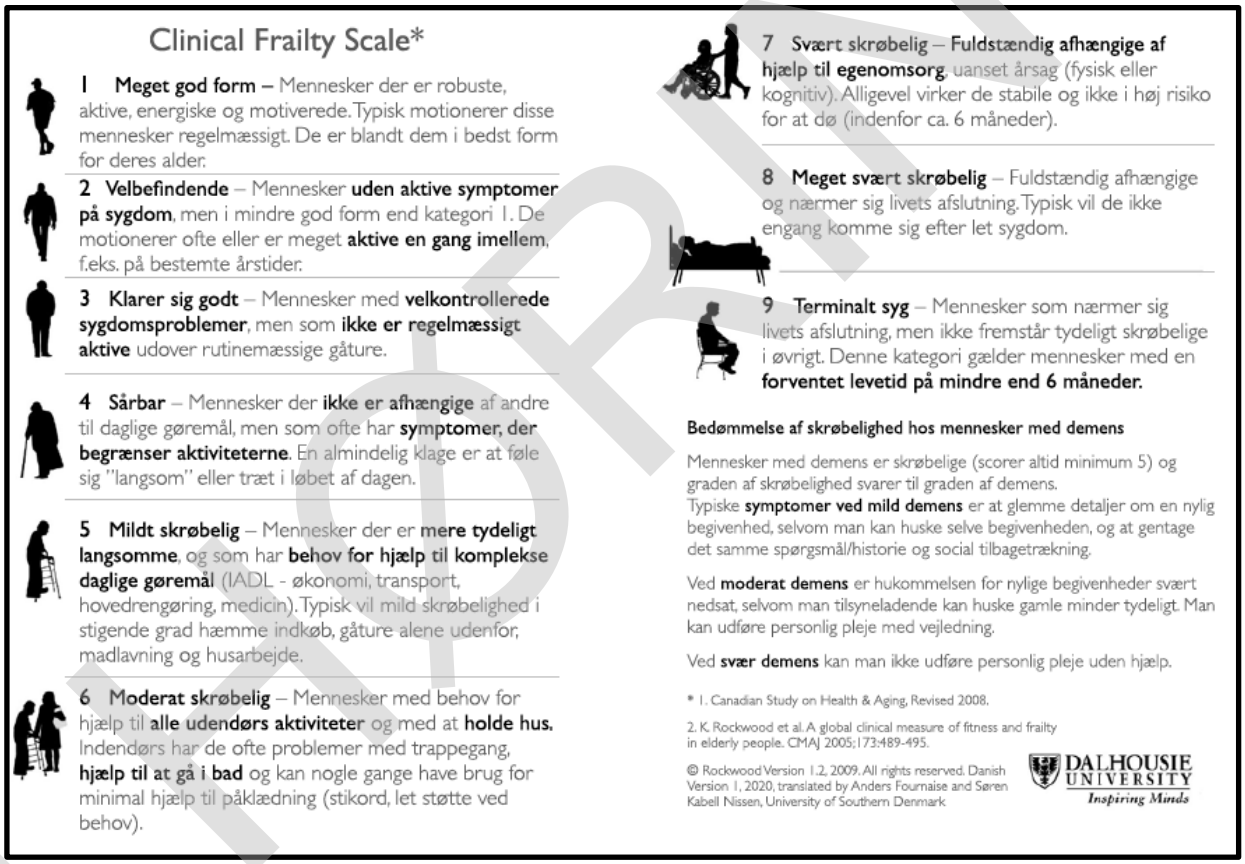
1. **Kort klinisk retningslinje:**

Er operativ behandling bedre end ikke-operativ behandling til forskudte stabile olecranonfrakturer (Mayo type II A+B) hos ældre patienter med lavt funktionsniveau?

Anbefaling:

Anvend kun operativ behandling til forskudte stabile olecranonfrakturer (Mayo type II A+B) hos ældre patienter med lavt funktionsniveau efter nøje overvejelse, da den gavnlige effekt er usikker og lille, og da der er dokumenterede skadevirkninger, såsom høj risiko for svigt af operation med senere frakturskred, dyb infektion og efterfølgende stort behov for fjernelse af osteosyntesemateriale.

Clinical Frailty Scale (CFS) kan benyttes som supplerende værktøj til at vurdere patientens funktionsniveau. Et lavt funktionsniveau defineres i denne retningslinje som en CFS-score ≥ 4. Skalaen blev introduceret i Canada i 2005 og er siden hen revideret i 2020 samt valideret og oversat til dansk i 2021[1,2].



Clinical Frailty Scale*

1 **Meget god form** – Mennesker der er robuste, aktive, energiske og motiverede. Typisk motionerer disse mennesker regelmæssigt. De er blandt dem i bedst form for deres alder.

2 **Velbefindende** – Mennesker **uden aktive symptomer på sygdom**, men i mindre god form end kategori 1. De motionerer ofte eller er meget **aktive en gang imellem**, f.eks. på bestemte årstider.

3 **Klarer sig godt** – Mennesker med **velkontrollerede sygdomsproblemer**, men som **ikke er regelmæssigt aktive** udover rutinemæssige gåture.

4 **Sårbar** – Mennesker der **ikke er afhængige** af andre til daglige gøremål, men som ofte har **symptomer, der begrænser aktiviteterne**. En almindelig klage er at føle sig "langsom" eller træt i løbet af dagen.

5 **Mildt skrøbelig** – Mennesker der er **mere tydeligt langsomme**, og som har **behov for hjælp til komplekse daglige gøremål** (IADL - økonomi, transport, hovedrengøring, medicin). Typisk vil mild skrøbelighed i stigende grad hæmme indkøb, gåture alene udenfor, madlavning og husarbejde.

6 **Moderat skrøbelig** – Mennesker med behov for hjælp til **alle udendørs aktiviteter** og med at **holde hus.** Indendørs har de ofte problemer med trappegang, **hjælp til at gå i bad** og kan nogle gange have brug for minimal hjælp til påklædning (stikord, let støtte ved behov).

7 **Svært skrøbelig – Fuldstændig afhængige af hjælp til egenomsorg**, uanset årsag (fysisk eller kognitiv). Alligevel virker de stabile og ikke i høj risiko for at dø (indenfor ca. 6 måneder).

8 **Meget svært skrøbelig** – Fuldstændig afhængige og nærmer sig livets afslutning. Typisk vil de ikke engang komme sig efter let sygdom.

9 **Terminalt syg** – Mennesker som nærmer sig livets afslutning, men ikke fremstår tydeligt skrøbelige i øvrigt. Denne kategori gælder mennesker med en **forventet levetid på mindre end 6 måneder.**

Bedømmelse af skrøbelighed hos mennesker med demens

Mennesker med demens er skrøbelige (scorer altid minimum 5) og graden af skrøbelighed svarer til graden af demens.
Typiske **symptomer ved mild demens** er at glemme detaljer om en nylig begivenhed, selvom man kan huske selve begivenheden, og at gentage det samme spørgsmål/historie og social tilbagetrækning.

Ved **moderat demens** er hukommelsen for nylige begivenheder svært nedsat, selvom man tilsyneladende kan huske gamle minder tydeligt. Man kan udføre personlig pleje med vejledning.

Ved **svær demens** kan man ikke udføre personlig pleje uden hjælp.

* 1. Canadian Study on Health & Aging, Revised 2008.

2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

DALHOUSIE UNIVERSITY
Inspiring Minds

Flere retrospektive serier har benyttet alder som inklusionskriterie og har vist gode resultater af ikke-operativ behandling af forskudte stabile olecranonfrakturer (Mayo type II A+B) for ældre patienter > 75 år. Der foreligger aktuelt et enkelt randomiseret studie, som sammenligner ikke-operativ og operativ behandling for ældre patienter med forskudte stabile olecranonfrakturer. Dette studie blev stoppet før tid, af etiske årsager, da man fandt en høj komplikationsrate for patienterne i den operativt behandlede gruppe (81,8%). Der kunne ikke påvises nogen signifikante forskelle i funktionelt resultat og patient rapporterede outcome scores mellem de operativt og de ikke-operativt behandlede patienter.

2. Udarbejdet af

Dansk Ortopædkirurgisk Traumeselskab (DOT) og Dansk Selskab for Skulder og Albue Kirurgi (DSSAK)

3. Forfattere:

Liv Vesterby (DOT), Michael Brix (DOT), Anne Kathrine Belling Sørensen (DSSAK)

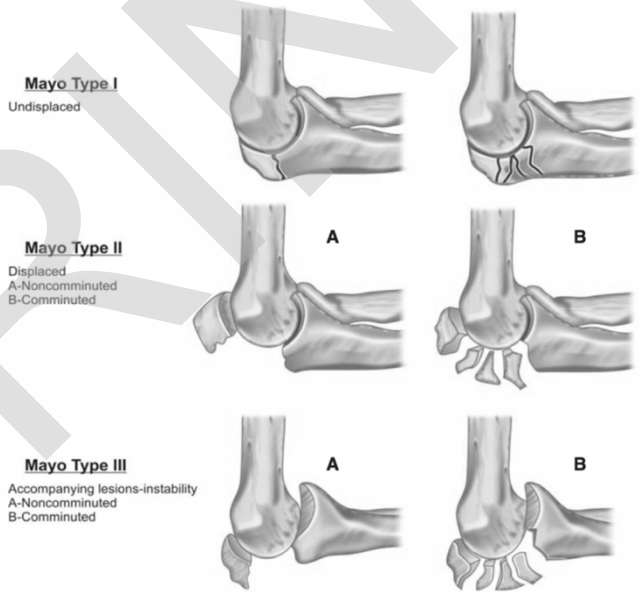
4. Dato:

Første udgivelse (2018): Godkendt ved generalforsamlingen til Dansk Ortopædkirurgisk Selskabs årskongres i oktober 2018.

Revision (2023): Afventer godkendelse ved generalforsamlingen til Dansk Ortopædkirurgisk Selskabs årskongres i november 2023.

5. Baggrund for valg af spørgsmål:

Fraktur i olecranon er hyppig og udgør op mod 20% af alle frakturer i den proksimale underarm[3]. Olecranonfrakturerne kan inddeles efter Mayo-klassifikationen.
De uforskudte frakturer, Mayo type I, behandles sædvanligvis ikke-operativt, mens de forskudte frakturer, Mayo type II, behandles operativt.
De hyppigst anvendte operationsmetoder er tension band wiring (TBW) og skinneosteosyntese (PF)[4,5].
Til trods for at de nævnte operationsmetoder er anerkendte, også til behandling af ældre patienter, er der i flere opgørelser beskrevet høje komplikationsrater. Der er tale om høj risiko for reoperation som følge af gener fra osteosyntesemateriale, postoperative infektioner og suboptimal reduktion af frakturen[6-11].
Et randomiseret studie fra 2017 har forsøgt at vurdere om ikke-operativ behandling af forskudte, stabile olecranonfrakturer, Mayo type II kan være favorabel for udvalgte patienter[12].



Målet med denne korte kliniske retningslinje er at foretage en systematisk gennemgang af foreliggende litteratur, med henblik på at give en samlet anbefaling til behandling af olecranonfrakturer, Mayo type II, for patienter med lavt funktionsniveau.

6. Retningslinjen er udarbejdet i følgende PICO-spørgsmål:

Er operativ behandling bedre end ikke-operativ behandling af forskudte stabile olecranonfrakturer (Mayo type II A+B) hos patienter med lavt funktionsniveau.

Population: Ældre patienter med lavt funktionsniveau, som har pådraget sig en forskudt stabil olecranonfraktur (Mayo type II A+B)

Intervention: Operativ behandling (skinneosteosyntese (PF), tension band wiring (TBW), tension band suture fixation)

Comparator: Ikke-operativ behandling (bandage, gips, slynge)

Outcome:
Kritiske; risiko for senere kirurgisk intervention efter primær behandling, smerte efter 1 år
Sekundære; funktionsscore (Mayo Elbow Peformence Index (MEPI), Disablilities of Arm, Shoulder and Hand (DASH), Oxford Elbow Score (OES))

7. Anbefaling:

↓ Anvend kun operativ behandling af forskudte stabile olecranonfrakturer (Mayo type IIA og B) hos patienter med lavt funktionsniveau efter nøje overvejelse, da den gavnlige effekt er usikker og lille, og da der er dokumenterede skadevirkninger med høj risiko for senere kirurgisk intervention.
↓ (+)(+)( ) ( )

Følgende symboler, indikerer styrken af anbefalingen:

↑↑ = Stærk anbefaling for

↑ = Svag/betinget anbefaling for

↓ = Svag/betinget anbefaling imod

↓↓ = Stærk anbefaling imod

√ God praksis. Anvendes hvor der ikke findes evidens på området, men hvor arbejdsgruppen ønsker at fremhæve særlige aspekter af anerkendt klinisk praksis.

Følgende symboler angiver evidensniveau:

(+)(+)(+)(+) = Høj

(+)(+)(+) = Moderat

(+)(+) = Lav

(+) = Meget lav

8. Litteratur:

Reviews:

Der foreligger i alt 3 reviews på området[13-15]. De 3 reviews er evidensvurderet med Amstar (se bilag 3) og her er det kun reviewet af Chen et al. som er fundet med høj kvalitet.

I studiet af Chen et al. var gennemsnitsalderen for patienter behandlet ikke-operativt højere (78-88 år) end for patienter behandlet operativt (henholdsvis 70-80 år for TBW og 75-85 år for PF).
Operativ behandling bliver i alle 3 reviews rapporteret med op til 82% risiko for komplikationer; omfattende dyb infektion, sårhelingsproblemer, frakturskred, nervelæsion samt behov for sekundær kirurgi med fjernelse af osteosyntesematerialet, mens ikke-operativ behandling kun sjældent har givet anledning til behov for senere kirurgisk intervention.
Resultaterne af de 2 typer af operativ behandling samt ikke-operativ behandling indgik i metaanalysen af Chen et al.. PF var generelt forbundet med mindre risiko for sekundært frakturskred, mindre risiko for sekundær kirurgi med fjernelse af osteosyntesematerialet som følge af gener (32%), men var til gengæld forbundet med højere risiko for dyb infektion (9%) og sårhelingsproblemer (12%). Operation med TBW var forbundet med høj risiko for sekundær operation (40%), hvoraf hovedparten (38%) bestod i fjernelse af osteosyntesematerialet. Der var ikke beskrevet behov for senere kirurgisk intervention for de ikke-operativt behandlede frakturer.
Non-union rate i den ikke-operativt behandlede gruppe var 86%, men til trods for dette, var der ingen forskel i funktionsscores, målt med MEPI og DASH.

Patienter behandlet operativt opnåede i gennemsnit en 4-5 graders mindre ekstensionsdefekt ved sammenligning med patienter behandlet ikke-operativt. Man fandt desuden en gennemsnitlig fleksion over albuen på 124-129 grader for de operativt behandlede patienter, mens den for de ikke-operativt behandlede patienter var 121.5 grader.

Alle 3 reviews rapporterer at operativ behandling medfører generelt god reetablering af ekstension i albuen. Der foreligger kun få studier med test af styrke efter ikke-operativ behandling. I Chen et al. rapporterer man ét studie med bevaret styrke i ekstension på M5 hos 65% og M4 hos 35% trods non-union rate på 82%. Denne observation støttes af et studie på en mindre kohorte af yngre patienter med gennemsnitsalder på 59 år, hvor man efter ikke-operativ behandling fandt strækkestyrken tilfredsstillende, trods non-union i alle cases[15]. Kun enkelte patienter rapporterede besvær med at rejse sig fra en stol.

Alle 3 reviews konkluderer at der fortsat foreligger sparsom evidens på området, men at alle foreliggende studier peger i samme retning og finder at der opnås sammenligneligt funktionelt resultat efter såvel operativ som ikke-operativ behandling af forskudte stabile olecranonfrakturer hos ældre patienter med lavt funktionsniveau.

- Den kirurgisk behandling, i form af såvel TBW som PF, er forbundet med høj risiko for komplikationer, rapporteret op til 82%.
- Den ikke-operative behandling er forbundet med høj risiko for non-union rapporteret optil 86%. De fleste non-unions er dog asymptomatiske. De få studier der foreligger med styrkemåling, finder at de fleste patienter trods non-union, genvinder en tilfredsstillende grad af strækkestyrke i albuen.

I reviewet af Abelmalek et al. er der foretaget en systematisk litteratursøgning, afledt af de senere års trend i form af en mere konservativ tilgang til frakturbehandling af ældre skrøbelige patienter med væsentlige komorbiditeter som blev forstærket under Covid-19 epidemien grundet øget smitterisiko. Forfatterne konkluderer at den ikke-operative tilgang til behandling af ældre patienter, bør fortsættes, også i fremtiden.

I reviewet af Savviddou et al. konkluderes det at behandlingen af ældre patienter med lavt funktionsniveau fortsat er kontroversiel, hvorfor den endelige beslutning bør vurderes individuelt i hvert enkelt tilfælde, baseret på patientens alder, komorbiditet, frakturtype og funktionsniveau.

Kritiske outcomes: risiko for senere kirurgisk intervention efter primær behandling, smerte efter 1 år:

RCT'er:

Der foreligger aktuelt blot ét RCT som har søgt at skildre resultaterne af ikke-operativ mod operativ behandling af ældre patienter med olecranonfrakturer[12]. Studiet inkluderede i alt 19 patienter med 1 års follow-up og alderskriteriet for inklusion var minimum 75 år. Alle frakturerne var initialt klassificeret som Mayo II. Patienterne blev randomiseret til to grupper, herunder en operativ behandlet gruppe (11) og en ikke-operativ behandlet gruppe (8). I den operativt behandlede gruppe blev 9 patienter osteosynteret med TBW, mens de resterende to patienter med mere komminutte frakturer blev opereret med PF. Postoperativt blev patienterne bandageret med en præfabrikeret vinkelskinne i 10 til 14 dage, hvorefter de overgik til genoptræning under vejledning af fysioterapeut. Patienterne i den ikke-operativt behandlede gruppe blev som udgangspunkt behandlet med collar'n'cuff i to uger, men fire af patienterne måtte på baggrund af smerter bandageres i en gips i ca. 60 graders fleksion.
Komplikationsraten var derimod signifikant højere i den operativt behandlede gruppe (81.4% versus 14.3%, p = 0.013), hvoraf den hyppigst registrerede komplikation var frakturskred. Øvrige komplikationer var udgjort af infektion samt gener fra osteosyntesemateriale. I den ikke-operativt behandlede gruppe blev blot én patient registreret med komplikationer. To uger inde i behandlingsforløbet blev den pågældende patient diagnosticeret med subluksation af caput radii, således en olecranonfraktur type III i henhold til Mayos klassifikation. Patienten blev opereret og det videre behandlingsforløb var kompliceret af fraktur-

skred og dyb infektion med efterfølgende behov for fjernelse af osteosyntesemateriale. Studiet blev afsluttet før planlagt, da forskerne bag studiet fandt at komplikationsraten i den operative gruppe var uacceptabel høj. Det har således ikke været muligt at konkludere at ikke-operativ behandling er mere effektiv end operativ behandling.

Kohortestudier:

Kohortestudierne er evidensvurderet ved brug af Robins-1, men skemaerne er for praktiske formål ikke vedlagt i denne KKR, da det af arbejdsgruppen er vurderet, at informationsværdien af dette evidensværktøj er lav. Alle studierne er foretaget på små kohorter.

Operativ behandling:
3 retrospektive studier af operativ behandling har vist en relativ høj risiko for reoperation. Kaiser et al. opgjorde resultaterne af 11 patienter opereret med PF og TBW[16]. Af disse gennemgik 5 patienter senere reoperation som følge gene fra osteosyntesematerialet. Parkes et al. inkluderede 176 patienter med olecranonfrakturer over en 12 års periode[17]. Gennemsnits follow-up var 19 uger. 66 patienter blev klassificeret med Mayo IIA og 58 patienter Mayo type IIB. Patienter med Mayo type IIA blev overvejende behandlet med TBW. Patienter med Mayo type IIB blev behandlet med enten TBW eller PF, hvor TBW overrasksende var benyttet som fiksationsteknik i omtrent halvdelen af tilfældene. Parkes et al. rapporterede en samlet reoperationsrate på 12.5%, hvoraf følger efter primær operation med TBW var den hyppigste årsag til reoperation.
Wenger et al. lavede en retrospektiv opgørelse på 239 patienter klassificeret med Mayo type IIA og B[18]. Heraf var 33 patienter behandlet med TBW og 7 patienter med PF. Af disse gennemgik 9 ud af de 33 patienter, som var primær opereret med TBW, reoperation. 2 ud af de 7 patienter opereret med PF gennemgik ligeledes reoperation.
Et retrospektivt kohortestudie på 36 patienter af Wise et al. har i modsætning til overstående studier vist en relativ lav risiko for reoperation på 11% efter primær operation med PF[,19].

Den relativ høje reoperationsrate har sammen med risiko for øvrige komplikationer, herunder infektion og frakturskred, ført til at en ny operationsteknik udelukkende med brug af non-absorberbar sutur sidenhen er udviklet i 2016. Resultaterne af suturteknikken er til dato sparsomme og begrænser sig til 2 retrospektive kohortestudier, hvor gennemsnitsalderen er 47 og 55 år[20,21]. Reoperationsraten er beskrevet lav i begge studier, men da operationsteknikken kun er afprøvet på kohorter af patienter med væsentlig lav gennemsnitsalder, kan arbejdsgruppen ikke udtale sig om resultater af suturteknikken for ældre patienter med lavt funktionsniveau.

Ikke-operativ behandling:
Aibinder et al. har lavet en retrospektiv kohorteopgørelse 28 patienter med en gennemsnitsalder 79 år[22]. Heraf var 27 patienter var klassificeret med Mayo type IIA eller B. Patienterne blev bandageret med enten en slynge, en gips eller en præfabrikeret skinne i ca. 5 uger. 23 patienter udviklede non-union og 2 patienter udviklede hudproblemer som følge af uhensigtsmæssig gipsanlæggelse.
Kaiser et al. opgjorde resultaterne af 6 patienter med en gennemsnitsalder på 85 år behandlet ikke-operativt[16], hvori behandlingen bestod i enten gips eller tidlig mobilisering. Én ud af de 6 patienter havde et kompliceret efterforløb med dysæstesi af nervus ulnaris.
I studiet af Parkes et al. blev 44 patienter behandlet ikke-operativt[17]. Studiet rapporterer blot 2 komplikationer for den konservativt behandlede kohorte, herunder én patient som senere i behandlingsforløbet pådrog en ipsilateral fraktur af humerusskaftet og én patient som helede frakturen med malunion.
Samtlige patienter i disse 3 kohortestudier undgik kirurgi gennem behandlingsforløbet.

Sekundære outcomes: funktionsscore (MEPI, DASH, Quick-DASH, OES)

RCT'et af Duckworth et al. har ikke har ikke beskrevet funktionsscores.

Kohortestudier

I studiet af Kaiser et al. var der ingen forskel i OES og MEPI ved sammenligning af operativt mod ikke-operativt behandlede patienter. Til gengæld rapporterede forfatterene af studiet en dårligere DASH-score for de ikke-operativt behandlede patienter.
Aibinder et al. rapporterede en gennemsnitlig Quick-DASH score og MEPI på hhv. 26 ± 28 og 76 ± 20.

Vedrørende scoringssystemerne:

- Mayo Elbow Performance Index (MEPI) er et PROM, der ud fra tre domæner, herunder smerte, bevægelighed, stabilitet og funktion, har udviklet en pointskala fra 0-100, hvor nul er værst, og 100 er bedst.
- Disability of the Arm, Shoulder and Hand questionnaire (DASH) er et 30-punkts-PROM med en pointskala fra 0-100, hvor nul er bedst, og 100 er værst.
- QuickDASH er en forkortet version af DASH med et 11-punkts-PROM og en pointskala fra 0-100, hvor nul er bedst, og 100 er værst.
- Oxford Elbow Score (OES) er et PROM, der adresserer tre domæner: funktion, smerte og psykosocial status. Hvert domæne konverteres til 100-pointskala, hvor nul er værst, og 100 er bedst.
- Broberg and Morrey rating system er et scorringssystem med en pointskala fra 0-100, hvor 4 domæner vurderes, herunder bevægelse (40 point), styrke (20 point), stabilitet (5 point) og smerte (35 point). En maksimumværdi på 100 præsenterer det bedste resultat.

9. Evidens:

Se bilag 3

10. Arbejdsgruppens overvejelser:

Der foreligger til dato kun et enkelt randomiseret studie omhandlende emnet. Dette studie blev stoppet før tid af etiske årsager. Da der ved supplerende gennemgang af litteraturen desuden findes case serier og studier omhandlende resultater og komplikationsrater ved behandling af olecranonfrakturer for ældre patienter, finder vi at der er tilstrækkelig evidens til at komme med en anbefaling vedrørende behandlingen af ældre patienter med lavt funktionsniveau.

Der blev ikke fundet evidens vedrørende behandlingen af yngre patienter med lavt funktionsniveau. Der findes således heller ingen evidens for at operativ behandling af patienter med lavt funktionsniveau er bedre end ikke-operativ behandling. Det er derfor arbejdsgruppens vurdering af operativ behandling af patienter med lavt funktionsniveau og høj risiko for komplikationer, kun bør foretages efter individuel vurdering og efter nøje overvejelse under inddragelse af patient og/eller de pårørende.

11. Balancen mellem effekt og skadevirkninger:

Der er vist en meget høj risiko for komplikationer ved operativ behandling og en meget lille risiko for komplikationer ved ikke-operativ behandling af patienter med lavt funktionsniveau. (+)(+)

Effekten af operativ behandling er den samme som effekten af ikke-operativ behandling for ældre patienter med lavt funktionsniveau. (+)

12. Kvaliteten af evidensen:

Det foreliggende enkelte RCT på emnet vurderes med lav risiko for bias af resultatet, om end med forbehold for manglende blinding af patient og observer. Studiet blev stoppet før tid, men antallet af patienter vurderes stort nok til at vurdere sekundære outcomes, men ikke stort nok til at vise en mindre forskel i det primære outcome.

Da der kun er publiceret ét RCT, må evidensen anses for at være lav.

13. Bilag:

Bilag 1: Søgestrategi og søgestreng

Bilag 2: Flowchart over litteraturudvælgelse efter revision af KKR fra 2018

Bilag 3: Risk of bias

14. Litteraturliste

(Referencer i gult svarer til litteraturudvælgelsen på databasesøgning efter revision af KKR fra 2018 – se også Bilag 2)

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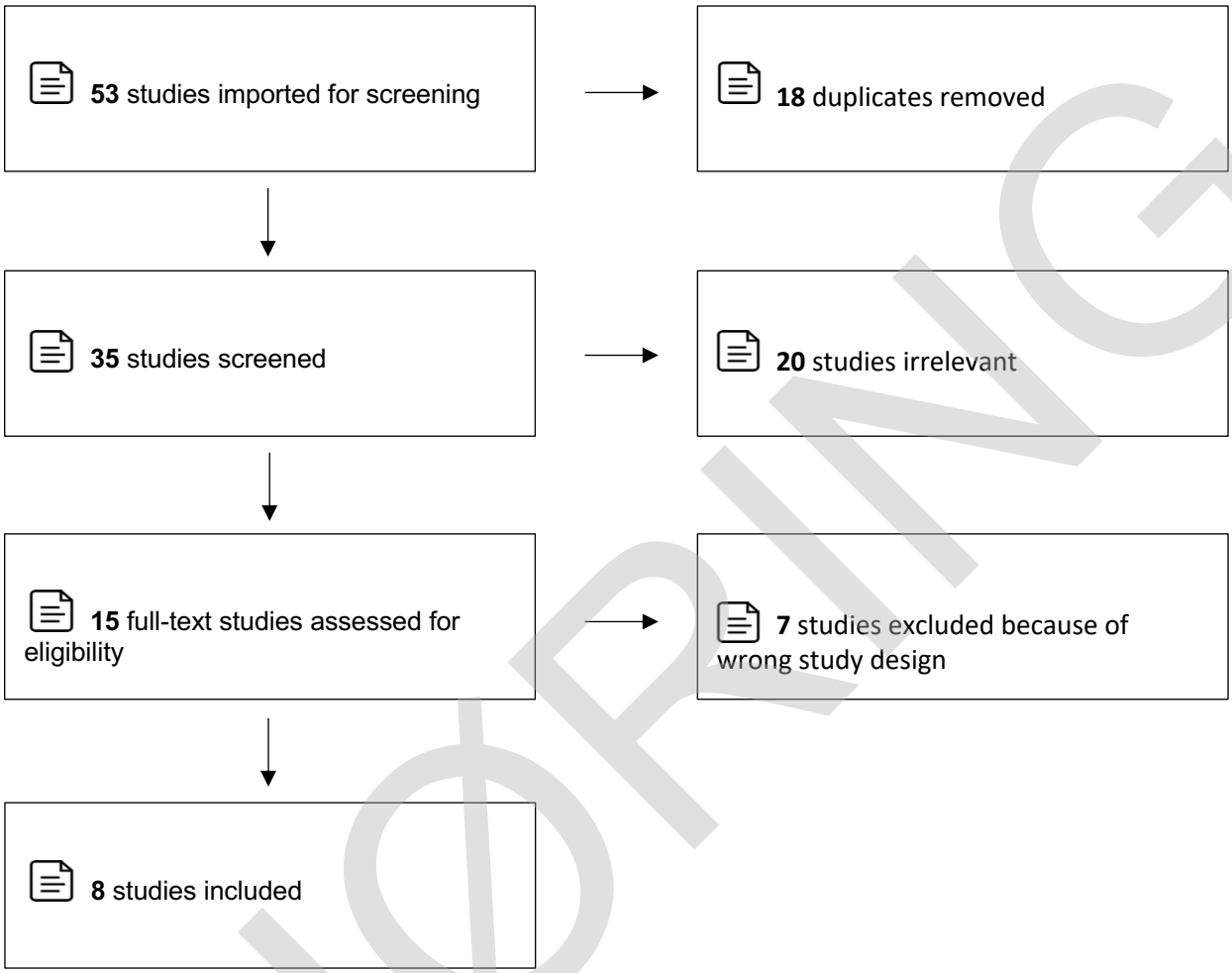
Bilag 1- Søgestreng

PubMed®

Search: (((((((("Olecranon Fracture"[Mesh]) OR (olecranon fracture*[Text Word])) OR (olecranon[Text Word])) OR ("Olecranon Process"[Mesh]))) OR (("Fractures, Bone"[Mesh]) AND ("Olecranon Process"[Mesh]))) AND ((((((("Conservative Treatment"[Mesh]) OR (non operativ*[Text Word])) OR (nonoperativ*[Text Word])) OR (bandage[Text Word])) OR (plaster of paris[Text Word])) OR (sling[Text Word]))) AND (((((((("Fracture Fixation"[Mesh]) OR (surgical*[Text Word])) OR (tension band[Text Word])) OR (plat*[Text Word])) OR (cerclage[Text Word])) OR (sutur*[Text Word])) OR (wiring[Text Word]))) AND (("2018/03/06"[Date - Publication] : "3000"[Date - Publication])) Sort by: Most Recent

Søgeresultat 27

Bilag 2 - Flowchart over litteraturudvælgelse



Bilag 3.1 – Risk of bias

BILAG 3: Prospective randomised trial of non-operativ *versus* operative management of olecranon fractures in the elderly, JBJS 2017						
Risk of Bias assessment iht. RoB 2-0			Review 1 kommentarer	Review 1	Review 2 kommentarer	Review 2
1. Bias arising from the randomisation	01:01	Was the allocation sequence random	Block randomisation, n=4, envelopes	Y	Block randomisation (n=4) with sequential opaque envelopes	Y
	01:02	Was the allocation sequence concealed until participats were recruited and assigned to interventions	Envelopes prepared by statistician	Y	Envelopes prepared by statician	Y
	01:03	Were there baseline imbalances that suggest a problem with the randomization process	The demographics of the patients and the characteristics of the patients were similar in both groups. The mean age was marginally younger in the non-operative group (80 versus 85)	N	The demographics and the characteristics of the patients were similar in the two groups. The mean age of the patients was marginally younger in the non-operative group, all other characteristics were comparable	N
		1. Risk of bias judgement		LOW		LOW
2. Bias due to deviations from intended intervention	02:01	Were participants aware of their assigned intervention during the trial		Y		Y
	02:02	Were carers and trial personnel aware of participatns assigned intervention during the trial	Outcome was assessed by a research physiotherapist or a covering research fellow, who were not involved in the patients management	N	The outcome was assesed by a research physiotherapist or a covering reseach fellow, who where not involved in the patient's management.	N
	02:03	Were there deviations from the intended intervention beyond what would b expected in usual practice	All patients recieved the treatment as allocated 8 versus 11	N	All patients recieved th treatment as allocated	N
	02:04	Not relevant				
	02:05	Were any participants analysed in a group different from the one to which they were assigned?	No, but the study was terminated prematurely, as the rate of complications in the operative group was considerede to be unacceptable.	N	No. One patient in the non-operative group was classified with a Mayo type 3 fracture that became apparant two weeks after injury. The patient should not have been included in the study. The study was stopped	N
	02:06	Not relevant				
		2. Risk of bias judgement		LOW		LOW
3. Bias due to missing outcome data	03:01	Were outcome data availabel for all or neraly all, participants randomized?	2 patients died in the non-operative group of unrelated causes in the year following injury; follow-up otherwise 100%, (89%)	Y	Two patients in the non-operative group died of unrelated causes in the year following injury. The follow-up rate of the patients who were alive one year after injury was 100%	Y
	03:02	Not relevant				
	03:03	Not relevant				
		3. Risk of Bias judgement		LOW		LOW
4.Bias in measurement of the outcome	04:01	Were outcome assessors aware of the interventions received by study participants	Outcome was assessed by a research physiotherapist or a covering research fellow, who were not involved in the patients management	NI	The outcome was assesed by a research physiotherapist or a covering reseach fellow, who where not involved in the patient's management.	NI
	04:02	Was the assessment of the outcome likely to be influenced by knowledge of intervention received?		PN		N
		4. Risk of Bias of judgement	No blinding of observers	LOW with some concern	No blinding of observers	LOW with some concern
5. Bias in selection of the reported result		Are the reported outcome data likely to have been selected, on the basis of the results, from:				
	05:01	Multiple outcome measurements?	All intended outcome meassures are reported: Elbow flexion, Forearm rotation, Broberg and Morrey Score, MES and DASH. Compared to the Trial Protocol, only return to activity was not reported	N	All intended outcome messurements are reported; DASH, MES, Broberg and Morrey Score, forearm rotation arc and elbow flexion arc	N
	05:02	Multiple analyses of the data		N		N
		5. Risk of bias judgement		LOW		LOW
			The study i judged to be at some concerne in one domain for this result; but low risk in all other 4 domains		4 out of 5 domains are rated to be low risk. 1 out of 5 domains are rated to be low with some concern	
y = yes						
py = partly yes						
Pn = partly no						
N = no						
NI = no information						

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

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For Yes:
- ☒ Population
- ☒ Intervention
- ☒ Comparator group
- ☒ Outcome

Optional (recommended)
- ☐ Timeframe for follow-up

☒ Yes
☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:
The authors state that they had a written protocol or guide that included ALL the following:
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- ☒ inclusion/exclusion criteria
- ☒ a risk of bias assessment

For Yes:
As for partial yes, plus the protocol should be registered and should also have specified:
- ☒ a meta-analysis/synthesis plan, if appropriate, *and*
- ☒ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

☒ Yes
☐ Partial Yes
☐ No

3. Did the review authors explain their selection of the study designs for inclusion in the review?

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- ☐ OR *Explanation for* including only NRSI
- ☒ OR *Explanation for* including both RCTs and NRSI

☒ Yes
☐ No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):
- ☒ searched at least 2 databases (relevant to research question)
- ☒ provided key word and/or search strategy
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For Yes, should also have (all the following):
- ☐ searched the reference lists / bibliographies of included studies
- ☐ searched trial/study registries
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AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

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☐ Yes
☒ No

det fremgår ikke i artiklen

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- ☒ provided a list of all potentially relevant studies that were read in full-text form but excluded from the review

For Yes, must also have:
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☐ Partial Yes
☐ No

8. Did the review authors describe the included studies in adequate detail?

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- ☒ described populations
- ☒ described interventions
- ☒ described comparators
- ☒ described outcomes
- ☒ described research designs

For Yes, should also have ALL the following:
- ☒ described population in detail
- ☒ described intervention in detail (including doses where relevant)
- ☒ described comparator in detail (including doses where relevant)
- ☒ described study's setting
- ☒ timeframe for follow-up

☒ Yes
☐ Partial Yes
☐ No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from
- ☒ unconcealed allocation, *and*
- ☒ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all-cause mortality)

For Yes, must also have assessed RoB from:
- ☒ allocation sequence that was not truly random, *and*
- ☒ selection of the reported result from among multiple measurements or analyses of a specified outcome

☒ Yes
☐ Partial Yes
☐ No
☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:
- ☒ from confounding, *and*
- ☒ from selection bias

For Yes, must also have assessed RoB:
- ☒ methods used to ascertain exposures and outcomes, *and*
- ☒ selection of the reported result from among multiple measurements or analyses of a specified outcome

☒ Yes
☐ Partial Yes
☐ No
☐ Includes only RCTs

10. Did the review authors report on the sources of funding for the studies included in the review?

For Yes
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☐ Yes
☒ No

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

RCTs

For Yes:

- ☒ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
  - ☒ AND investigated the causes of any heterogeneity

☒ Yes
☐ No
☐ No meta-analysis conducted

For NRSI

For Yes:

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  - ☒ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
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☒ Yes
☐ No
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12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
- ☒ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

☒ Yes
☐ No
☐ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
- ☒ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

☒ Yes
☐ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
- ☒ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

☒ Yes
☐ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☒ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

☒ Yes
☐ No
☐ No meta-analysis conducted

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- ☐ The authors reported no competing interests OR
- ☒ The authors described their funding sources and how they managed potential conflicts of interest

☒ Yes
☐ No

To cite this tool: Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, Moher D, Tugwell P, Welch V, Kristjansson E, Henry DA. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008.

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

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- ☒ Population
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- ☒ Outcome

Optional (recommended)
- ☒ Timeframe for follow-up

- ☒ Yes
- ☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

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- ☒ Partial Yes
- ☐ No

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- ☒ Yes
- ☐ No

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- ☐ searched trial/study registries
- ☐ included/consulted content experts in the field
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- ☐ Partial Yes
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5. Did the review authors perform study selection in duplicate?

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AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

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AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

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For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
  - ☐ AND investigated the causes of any heterogeneity

☐ Yes
☐ No
☒ No meta-analysis conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
  - ☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available
  - ☐ AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review

☐ Yes
☐ No
☒ No meta-analysis conducted

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

☐ Yes
☐ No
☒ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☒ included only low risk of bias RCTs
- ☐ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

☒ Yes
☐ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
- ☐ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

☐ Yes
☒ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

☐ Yes
☐ No
☒ No meta-analysis conducted

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

☒	The authors reported no competing interests OR	☒ Yes
☐	The authors described their funding sources and how they managed potential conflicts of interest	☐ No

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4 yes, 3 partial yes, 7 no