal radial fracture to all patients regardless of the treatment method.

7.3 Practical advice and special patient considerations

All patients are entitled to receive a rehabilitation plan, if rehabilitation is justified from a medical view at the time of discharge from the hospital.

Patients require instructions and knowledge of an appropriate rehabilitation programme as well as the amount of daily training and the physical load in daily activities. It is a good idea to hand out written guidance on these matters and advice on where to look for additional guidance to the patient at the time of cast or similar immobilising bandage removal.

Rehabilitation supervised by an occupational therapist or a physiotherapist specialising in rehabilitation in case of hand issues should be offered to patients with complicated cases, for example in case of major oedema, signs of incipient CRPS-related disabling reduced range of movement and/or pain.

7.4 Background of the choice of question

Subsequent to distal radial fracture cast or similar immobilising bandage removal, a large part of the patients ask for rehabilitation. The rehabilitation offered varies a great deal among patient groups. In some places, the rehabilitation plan refers the patient to specialised rehabilitation (in a hospital) on a routine basis, while, elsewhere, the patient is referred to general rehabilitation (arranged by the municipality) on a routine basis. Others receive a self-training programme following instruction. Rehabilitation is quite demanding on resources due to the large number of patients. Therefore, it was considered relevant to determine whether the patient will benefit the most from independent rehabilitation based on a written training plan or rehabilitation supervised by a therapist.

In the opinion of the working group, it is within the competencies of the trained therapist to assess the suitability of specific training techniques or treatment modalities for each individual patient. Therefore, the supervised rehabilitation is not specified in details in this guideline.

7.5 Literature

The evidence for this focused question is based on three randomised controlled studies ⁽⁵⁶⁻⁵⁸⁾. The topic of focused question 10 was the object of a Cochrane review ⁽⁵⁹⁾ in 2006. The literature included is up to 30 years old and the quality of it is very low. The literature found also comprises two systematic reviews ^(60,61), in which some of the studies are rather old. Therefore, the working group did not include these studies, but only the more recent literature when answering the focused question.

One study focused on conservatively treated patients, and two other studies focused on patients who had undergone surgery with the insertion of a volar angular stable locking plate. The studies compared supervised rehabilitation to non-supervised rehabilitation. They differ as regards the actual interventions.

In the study ⁽⁵⁶⁾ focusing on conservatively treated patients, the non-supervised rehabilitation was based on instruction provided twice after cast or similar immobilising bandage removal. The non-supervised rehabilitation was compared to activity-focused supervised training carried out by the patients four times on average. The actual contents of the training are not described in the study.

In one of the studies ⁽⁵⁷⁾ focusing on operated patients, the non-supervised training was based on a home programme upon receipt of instructions and hand-out of a diary to each patient, in which he/she was to make notes about the training. The weekly duration of the training was 4.6 hours on average. This was compared to 12 times treatment supervised by a therapist chosen by the patient and comprising 1 hour of training per week. The contents of the supervised training are not described in the study. After 6 weeks and 24 weeks, there was no difference between the two groups in terms of the patient-related outcome PRWE.

In the other study focusing on operated patients ⁽⁵⁸⁾, each patient was instructed how to exercise and train at home beyond the pain threshold by a surgeon. The surgeon also handed out wrist cast or similar immobilising bandage to be applied by the patient as needed. This was compared to the 'usual' occupational therapy. The contents and extent of this training are not described in the study.

A meta-analysis of the two studies identified no difference between non-supervised training following a single instruction and training supervised by a physiotherapist or occupational therapist in terms of PRWE and DASH after 6 weeks, 3 and 6 months. Patients with complications were not included in any of these three studies.

7.6 Summary of Findings

Table 7: Focused question 10; Supervised rehabilitation vs. self-rehabilitation with a programme after distal radial fracture surgery with the insertion of a volar angular stable locking plate

Population: Patients over the age of 18 with distal radial fracture cf. focused question 1, who had undergone surgery with the insertion of a volar angular stable locking plate **Intervention:** Rehabilitation supervised by an occupational therapist or a physiotherapist more than once

Comparison: Rehabilitation based on a training programme following a single instruction from a healthcare professional at the time of cast or similar immobilising bandageremoval

Outcomes	Absolute effe	ect* (95% CI)	Relative			Comments
	Control group	Intervention group	risk (95% Cl)	participants (studies)	of the evidence (GRADE)	
	Non- supervised rehabilitation	Supervised				
PRWE and DASH Follow-up: Mean 8 weeks		The mean DASH and PRWE score after 8 weeks in the intervention group was 0.42 standard deviations lower		118 (2 studies (^{57,58)})	⊕⊝⊝⊝ very low ^{1,2}	SMD -0.42 (- 0.79 to -0.05) No difference
PRWE and DASH Follow-up: Mean 6 months		(-0.79 to -0.05) The mean DASH and PRWE score after 6 months in the intervention group was 1.10 higher (-2.18 to 4.38)		75 (1 study ⁽⁵⁸⁾)	⊕⊝⊝⊝ very low ^{1,3}	No difference
Pain VAS (scale 0-10) Follow-up: Mean 3 months		The mean VAS score after 3 months in the intervention group was 0.10 higher (-0.46 to 0.26)		72 (1 study ⁽⁵⁸⁾)	⊕⊖⊝⊝ very low ^{1,2,3}	No difference
Pain VAS (scale 0-10) Follow-up: Mean 6 months		The mean VAS score after 6 months in the intervention group was 0.40 higher (-0.22 to 1.02)	-	76 (1 study ⁽⁵⁸⁾)	very low ^{1,2,3}	No difference

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

¹ Lack of blinding and high patient attrition rate

² Wide confidence interval. The recommendation will vary depending on the upper and lower limits

³ Uncertainty due to only one published study

Table 8: Focused question 10; Supervised rehabilitation vs. self-rehabilitation with a programme after conservative treatment of distal radial fracture

Population: Patients over the age of 18 with distal radial fracture cf. focused question 1, who had been treated with reduction and plaster (conservative treatment) Intervention: Rehabilitation supervised by an occupational therapist or a physiotherapist more than

once

Comparison: Rehabilitation based on a training programme following a single instruction from a healthcare professional at the time of cast or similar immobilising bandage removal

Outcomes	Absolute effect	* (95% CI)	Relative		Quality of	Comments
	Control group	Intervention group	risk (95% Cl)	participants (studies)	the evidence (GRADE)	
	Non- supervised rehabilitation	Supervised rehabilitation				
Function, 6 weeks PRWE, activity part Follow-up: Mean 6 weeks		The mean PRWE score, activity part, after 6 weeks in the intervention group was 6.8 lower (-25.55 to 11.95)		35 (1 study ⁽⁵⁶⁾)	⊕⊖⊖⊖ very low ^{1,2}	No difference
Pain, 6 weeks PRWE, pain part Follow-up: Mean 6 weeks		The mean PRWE score, pain part, after 6 weeks in the intervention group was 5.50 lower (-23.03 to 12.03)		35 (1 study ⁽⁵⁶⁾)	⊕⊖⊖⊖ very low ^{1,2,3}	No difference
Function, 24 weeks PRWE, activity part Follow-up: Mean 24 weeks		The mean PRWE score, activity part, after 24 weeks in the intervention group was 5.10 lower (-24.33 to 14.03)		33 (1 study ⁽⁵⁶⁾)	⊕⊖⊝⊖ very low ^{2,3,4}	No difference
Pain, 24 weeks PRWE, pain part Follow-up: Mean 24 weeks		The mean PRWE score, pain part, after 24 weeks in the intervention group was 8.4 lower (-27.07 to 10.27)		33 (1 study ⁽⁵⁶⁾)	⊕⊖⊖⊖ very low ^{1,2,3,4}	No difference

*The baseline risk is based on the median control group risk across the studies included. If other baseline risk levels were selected, they are explained in associated footnotes. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval RR: Relative risk;

¹ Lack of blinding ² Uncertainty due to only one published study

³ Wide confidence interval. The recommendation will vary depending on the upper and lower limits

⁴ Lack of blinding and a 19% patient attrition rate

Quality of the evidence	The overall quality of the evidence is very low.
	In general, the studies are characterised by high attrition rates, lack of blinding and wide confidence intervals. Therefore, the evidence was downgraded significantly.
Balance between	The treatment methods stated are not known to have
beneficial and adverse	caused adverse effects. However, the studies
effects	concluded that the patients' level of function will benefit from some rehabilitation.
Values and preferences	The patients' preferences are deemed inconsistent. It
	is predicted that most patients will ask for
	rehabilitation. Some patients will ask for supervised
	rehabilitation, whereas others would prefer a single
	instruction.
Other considerations	Some patients will need additional guidance as
	regards the amount of training during the
	rehabilitation period.
	I de la companya de la

7.7 Working group considerations

7.8 Rationale for recommendation

All patients are entitled to a medical assessment of their rehabilitation needs at the time of discharge from the hospital. In case it is assessed that a patient needs rehabilitation, the patient should, as a minimum, be instructed and guided in independent rehabilitation. Rehabilitation needs will vary quite a lot among patients. However, most patients would want to be offered rehabilitation following distal radial fracture. Based on the available literature, there is no evidence that all patients should be offered supervised rehabilitation. Therefore, supervised rehabilitation training is only recommended for patients with complicated cases.

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9 Appendixes

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10 Appendix 1: Background

The treatment of distal radial fractures has undergone a major development within the past 30 years. It has changed from being very defensive – based on the assumption that most patients would not obtain a better outcome from surgery – towards an increased willingness to perform surgery. Included is, e.g., an increased frequency of offering surgery to elderly patients aged up to 80-90 years. The changed treatment strategy has probably been driven by the development within the speciality field and medical science in general. During the same period, the proportion of active elderly people in the Danish population has increased. The majority of distal radial fractures are due to falls onto an outstretched arm from an upright position. There is a predominance of women among the patients due to the fact that osteoporosis is often an underlying cause.

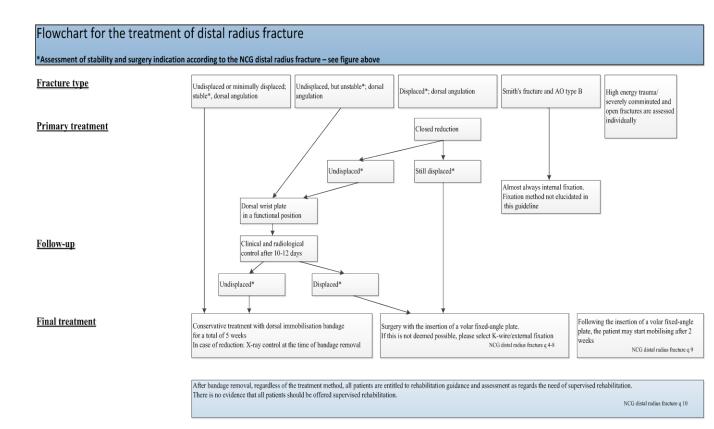
The Danish incidence has been stable at approx. 20,000 fractures per year. Therefore, distal radial fracture is one of the most frequently treated fractures in the Danish healthcare system. The annual incidence of distal radial fracture was 1:100 in the 50+ age group during the period 2003-2013. During the same period, distal radial fracture surgery was performed in between 3,000 and 4,000 patients each year. There was a slight increase in the number of surgical interventions during this period and a simultaneous change of preferred surgical methods from the less invasive methods, including K-wires and external fixation, towards internal fixation with the insertion of plate and screws. This change has taken place gradually, along with the development and marketing of new and better implants for the more invasive methods, including anatomical plates with fixed-angle screws.

Based on the above, it was decided to review the evidence for the treatment of distal radial fracture in Denmark to provide national evidence-based recommendations for the treatment of this type of fracture.



11 Appendix 2: Treatment algorithm for distal radial fracture with dorsal angulation

NCG Distal radius fracture – tro	eatment algorithm 2014
In case of suspected distal radius fracture, perform an X-ray exa	mination of the wrist.
If one or more of the following conditions are met, the fracture s means that reduction and/or surgery is indicated:	should be considered unstable and/or displaced, which
 More than 10 degrees of dorsal angulation of the articular su perpendicular to the longitudinal axis of the radius Ulnar variance of more than 2 mm 	rface of the radius in a side view as compared to
Articular step-off of more than 2 mm	
 Incongruity of the distal radioulnar joint Loss of substance/comminuted fracture of the dorsal cortex of 	of the distal radius
 Loss of substance/comminuted fracture of the dorsal cortex of the dorsal cortex	NCG distal radius fracture q 1
If relevant following a medical assessment, perform a suppleme	ntary CT scan to
clarify doubt as regards surgery indication or method.	
	NCG distal radius fracture q 2



12 Appendix 3: Radiological measuring of the radial – angle and length

Normal right wrist



Ulnar variance of 1 mm

11 degrees of volar angulation of the articular surface of the radial

13 Appendix 4: Implementation

The regions and the regional hospitals play an important role in facilitating the implementation of the national clinical guideline through communicating the content of the guideline and supporting the practical application of the guideline. To support application of the national clinical guideline locally, it should preferably be attuned with or integrated into process descriptions, instructions and guidelines which are already in use in clinical practice. Each regional hospital should ensure that the recommendations of relevance to departments at that hospital are incorporated into instructions and guidelines at hospital and/or department level. Additionally, individual departments may benefit from presenting the national clinical guideline at morning conferences or similar meetings or during actual teaching. Such departments are mainly emergency rooms and departments, orthopaedic surgery departments. Furthermore, it may be advantageous to include a link to the full national clinical guideline in pre-existing documents.

The professional organisations are important stakeholders as regards disseminating knowledge of the guideline, and the relevant professional organisations in connection with this guideline are the Danish Society of Radiology (DRS), the Danish Orthopaedic Society (DOS), the Danish Society for Surgery of the Hand (DSFH), the Danish Orthopaedic Society for Traumatology (DOT), the Danish College of General Practitioners (DSAM), the former Danish Society of Occupational Hand Therapy (Ergoterapifagligt Selskab for Håndterapi), the Danish Society of Physiotherapy (DSF), the Danish Nursing Society (DASYS), the Danish Society of Orthopaedic Surgery Nurses (FSOS, Fagligt Selskab for Ortopædkirurgiske Sygeplejersker) and the Danish Association of Nurses Working in Emergency Rooms (Sammenslutningen af sygeplejersker, der arbejder i akutmodtagelser). The working group, therefore, suggests to mention the national clinical guideline on the websites of the relevant professional organisations, including a description of the implications of it for the professional group in question and with a link to the full version of the guideline. Also, the working group suggests to present the guideline at annual meetings and theme days and to communicate information via professional magazines and electronic newsletters.

The professional organisations are represented in the working group, and the individual members will support this implementation process in their respective organisations.

As a starting point, implementation of the national clinical guideline on the treatment of distal radial fractures is a regional responsibility.

In addition to publication of the full guideline, it has been decided to publish a quick guide which is a short version of 1-2 A4 pages. It only contains the guideline recommendations and key messages with specification of evidence rating and strength of the recommendations in pictograms.

The DHA has published a digital implementation toolbox at its website. The toolbox is meant to assist the manager or project manager who is to work on implementing national clinical guidelines locally. The toolbox contains an implementation model and tools for the implementation and is based on a review of the evidence of the effect of interventions.

14 Appendix 5: Monitoring

The work on this national clinical guideline was initiated due to a shift in treatment methods and major variations among hospitals and regions as regards the willingness to perform surgery. Furthermore, the practice as regards rehabilitation varies considerably. The guideline recommendations are expected to address these challenges. In the opinion of the working group, the most important expected results or effects to which this guideline is to contribute are:

- More consistent practice across hospitals and regions as regards the willingness to perform surgery
- More consistent practice across hospitals and regions as regards the type of surgical method. The use of internal fixation with a volar angular stable locking plate is expected to increase
- More consistent practice as regards rehabilitation.

Consistent practice: Willingness to perform surgery

The frequency of surgery in case of distal radial fracture varies significantly among regions and hospitals. In some departments, a large part of the patients with distal radial fracture are operated, whereas other departments exercise caution as regards the use of surgical treatment and tend to prefer conservative treatment. Therefore, this guideline is expected to result in a more consistent practice. This can be monitored based on extracts from the Danish National Patient Registry (LPR) at specified intervals such as four times per year.

A more consistent practice may reflect a tendency towards following the guideline recommendations in relation to indicating surgery – and possibly supplementary CT scan – in practice. In addition, this is expected to result in offering optimal treatment to the patients so that, in the long term, patients with wrist fractures will experience fewer complications and obtain the best possible functional capacity.

Consistent practice: Treatment method

The other reason for initiating the work on this guideline was the shift, over the past 10 years, as regards the preferred surgical method towards osteosynthesis with a volar angular stable locking plate rather than external fixation – without sufficient support from the literature in this field. A key message in the guideline is that osteosynthesis with a volar angular stable locking plate is generally recommended rather than K-wires and external fixation, since the patient-related effects in terms of DASH and PRWE are significantly better for the osteosynthesis method. Therefore, it is relevant to monitor whether osteosynthesis with a volar angular stable locking plate will be the most preferred surgical method in future. This can be assessed based on extracts from the Danish Fracture Database and the LPR, for example four times per year. Furthermore, when the recommendation is followed, patients with wrist fractures are expected to experience fewer complications and obtain the best possible functional capacity.

Consistent practice: Rehabilitation

The guideline recommendations in relation to rehabilitation are based on consensus among the members of the working group concerning good clinical practice, since the existing literature does not provide evidence for supervised rehabilitation vs. a single instruction for uncomplicated cases.

Therefore, it may be relevant to monitor whether the patients are offered rehabilitation, the type of it and whether they complete it.

Danish Fracture Database

The working group draws attention to the Danish Fracture Database – a new database under development, which is popular among clinicians. This database allows to monitor the type of surgical method used and the time of surgery. In future, it may be possible to pool data from this database with data from the LPR and possibly patient-reported data.

For example, it might be interesting to monitor:

- the complication rate, including the number of re-operations, in relation to the time of surgery
- the correlation between the number of operations and the time of surgery, including within the first 24 hours, and whether the number of operations increases if monitored after more than 10 days (the time of control for conservatively treated fractures)

Ongoing monitoring and feedback

The working group also draws attention to the possibility of campaign measurements, in which wrist fractures are brought into focus during (a few) specific weeks of the year, e.g. during medical record audit, and where the patients are followed up at a specific time following the occurrence of a wrist fracture and where their level of function is assessed. This will enable focused, real-time and local monitoring which, in general, promotes implementation. It also enables obtaining data that may be used for research into the development of the patients' level of function.

15 Appendix 6: Update and further research

As a starting point, the guideline will be updated 3 years from the date of publication, unless new evidence or the technological development in this field justifies otherwise.

Sub-field 1: Rehabilitation following distal radial fracture.

Based on the work on this guideline, the working group finds that there is an extensive need for further research into the need for and effect of various rehabilitation programmes, including occupational therapy and physiotherapy. Likewise, it remains unclear whether rehabilitation needs vary according to type of treatment, and whether patient age, comorbidities and complications should influence on the rehabilitation offered.

There is a need to identify the preferred components of supervised rehabilitation, since lack of this information is one of the weaknesses of the currently available studies concerning this topic.

Sub-field 2: National monitoring project in the form of a cohort study.

As part of the monitoring of the effect of this guideline, the working group recommends national focus weeks of a duration of 2-3 weeks for nationwide collection of data on patients with distal radial fracture. Such cohort would be very suitable for investigating whether delay of the surgery, after deciding that surgery is indicated, impacts on the final outcome for the patients in terms of Quick DASH, DASH and/or PRWE^(12,62). Also, it would be possible to test many of the patient preferences stated in this guideline with a view to updating future revisions of this guideline according to the results. The special groups of elderly patients and patients with a low level of function who have not been studied in the available literature could be described with a national cohort study.

A national cohort study would be of major professional interest, since it would be able to provide results unaffected by the inclusion and exclusion criteria that always limit the results from randomised controlled studies.

16 Appendix 7: Description of the method used

The national clinical guideline on the treatment of distal radial fractures was prepared by a working group established by the DHA with representatives from relevant specialities and professions. In a number of meetings, the working group delimited and clarified 10 key focused questions ('PICO' questions).

This national clinical guideline was prepared following the method described in detail in *the DHA's NCG method guide (in Danish only)*.

Initially, the working group identified the pre-existing guidelines in this field. The group identified two national guidelines in this field, an American guideline from the AAOS⁽⁷⁾ and a Norwegian guideline from the Norwegian Knowledge Centre for the Health Services in Oslo, Norway⁽⁶³⁾. However, based on an AGREE II assessment of quality and relevance none of these guidelines were deemed suitable for answering the questions asked directly.

This was followed by a systematic literature search for systematic survey articles and a second search for randomised clinical studies dated 2003 and onwards. Studies matching the population selected and the focused questions were selected and validated using AMSTAR for the assessment of systematic survey articles and Cochrane's tool for the assessment of Risk of Bias for the randomised controlled studies. Bias in diagnostic studies was assessed using the tool QUADAS II. Where necessary, a few supplementary meta-analyses were made using Review Manager. Where possible, profiles of the overall evidence for the individual PICO questions were prepared. Please refer to <u>Appendix 11</u> for further details.

The initial searches identified no literature to support the individual questions. This was the case for PICO 1-3. Therefore, for these questions, it was decided to extend the search back to 1983 and to search for follow-up studies as well. <u>Appendix 10</u> includes a detailed description of the literature search.

During the work on preparing the guideline, the process and the recommendations were presented to and discussed with a broad-based reference group, and a draft guideline was subjected to a wide public consultation.

The members of the working group and the reference group are listed in <u>Appendix</u> <u>12</u>.

17 Appendix 8: Focused questions

The working group weighted the various outcomes as Critical (C), Important (I), less important (-), adverse reactions (A). This weighting was used in GRADE profiles when preparing the Summary of findings (SoF) tables.

Focused question 1: Is there any evidence that one or more of the radiological parameters below, assessed during wrist X-ray examination, may be used as the basis for deciding on a reduction and/or surgery indication?

Population	Patients over the age of 18 with distal radial fracture as identified during wrist X-ray examination and with one or more of the following findings prior to reduction
	 More than 10 degrees of dorsal angulation of the articular surface of the radial in a side view as compared to perpendicular to the longitudinal axis of the radial Intra-articular step-off or diastasis of more than 2 mm Ulnar variance of more than 3 mm Incongruity of the distal radioulnar joint Loss of substance of the dorsal cortex
Intervention/index test	Treatment using K-wire, external fixation, ORIF and volar angular stable locking plate or stable reduction (which is still in position at a control after 12-14 days)
Comparison/reference standard	Conservative treatment with plaster or another immobilising material (no further intervention)
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I) Movement (-) Median, ulnar, radial nerve affection (A) Tendon injury (A) (CDDS (A))

- CRPS (A)
- Finger stiffness (A)

Focused question 2: How is a surgery indication affected by supplementary CT scan following conventional wrist X-ray examination?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1
Intervention/index test	CT-scan performed following conventional wrist X-ray examination
Comparison/reference standard	Wrist X-ray examination
<i>Outcome</i> [indicate whether the outcome is important or critical]	Changed treatment indication (C)
	Changed fracture classification (AO and others) (I)

No adverse reactions

Focused question 3: What is the effect and what are the risks of surgery within the first 48 hours vs. more than 48 hours after deciding that surgery is indicated for a distal radial fracture?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1
Intervention/index test	Surgery within the first 48 hours after deciding that surgery is indicated
Comparison/reference standard	Surgery more than 48 hours after deciding that surgery is indicated
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I) Movement (-) Median, ulnar, radial nerve affection (A) Tendon injury (A)

- CRPS (A)
- Finger stiffness (A)

Focused question 4: What is the effect and what are the risks of conservative treatment with reduction and plaster/cast or similar immobilising bandage vs. K-wire surgery (Kapandji or Willenegger technique)?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 as well as patients over the age of 65 and patients with a low level of function (not able to go shopping without assistance)
Intervention/index test	K-wire surgery (Kapandji or Willenegger technique)
Comparison/reference standard	Conservative treatment (closed reduction and plaster or similar immobilising material)
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I) Movement (-) Median, ulnar, radial nerve affection (A)

- Tendon injury (A)
- CRPS (A)
- Finger stiffness (A)

Focused question 5: What is the effect and what are the risks of conservative treatment with reduction and plaster/cast or similar immobilising bandage vs. surgical treatment comprising bridging external fixation with or without supplementary K-wires?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 as well as patients over the age of 65 and patients with a low level of function (not able to go shopping without assistance)
Intervention/index test	Surgery with bridging external fixation
Comparison/reference standard	Conservative treatment (closed reduction and plaster or similar immobilising material)
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I)

- Movement (-)
- Median, ulnar, radial nerve affection (A)
- Tendon injury (A)
- CRPS (A)
- Finger stiffness (A)

Focused question 6: What is the effect and what are the risks of conservative treatment with reduction and plaster vs. surgery with internal fixation and a volar angular stable locking plate?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 as well as patients over the age of 65 and patients with a low level of function (not able to go shopping without assistance)
Intervention/index test	Surgery with ORIF and insertion of a volar angular stable locking plate
Comparison/reference standard	Conservative treatment (closed reduction and plaster or similar immobilising material)
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I) Movement (-) Median, ulnar, radial nerve affection (A) Tendon injury (A)

- CRPS (A)
- Finger stiffness (A)

Focused question 7: What is the effect and what are the risks of surgery comprising bridging external fixation, possibly supplemented with K-wires, vs. open surgery with reduction and insertion of a volar angular stable locking plate?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 as well as patients over the age of 65 and patients with a low level of function (not able to go shopping without assistance)
Intervention/index test	Surgery with bridging external fixation
Comparison/reference standard	Surgery with ORIF and insertion of a volar angular stable locking plate
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I) Movement (-)

- Median, ulnar, radial nerve affection (A)
- Tendon injury (A)
- CRPS (A)
- Finger stiffness (A)

Focused question 8: What is the effect and what are the risks of K-wire surgery vs. open reduction and internal fixation with a volar angular stable locking plate?

Do special circumstances apply to patients with a low level of function or to patients over the age of 65?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 as well as patients over the age of 65 and patients with a low level of function (not able to go shopping without assistance)
Intervention/index test	K-wire surgery (Kapandji or Willenegger technique)
Comparison/reference standard	Surgery with ORIF and insertion of a volar angular stable locking plate
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (I) Return to work (I) Movement (-) Median, ulnar, radial nerve affection (A) Tendon injury (A) CRPS (A)

• Finger stiffness (A)

Focused question 9: What is the effect of short-term (less than 2 weeks) vs. longterm (more than 5 weeks) cast or similar immobilising bandagefollowing surgery with the insertion of a volar angular stable locking plate?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 and treated with ORIF and insertion of a volar angular stable locking plate
Intervention/index test	Postoperative cast or similar immobilising bandage time < 2 weeks
Comparison/reference standard	Postoperative cast or similar immobilising bandage time >/= 5 weeks
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Re-operation due to complication (non-simple removal of

osteosynthesis material) (I)

- Return to work (I)
- Movement (-)
- Median, ulnar, radial nerve affection (A)
- Tendon injury (A)
- CRPS (A)
- Finger stiffness (A)

Focused question 10: What is the effect of independent rehabilitation based on a written training plan following a single instruction from a healthcare professional vs. rehabilitation supervised by a physiotherapist or an occupational therapist more than once?

Population	Patients over the age of 18 diagnosed with DRF cf. PICO 1 and treated with either conservative treatment, K-wire osteosynthesis, bridging external fixation or ORIF with insertion of a volar angular stable locking plate
Intervention/index test	Rehabilitation supervised by a physiotherapist or an occupational therapist more than once – after cast or similar immobilising bandage removal
Comparison/reference standard	Independent rehabilitation based on a written training plan following a single instruction from a healthcare professional after cast or similar immobilising bandage removal
<i>Outcome</i> (measured after 3 and 12 months)	 DASH/PRWE (C) Pain (VAS) (I) Movement (I) Return to work (I) Re-operation due to complication (non-simple removal of osteosynthesis material) (-) Median, ulnar, radial nerve affection (A) Tendon injury (A) CRPS (A) Finger stiffness (A)

18 Appendix 9: Description of the strength and implications of recommendations

Presented below are, firstly, the four types of recommendations to be used in case of evidence and, afterwards, the recommendations which may be given for questions for which the systematic search showed that there was no evidence.

The four types of evidence-based recommendations

A recommendation can be either for or against a given intervention. A recommendation can be either strong or weak/conditional. Therefore, the following four types of recommendations are available:

Strong recommendation for $\uparrow\uparrow$

Give/use ...

The DHA makes a strong recommendation for in case of high-quality evidence showing that the desirable consequences of an intervention clearly outweigh its undesirable consequences.

The following will point in the direction of a strong recommendation for:

- High-quality evidence
- High intended effect and few, if any, unintended adverse effects of the intervention
- The patients' values and preferences are well-known and consistent in favour of the intervention

Implications:

- Most patients would want the intervention.
- The vast majority of clinicians would prescribe the intervention.

Weak/conditional recommendation for \uparrow

Consider ...

The DHA makes a weak/conditional recommendation for when the desirable consequences of an intervention are judged to marginally outweigh its undesirable consequences or when the available evidence cannot rule out a significant benefit of an existing practice if the adverse effects of the latter are judged to be few or absent.

The following will point in the direction of a weak recommendation for:

- Low-quality evidence
- The intended effect of the intervention is assessed to marginally outweigh the unintended adverse effects

• Preferences and values vary significantly among patients or are unknown

Implications:

- Most patients would want the intervention, but a substantial number would not
- The clinicians will need to help the patient make a decision that matches the patient's values and preferences.

Weak/conditional recommendation against ↓

Use only ... upon due consideration, since the beneficial effect is uncertain and/or low and there are documented adverse effects such as ...

The DHA makes a weak/conditional recommendation against when the undesirable consequences of an intervention are judged to outweigh its desirable consequences and this is unsupported by strong evidence. This recommendation is also made in case of strong evidence of both beneficial and adverse effects when the balance between them is difficult to determine.

The following will point in the direction of a weak recommendation against:

- Low-quality evidence
- Uncertain effect of the intervention
- Uncertain adverse effects of the intervention
- The unintended adverse effects of the intervention are assessed to marginally outweigh the intended effect
- Preferences and values vary significantly among patients or are unknown

Implications:

- Most patients would not want the intervention, but a certain number would
- The clinicians will need to help the patient make a decision that matches the patient's values and preferences.

Strong recommendation against $\downarrow\downarrow$

Do not give/do not use/avoid ...

The DHA makes a strong recommendation against in case of high-quality evidence showing that the undesirable consequences of an intervention clearly outweigh its desirable consequences. The DHA also makes a strong recommendation against when the review of the evidence shows with great certainty that an intervention is useless.

The following will point in the direction of a strong recommendation against:

• High-quality evidence

- The intended effect of the intervention is low
- Some or significant unintended adverse effects of the intervention
- The patients' values and preferences are well-known and consistent against the intervention

Implications:

- Most patients would not want the intervention.
- Clinicians would typically not prescribe the intervention.

The two types of good practice recommendations

Good practice $\sqrt{}$ For: It is good practice to ...

Against: It is not good practice to ... It is not good practice, on a routine basis, to ... It is good practice to avoid ... It is good practice to avoid, on a routine basis, ...

Good practice based on professional consensus among the members of the working group that prepared the clinical guideline. The recommendation may be either for or against the intervention. A good practice recommendation is made when relevant evidence is not available.

19 Appendix 10: Search description incl. flowchart

The literature searches were performed in a predefined group of databases selected for search for clinical guidelines in general. For a detailed description, please see the DHA's NCG method guide (in Danish only). The searches were performed by the Medical Library, Aalborg University Hospital, by Conni Skrubbeltrang in collaboration with special subject adviser Camilla Ryge. Search protocols with the search strategies for the individual databases are available via <u>sst.dk</u> (in Danish only).

An initial search for clinical guidelines was performed in the following sources of information: the Guidelines International Network (G-I-N), NICE (UK), the National Guideline Clearinghouse, the Scottish Intercollegiate Guidelines Network (SIGN), the HTA database, the Cochrane Library, the SBU (Sweden), the Swedish National Board of Health and Welfare, the Norwegian Directorate of Health, the Norwegian Knowledge Centre for the Health Services, Medline and Embase.

The searches were performed during the period January to May 2014 and comprised a total of five searches. As a starting point, the searches focused on literature published during the period 2003 to 2014. In case a search did not identify relevant literature within this 10-year period, it was extended to older literature. The date ranges appear from the search protocols.

The first search was for international guidelines published during the period 2003 to 2014. The second search was a follow-up search for meta-analyses and systematic reviews. The third search was an additional follow-up search for randomised controlled studies. In a fourth search, the third search was extended back to 1983 for PICO 1 and 3, and in a fifth search it was extended to comprise follow-up studies or cohort studies as well.

The literature identified in searches was supplemented by known literature from other sources, primarily for use in the Reference list of background literature.

The search for guidelines included the following search terms:

English: distal radial fracture*, distal radial fracture* Colles fracture*, Barton fracture*, Smith fracture* fractura radii (distralis), wrist fracture, Colles' fracture, radial fractures.

Danish: distale radial frakturer, håndledsnære underarmsbrud, håndledsbrud, Colles frakturer.

Norwegian: distale radial frakturer, distal radial fraktur, distale radial, håndleddsbrudd, Colles fraktur, fractura Collesi.

Swedish: Colles fraktur, fraktura Collesii, distala radial frakturen, distala radial frakturer, underarmsfraktur, handledsfraktur, handledsbrott.

For the follow-up searches, the list of search terms is very long, and reference is therefore made to the search protocols.

Inclusion criteria:

Years of publication: The past 10 years (2003 through April 2014), for supplementary searches 1983-2002.

Languages: English, Danish, Norwegian and Swedish

Document types: Guidelines, clinical guidelines, meta-analyses, systematic reviews, randomised controlled studies, follow-up studies and cohort studies.

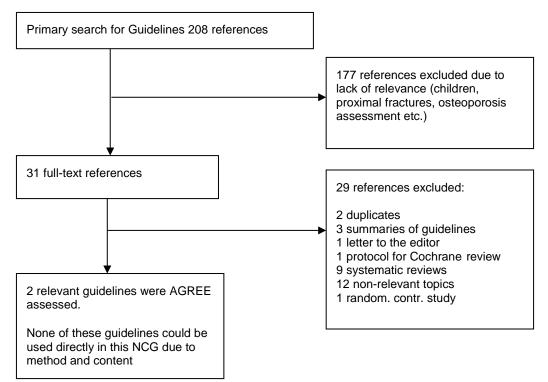
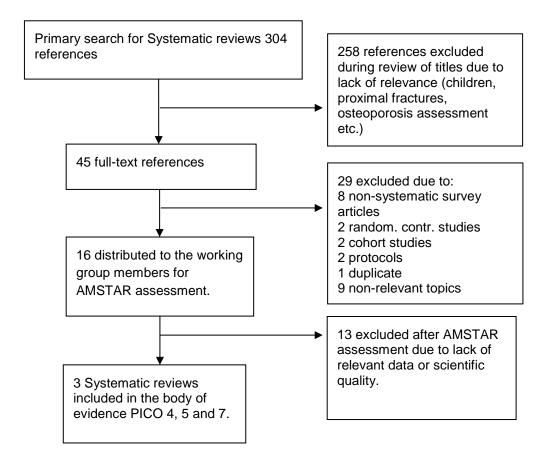


Figure 1: Background search: Clinical guidelines and Cochrane reviews

Figure 2: Secondary literature: Follow-up systematic reviews and meta-analyses



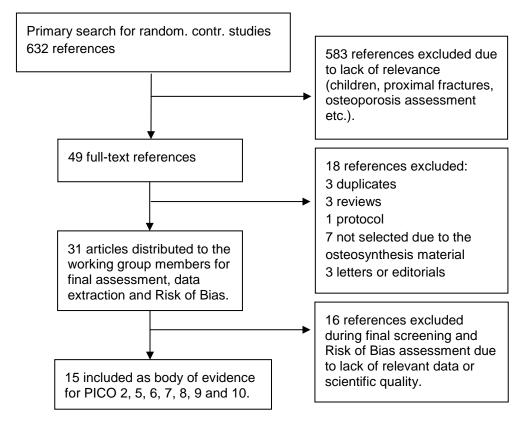


Figure 3: Follow-up search for randomised controlled studies

Figure 4: Extended follow-up search for randomised controlled studies

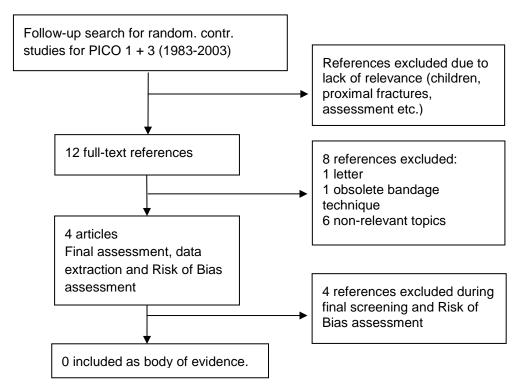
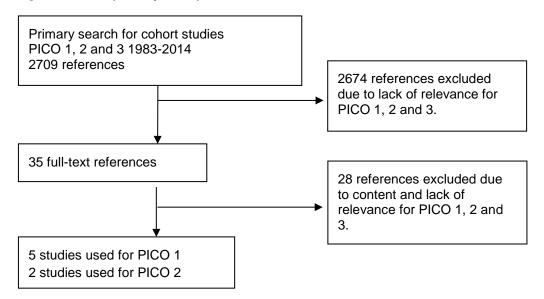


Figure 5: Extended follow-up search for cohort studies



20 Appendix 11: Assessment of evidence

The working group's AGREE assessments of guidelines are available <u>here</u> (in Danish only).

The working group's AMSTAR assessments of guidelines are available <u>here</u> (partially in English).

Evidence profiles are available <u>here</u> (partially in English).

Overview of primary studies with associated risk of bias assessments are available here (partially in English).

21 Appendix 12: Working group and reference group

The working group

The working group that prepared the national clinical guideline on the treatment of distal radial fractures consists of the following persons:

- Peter Frandsen (chairman), medical consultant, the DHA
- Nanna Salling, staff doctor, Department of Orthopaedic Surgery, Herlev Hospital, appointed by the Danish Orthopaedic Society for Traumatology
- Thomas Sandholdt Andreasen, staff doctor, Department of Orthopaedic Surgery, Odense University Hospital, appointed by the Danish Orthopaedic Society for Traumatology
- Anders Ditlev Foldager-Jensen, consultant doctor, Department of Orthopaedic Surgery, Aarhus University Hospital, appointed by the Danish Society for Surgery of the Hand
- Hans Tromborg, consultant doctor, Department of Orthopaedic Surgery, Odense University Hospital, appointed by the Danish Society for Surgery of the Hand
- Anette Skjold Sørensen, occupational therapist, Department of Rehabilitation, Odense University Hospital, appointed by the Danish Association of Occupational Therapists
- Kirsten Krabsen, clinical nurse specialist, Emergency Department, Viborg Regional Hospital, Regional Hospital Central Jutland, appointed by the Danish Nursing Society
- Anette Pedersen, charge nurse, Department of Orthopaedic Surgery, Aalborg University Hospital, appointed by the Danish Nursing Society
- Claus Munk Jensen, chief consultant doctor, Department of Orthopaedic Surgery, Gentofte Hospital, appointed by the Danish Orthopaedic Society
- Karen-Lisbeth Bay Dirksen, consultant doctor, Diagnostic Imaging Department, Nordsjællands Hospital, appointed by the Danish Society of Radiology
- Trine Torfing, speciality responsible, consultant doctor, Department of Radiology, Odense University Hospital, appointed by the Danish Society of Radiology
- Ynse de Boer, general practitioner, Lægerne i Vestergade Helsinge (the general practitioners in Vestergade, Helsinge, Denmark), appointed by the Danish College of General Practitioners
- Josef M. Andersen, physiotherapist in private practice, FysioConsultCopenhagen, appointed by the Danish Society of Physiotherapy

Conflicts of interest

Any person who works within public administration and has a personal interest in the outcome of a specific case may not participate in any processing of that case. If a person has conflicting interests, there is a risk that he or she may not provide an independent assessment of a given case. Declaration of interest forms for all the working group members are available <u>here</u> (in Danish only).

The reference group

The reference group was appointed by regions, municipalities, patient organisations and other relevant stakeholders in this field, and its assignment has been to comment on the delimitation of and the professional content of the guideline.

The reference group in connection with the national clinical guideline on the treatment of distal radial fractures consists of the following persons:

- Peter Frandsen (chairman), medical consultant, the DHA
- Benn Duus, chief consultant doctor, Department of Orthopaedic Surgery, Bispebjerg Hospital, appointed by the Capital Region of Denmark
- Ulrich Jensen, chief consultant, the health staff, Region of Southern Denmark, appointed by the Region of Southern Denmark
- Christian Pedersen, chief consultant doctor, Speciality of Orthopaedic Surgery, Aalborg University Hospital, appointed by the North Denmark Region
- Torben Bæk Hansen, professor, chief consultant doctor, Department of Orthopaedic Surgery, Regional Hospital Holstebro, appointed by the Central Denmark Region
- Jesper Ryg, specialist registrar, Department of Geriatric Medicine, Odense University Hospital, appointed by the Danish Geriatric Society
- Elna Kæstel, Head of Centre, Orthopaedic Rehabilitation Centre, City of Aarhus, appointed by the Local Government Denmark
- Bente Langdahl, professor, consultant doctor, Department of Endocrinology and Internal Medicine, Aarhus University Hospital, appointed by the Danish Osteoporosis Society
- Kasper Ø. Nielsen, Head of Section, the Danish Ministry of Health, appointed by the Danish Ministry of Health

Secretariat

The secretariat for both groups:

- Malene Kristine Nielsen (project manager), Head of Section, the DHA
- Camilla Ryge, special subject adviser, the DHA

- Annette de Thurah, method consultant, the DHA
- Conni Skrubbeltrang, search specialist, the DHA
- Annette Wittrup Schmidt, Head of Section, the DHA

Peer review and public consultation

Prior to publication, the national clinical guideline on the treatment of distal radial fractures was submitted for consultation among the following parties:

- the Danish Trade Association for Private Hospitals and Clinics
- the Danish Orthopaedic Society for Traumatology
- the Danish Orthopaedic Society
- the Danish Society of Radiology
- the Danish College of General Practitioners
- the Danish Society of Physiotherapy
- the Danish Geriatric Society
- the Danish Society for Surgery of the Hand
- the Danish Nursing Society
- the Danish Regions
- the Danish Association of Occupational Therapists
- the Local Government Denmark
- the Danish Ministry of Health
- the Danish Osteoporosis Society

During the same period of time, the guideline was peer reviewed by:

- Per Hølmer, consultant doctor, Nordsjællands Hospital and the Copenhagen University Hospital
- Hebe Kvernmo, professor, Tromsø University Hospital, Norway

22 Appendix 13: Abbreviations and concepts

CRPS	Complex Regional Pain Syndrome
СТ	Computer Tomography
DASH	Disabilities of the Arm, Shoulder and Hand – a validated tool for measuring the overall patient-experienced function of the arm, shoulder and hand
DRF	Distal Radial Fracture – wrist fracture
LPR	The Danish National Patient Registry
ORIF	Open Reduction Internal Fixation – an abbreviation for open surgical treatment comprising realignment of the bone fracture into the normal position and fixation with a plate on the bone to keep the fracture stable
PICO	Population Intervention Comparator Outcome
PROM	Patient Reported Outcome Measures
PRWE	Patient Rated Wrist Evaluation – a validated tool for measuring the patient-experienced function of the wrist
SF-36	Short Form 36 – a validated tool for measuring the patient- experienced quality of life
SoF	Summary of Findings tables
VAS	Visual Analogue Scale – scale for quantification of pain