

KKR

Total hoftealloplastik hos ældre – cementeret eller ikke-cementeret stem fiksdation?

Anbefaling:

↑ Overvej anvendelse af cementeret stem fiksdation til patienter over 70 år, da risikoen for reoperation reduceres (+)

Det er arbejdsgruppens opfattelse, at litteraturen viser en forskel i risikoen for reoperation for kvinder helt ned til 60 år. Risikoen for reoperation bliver mere tydelig med stigende alder.

Udarbejdet af:

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Baggrund for valg af spørgsmål:

Total hoftealloplastik bliver i Danmark udført med cementeret eller ucementeret stem fiksdation. En ucementeret stem fiksdation er vist at være associeret til en øget risiko for tidlig reoperation grundet periprostetisk fraktur, mens cementeret stem fiksdation i nogle studier har vist øget risiko for sen revision grundet aseptisk løsning.

Begge fiksdations tekniker anvendes i dag, hvorfor DSHK har fundet det relevant at sammenligne fiksdationsteknikerne for patienter over 60 år mht. mortalitet, risiko for reoperation, luksation, tromboemboliske komplikationer samt patient reporteret funktionsevne.

Denne retningslinje omhandler:

PICO spørgsmål:

Retningslinjen er udarbejdet med udgangspunkt i følgende PICO-spørgsmål:

Har patienter over 60 år med primær hofteledsartrose som indikation for indsættelse af en THA bedre effekt af cementeret stem fiksdation end ucementeret stem fiksdation med hensyn til reoperation samt funktionsevne?

Population: Alle patienter over 60 år i 10 år kohorter med primær hofteledsartrose som indikation for indsættelse af en total hoftealloplastik

Intervention: Cementeret stem fiksdation

Comparator: Ucementeret stem fiksdation

Outcome: Reoperation indenfor 2 år (Kritisk outcome)
Reoperation indenfor 10 år (Kritisk outcome)
Mortalitet indenfor 1 år (Kritisk outcome)
Luksation indenfor 1 år (Sekundært outcome)
Tromboemboliske komplikation indenfor 1 år (Sekundært outcome)
Patient reporteret funktionsevne samt funktionsmåling efter 1 år (Sekundært outcome)

Anbefaling:

Følgende symboler, indikerer styrken af anbefalingerne:

↑↑ = 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

↑ Overvej anvendelse af cementeret stem fiksdation til patienter over 70 år, da risikoen for reoperation reduceres (+)

Det er arbejdsgruppens opfattelse at litteraturen viser en forskel i risikoen for reoperation for kvinder helt ned til 60 år. Risikoen for reoperation bliver mere tydelig med stigende alder.

Litteratur:

Reoperation

Overordnet set tegner der sig et billede af lavere revisionsrate for cementerede THA og hybrid A. Dette gælder særligt for patienter over 70 år. Der synes at være en stigende risiko med stigende alder. Mænd har generelt en højere revisionsrate uafhængig af fiksdationstype. De færreste studier opgør revisionsårsager, men periprostetiske frakturer synes at være en hyppigere tidlig komplikation for ucementeret teknik, mens aseptisk løsning fylder mest for cementeret teknik ved sen revision.

Mortalitet indenfor 1 år

De ikke justerede data viser generelt en højere mortalitet for cementeret stem fiksdation som efter justering udlignes. Enkelte studier finder en let forøget mortalitet i de første postoperative dage ved cementeret stem fiksdation, der er dog ikke konsensus omkring dette. Forskellen udligner sig ganske

hurtigt og efter et år ses ingen signifikant forskel på mortalitet. Mortaliteten syntes ikke relateret til fiksstypen, men i langt højere grad til alder, køn og comorbiditet.

Luksation indenfor 1 år

Hermansen et al. rapporterede, at cementeret fiksstation beskytter mod luksation (OR 0,71 P = 0,001) sammenlignet med ucementeret.

Tromboemboliske komplikation indenfor 1 år

Tromboemboli er en kendt komplikation efter operation med THA. I forhold til fikstationsmetoden konkluderes følgende:

Lindberg-Larsen et al. 2020, finder i deres opgørelse signifikant øget 30 dages postoperativ risiko for lungeemboli efter cementeret THA sammenlignet med ucementeret THA.

Ekman et al. 2019, finder sammenlignelig mortalitet i forhold til kardiovaskulære komplikationer mellem cementeret, hybrid og ucementeret THA.

McMinn et al. 2012, undersøgte med intraoperativt transøsofageal ekkokardiografi og viste forskel i embolisering af ekkogen materiale til højre hjertekammer og lungerne under operation med cementeret THA og resurfacing alloplastik. Operation med resurfacing alloplastik gav transient eller ingen embolisering, mens operation med cementeret THA gav betydelig embolisering i op til 20 minutter.

Patient reporteret funktionsevne samt funktionsmåling efter 1 år

Der er fundet 2 studier, der undersøger PROMS. Begge studier lider under meget små svarprocenter. Rolfson et al. finder at der er bedre resultater for alle parametre i den ucementerede gruppe. Jameson et al. finder at der ikke er nogen forskel mellem cementerede og ucementerede hofter, hverken i EQ5D eller HHS.

Da begge studier kigger på en meget lille andel af de producerede hofter i studieperioden, er det ikke muligt at konkludere noget ud fra disse studier.

Evidens:

Data er udelukkende indhentet fra register-studier, idet der ikke foreligger randomiserede studier af tilstrækkelig størrelse. Studierne er kendetegnet ved store populationer, men typisk er grupperne uensartede i forhold til blandt andet alder og køn (case-mix), og nogle gange meget uens i størrelse. Der justeres for risikofaktorer, men hvilke varierer fra studie til studie. De statistiske metoder varierer en del, og nogle er baseret på kompleks modellering.

Reoperation

Evidensen er baseret på otte registerstudier. Der er i alle studier betydelig confounding og imprecision.

Mortalitet indenfor 1 år

Evidensen er baseret på seks registerstudier. Der er i alle studier betydelig confounding. Nogle studier sammenligner totalcementeret med ucementeret hvor andre sammenligner ucementeret med hybrid A. Evidens niveauet vurderes meget lavt (+)

Luksation indenfor 1 år

Luksationsrisikoen er vurderet ud fra et enkelt studie som opgør den sande luksationsrate i dansk setting.

Tromboemboliske komplikation indenfor 1 år

Evidensen er baseret på to registerstudier. Der er risiko for at resultaterne er påvirket af confounding.

Patient reporteret funktionsevne samt funktionsmåling efter 1 år

Studierne lider under meget lave svarprocenter, hvorfor det er vanskeligt at konkludere på. Evidensniveauet vurderes meget lavt (+)

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11. Lindberg-Larsen M, Petersen PB, Jorgensen CC, Overgaard S, Kehlet H, Lundbeck Foundation Center for Fast-track Hip, et al. Postoperative 30-day complications after cemented/hybrid versus cementless total hip arthroplasty in osteoarthritis patients > 70 years. *Acta Orthop*. 2020;91(3):286-92.
12. McMinn DJ, Snell KI, Daniel J, Treacy RB, Pynsent PB, Riley RD. Mortality and implant revision rates of hip arthroplasty in patients with osteoarthritis: registry based cohort study. *BMJ*. 2012;344:e3319.
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14. Rolfson O, Donahue GS, Hallsten M, Garellick G, Karrholm J, Nemes S. Patient-reported outcomes in cemented and uncemented total hip replacements. *Hip Int*. 2016;26(5):451-7.
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Summary:

Abstract:

Short Clinical Guideline on total hip arthroplasty in the elderly, cemented or non-cemented stem fixation.

Background:

Total hip arthroplasties in Denmark is performed with either cemented or non-cemented stem fixation. The non-cemented stem has been showed to be associated to a higher risk of early reoperation due to periprosthetic fracture. The cemented stem has, in some studies, shown increased risk of late revision due to aseptic loosening.

Purpose / Aim of study:

Both cemented and non-cemented stems are used today, thus DSHK has found it relevant to compare these two fixation methods for patients above the age of 60 years, with regard to risk of reoperation, dislocation, risk of thromboembolic complication and patient reported outcome.

Materials and Methods:

The following PICO questions were investigated:

Does patients above 60 years of age with primary osteoarthritis operated with total hip arthroplasty have better effect of a cemented fixation than non-cemented stem fixation with regard to reoperation, mortality, dislocations within the 1st year, thromboembolic complications and functional outcome.

Findings/results

Reoperation:

Overall, there is a lower revision rate for cemented and hybrid A THA especially for patients above 75 years of age. Men tend to have a higher revision rate. Few studies report cause for revision, but periprosthetic fracture seems to be a common early complication for the non-cemented THA, whereas the aseptic loosening is more common for the cemented THA in the late revisions.

Mortality:

The non-adjusted numbers show a higher mortality for the cemented stem but after adjusting the numbers even out. Some studies find a higher mortality in the first days following surgery for cemented fixation but this evens out quite quick and after one year there is no difference between the two groups. Mortality seems not to be associated to fixation type, more to age, gender and comorbidities.

Dislocation within the 1st year

One study reported that cemented fixation prevents dislocation (OR 0,71 p=0,001) compared to non-cemented.

Thromboembolic complications

Thromboembolic complications is a well-known complication after THA.

One study showed significant increase in pulmonary embolism with in 30 days when comparing cemented to non-cemented. Another study showed no difference between the two groups.

Functional outcome:

Only two studies were found and due to the low number of included patients, the conclusion were very unclear.

Conclusions:

To consider the use of cemented fixation of the stem in patients above the age of 70 years since the risk of reoperation is reduced in cemented stem fixation.

The literature shows lower risk of revision in women down to the age of 60 years, the difference increases with rising age.

Bilag 1: Søgestrategi og søgestreng

Patient:

"arthroplasty, replacement, hip"[MeSH Terms] OR "Hip Prosthesis"[MeSH Terms] OR ("hip"[Text Word] AND ("arthroplast*"[Text Word] OR "prothes*"[Text Word] OR "implant*"[Text Word] OR "replacement*"[Text Word]))

"osteoarthritis, hip"[MeSH Terms] OR "osteoarthrit*"[Text Word] OR "coxarthros*"[Text Word] OR "Arthroses"[Text Word] OR "arthrosis"[Text Word]

Intervention + Comparison:

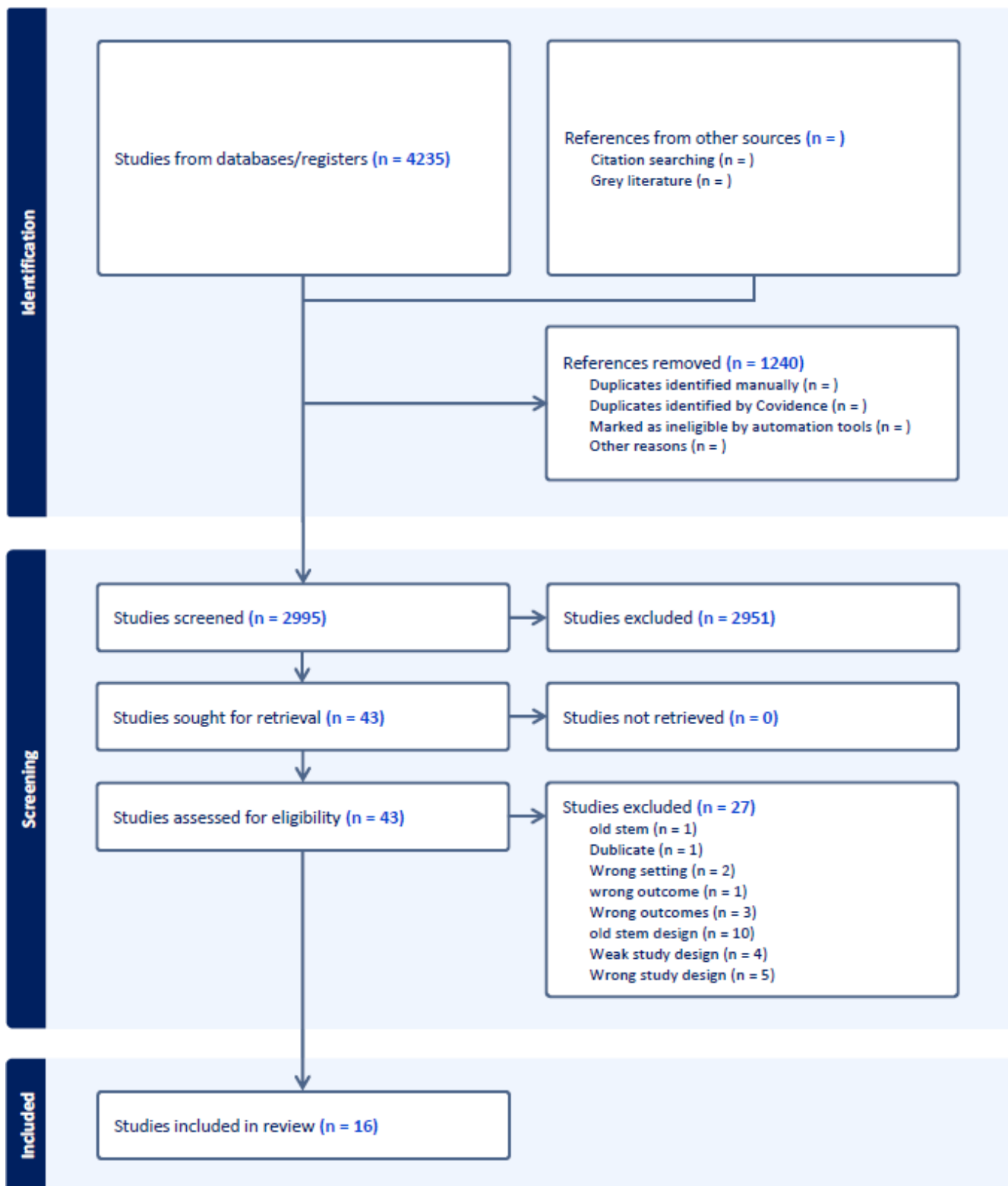
"Bone Cements"[Pharmacological Action] OR "Bone Cements"[MeSH Terms] OR "Cementation"[MeSH Terms] OR "cement*"[Text Word] OR "uncement*"[Text Word] OR "noncement*"[Text Word]

Samlet søgestreng:

("arthroplasty, replacement, hip"[MeSH Terms] OR "Hip Prosthesis"[MeSH Terms] OR ("hip"[Text Word] AND ("arthroplast*"[Text Word] OR "prothes*"[Text Word] OR "implant*"[Text Word] OR "replacement*"[Text Word]))) AND ("Bone Cements"[Pharmacological Action] OR "Bone Cements"[MeSH Terms] OR "Cementation"[MeSH Terms] OR "cement*"[Text Word] OR "uncement*"[Text Word] OR "noncement*"[Text Word]) AND ("osteoarthritis, hip"[MeSH Terms] OR "osteoarthrit*"[Text Word] OR "coxarthros*"[Text Word] OR "Arthroses"[Text Word] OR "arthrosis"[Text Word])

Søgning foretaget d. 9.marts 2023 i Pubmed og Embase.

Bilag 2: Flowskema over litteraturudvælgelse



Bilag 3: Vurdering af evidens

Quality assesment (GRADE)							
Design	Risk og bias	Inconsistency	Indirectness	Imprecision	Publication	Quality	
Outcome: Reoperation (Kritisk outcome)							
8 Registerstudier	Moderat til alvorlig risiko for bias	General enighed	Ja, der konkluderes ud fra fuld cementering i flere studier	Nej	Nej	Meget lav	Nedgraderet grundet risk of bias
Outcome: Mortalitet indenfor 1 år (Kritisk outcome)							
6 Registerstudier	Moderat til alvorlig risiko for bias	Ja, i de første postoperative døgn	Ja, der konkluderes ud fra fuld cementering i flere studier	Ja, brede confidensintervaller i hazrd ratio's	Nej	Meget lav	Nedgraderet grundet risk of bias
Outcome: Luksation indenfor 1 år (Sekundært outcome)							
1 Registerstudie	Moderat til alvorlig risiko for bias	Nej	Ja, der konkluderes ud fra fuld cementering. Hybrid A og B blandes.	Nej	Nej	Meget lav	Nedgraderet grundet risk of bias
Outcome: Tromboemboliske komplikation indenfor 1 år (Sekundært outcome)							
3 Registerstudier	Moderat til alvorlig risiko for bias	Ja	Der observeres på ultralydsfund i højre hjertekamre og lunge i et studie i stedet for klinisk emboli.	Nej	Nej	Meget lav	Nedgraderet grundet risk of bias
Outcome: Patient reporteret funktionsevne samt funktionsmåling efter 1 år (Sekundært outcome)							
2 Registerstudier	Moderat til alvorlig risiko for bias	Ja, forskellige resultater i de to studier	Nej	Nej	Nej	Meget lav	Nedgraderet grundet risk of bias

Bilag 4: Summary of Findings table

Reoperation

Authors			2-year results		10-year results					
1	Kandale et al.	Results 1: Cemented/Hybrid lower revision than uncemented 2: Men higher revision-rates Conclusions 1: 10-year revision-rates <5% for all types of THAs	Groups CeMoP CeLMOp CeLoC HyMoP CeCop All	n in groups 125285 37874 34754 28471 12705 239069	Statistics: Competing risk (flexible model) 2,22 (2,06-2,38) 3,20 (2,85-3,66) 3,96 (3,41-4,51) 2,42 (2,09-2,81) 1,88 (1,37-2,40) 2,54 (2,41-2,67)	Male >70 2,93 (2,62-3,28) 4,31 (3,66-5,07) 4,39 (3,58-5,37) 3,18 (2,54-3,98) 2,10 (1,39-3,16) 3,25 (3,02-3,50)	Female >70 2,67 (2,44-2,92) 3,37 (2,92-3,88) 3,76 (3,07-4,61) 2,63 (2,17-3,18) 1,68 (1,17-2,41) 2,79 (2,62-2,97)			
2	Kelly et al.	Results 1: Hybrid has a higher risk of septic revision 2: Hybrid has a lower risk of PPF 3: Hybrid has a higher risk of aseptic loosening	Groups Hybrid Uncemented (index) Female / Male <65 Female / Male 65-75 Female / Male >75	n in groups 4939 84291	Statistics: COX regression 3,1 3,4 3,4 / 5,9 3,0 / 3,6 2,9 / 2,6	Septic revision *HR 1,5 index # / # # / # # / #	Loosening *HR 2,18 (3yr) HR 6,26 (>3yr) index # / # # / # # / #	Instability # index # / # # / # # / #	PPF *HR 0,41 index # / # # / # *HR 0,27 / #	
3	McMinn et al.	Results Conclusions Slightly higher revision in uncemented THA	Groups Cemented (index) Uncemented	n in groups 154996 120017	Statistics: Royston-Parmer adjusted HR *HR 0,58 (0,54-0,62)					
4	Stea et al.	Results 1: hybrid lower risk of revision for 45-65/65-75/>75 2: female lower risk of revision compared to men (HR 0,8, p<0,001) 3: Head size >32mm lower risk of revision (HR 0,83, p<0,001)	Groups cemented hybrid (index) uncemented	n in groups 52792 60502 126148	Statistics: Linear mixed models 45-64 yr # *HR 1,21 (1,01-1,44)	65-74yr # *HR 1,16 (1,02-1,31)	>75yr # *HR 1,58 (1,39-1,79)			
5	Tanzer et al.	Results 1: >75yr at 3 m. lower revision in 3 best cemented HR 3,31, p<0,006 2: at 13 yrs no difference in revision 3: Male higher risk of revision in both groups 4: early revision due to fractures	Conclusions Proper training in cementless technique	Groups cemented stem >75yr uncemented stem >75yr	n in groups 26627 4523	3 months (index cemented stem) *HR 3,31 (1,39-7,90)	Statistics: Kaplan Meier /COX 13 years 2,00 # HR 3,7			
6	Babazadeh et al.	Results 1: Fracture was most common cause for revision in cemented (47%) 2: Loosening most common cause for revision in uncemented (39%) 3: early revision due to fracture in cementless group 4: hybrid lower revision in young patients	Conclusions use cement for all ages with polished stem	Groups Polished stem (hybrid) Uncemented stem (3 most popular)	n in groups 101028 100861	2 weeks (index hybrid) *HR 0,48	Statistics: Kaplan Meier /COX 17 year (all) *HR 0,70 (0,5-0,99) 6,4 (6,0-6,8) 10,5 (8,4-13,1)	<65 HR 0,74		
7	Bloemheuvel et al.	Results 1: Higher revision in uncemented THAs compares to cemented 2: Male higher revision risk 3: Uncemented stem mostly revised due to fracture 4: cemented stem mostly revised due to dislocation	Conclusions 1: cement might be safer for patients >80 years	Groups cemented hybrid reverse hybrid Uncemented	n in groups 22025 3243 987 16376	1-year results 1,3 1,4 4,0 2,0	Statistics: KM/ competing risk /COX >80 years ONLY 2,2 HR 1,00 2,0 HR 1,00 6,2 *HR 2,9 (2,1-3,8) 2,8 *1,6 (1,4-1,8)			
8	Dale et al.	Results 1: men higher risk of revision (HR 1,6) 2: uncemented higher risk of revision 3: uncemented more PPF 4: uncemented less aseptic 5: the older the higher risk of PPF	Conclusions Uncemented stem should not be used in women >55	Groups Cemented Uncemented Reverse hybrid Hybrid All	n in groups 25678 16006 23312 1999	2-year results 1,20%	Statistics: Kaplan Meier /COX infection index M/F: #/# 0,70%	10-year results (mean follow up 4 years) dislocation index M/F: HR 2,6 / HR 1,8 0,70%	aseptic loosening index M/F: #/# HR 0,3 0,70%	fractures index M/F: #/# HR 12,3 0,40%

* significant resultat
 # ikke-signifikant resultat

Mortalitet

	Cemented			Hybrid A			Uncemented			Adjusted HR mortality for cementing			
	n	30 days mortality	90 days mortality	1 year mortality	n	30 days mortality	90 days mortality	1 year mortality	n		30 days mortality	90 days mortality	1 year mortality
McMinn et al.	155.996								120.017				HR 1.11; 95% CI 1.07 to 1.16, P<0.001
Pedersen et al.	108.572	HR 0.94; 95% CI 0.71-1.3	HR 0.97; 95% CI 0.79-1.2						80.034				
Bloemhevel 2022				3.036	0.4%; 95% CI 0.3-0.5	0.7%; 95% CI 0.5-0.9	2.3%; 95% CI 2.0-2.6		15.215	0.4%; 95% CI 0.3-0.5	0.8%; 95% CI 0.7-0.9	2.6%; 95% CI 2.5-2.7	HR 1.0; 95% CI 0.9-1.0
Dale 2020 IV				2.955					21.553				No difference in 30days, 90 days, 10 years
Ekman 2019				11.802	HR 0.8; 95% CI 0.4-1.4	HR 0.7; 95% CI 0.5-1.1	HR 0.1.2; 95% CI 0.9-1.5		38.477				
Garland 2017*	146.818	HR 0.7; 95% CI 0.62-0.87	HR 0.5; 95% CI 0.40-0.50						15.410	HR 0.8; 95% CI 0.23-2.74	HR 0.2; 95% CI 0.07-0.56		

*Study comparing with matched controls from general population (HR 1.0)

Luksation

Author	Hybrid							Uncemented						
	n	in-hospital compl	30d readmis.	30d PE	30d mortality	30d dislocation	30d PPF	in-hospital compl	30d readmis.	30d PE	30d mortality	30d dislocation	30d PPF	
Lindberg-Larsen et al.	8096	*7,7% (not multivariate)	#5,7%	*0,4% (uni/multi)	HR=3,9	#0,2%	*1,2% (univariate)	*0,2% (univariate)	*5,3% (not multivariate)	#6,2%	*0,1% (uni/multi)	#0,3%	*1,8% (univariate)	*1,5% (univariate)

Tromboemboli

Lindberg-Larsen et al, 2020	cemented / hybrid stem fixation (n=3368)				uncemented stem fixation (n=4728)			
	n	30 days PE			30 days PE			p
	8096	15 (0,4%), RR 3,9	(uni/multivariate)		4(0,1%)	(uni/multivariate)		<0,001
Ekman et al, 2019		cemented fixation (n=23636)		hybrid fixation (n=11802)		uncemented fixation (n=38477)		
	n=73915	PE 0-10d		PE 0-10d		PE 0-10d		
		1 (0,00%)		0		2 (0,01%)		
		PE 90d		PE 90d		PE 90d		
		15 (0,06%)		4 (0,03%)		14 (0,04%)		
		PE 365d		PE 365d		PE 365d		
		30 (0,13%)		20 (0,05%)		7 (0,06%)		

PROM

Author	n	Cemented				Uncemented			
		EQ5D	EQ Vas	Pain VAS	Satisfaction VAS	EQ5D	EQ Vas	Pain VAS	Satisfaction VAS
Rolfson et al.	3,1+3,1k	*0,78	*76,6	*14,1	*14,6	*0,82	*79,4	*11,6	*12,1

* significant resultat

ikke-signifikant resultat

Tolkning: Ucementeret er bedre på alle parametre også når der justeres

Bilag 5: Høringskommentarer og svar

Efter høring på DOS hjemmeside i 6 uger er der indkommet et enkelt høringssvar:

Jens Lauritsen

”Der mangler præcis angivelse af diagnosekoder og relevante behandlingskoder.

Bør det ikke følge patientens funktionsniveau mere end en fast aldersgrænse?”

Forfattergruppen har diskuteret høringssvaret og ikke ændret i den oprindelige version af retningslinjen.