

Kort klinisk retningslinje vedr.

## Patella komponent i primær total knæ alloplastik

### Anbefaling:

↑ Svag anbefaling for brug af patella komponent i total knæ alloplastik (TKA). Overvej brug af patella komponent da 5 års reoperations risikoen kan reduceres og 5 år funktionsscoren kan forbedres (+).

### Udarbejdet af:

Dansk Selskab for Hofte- og Knæalloplastik (DSHK)

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### Baggrund for valg af spørgsmål:

Der er ikke konsensus vedrørende brug af patella resurfacing ved primær total knæalloplastik (TKA). Hvilken teknik der giver bedst resultater, er uklart. I Danmark blev i 2020 foretaget patella resurfacing ved 71,8% af primær total knæalloplastik operationer[1]. Den høje procentdel af patella resurfacing afspejler en antagelse af at færre patienter revideres for anteriore knæsmarter ved brug af denne teknik. Begge teknikker anvendes i dag og regnes for ligestillede, hvorfor DSHK finder det relevant at sammenligne teknikkerne mht. risiko for reoperation, patientrapporteret funktionsevne og smerter.

Denne retningslinje omhandler:

### PICO spørgsmål:

Retningslinjen er udarbejdet med udgangspunkt i følgende PICO-spørgsmål:

*Har patienter med primær knæledsartrose med indikation for indsættelse af en TKA bedre effekt uden indsættelse patellakomponent end TKA med indsættelse af patellakomponent, med hensyn til reoperation samt funktionsevne og smerter?*

Population: Alle patienter med primær knæledsartrose, hvor der er indikation for indsættelse af en total knæalloplastik

Intervention: Total knæalloplastik uden patellakomponent

Comparator: Total knæalloplastik med patellakomponent

Outcome: Reoperation indenfor 1 år (Kritisk outcome).  
Reoperation indenfor 5 år (Kritisk outcome)  
Patient reporteret funktionsscore (PROM) og smerter 1 år postoperativt  
(sekundært outcome)

**Eksklusion:** Patella omformning (reshaping), neurogen denervering af patella, patellofemoral protese vs. TKA, ikke engelsk sprogede publikationer.

**Studier:** RCT, Meta-analyser

Reoperation definition: Alle kirurgiske indgreb på same knæ efter primær TKA.

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

↑ Svag anbefaling for brug af patella komponent i total knæ alloplastik (TKA). Overvej brug af patella komponent, da 5 års reoperations risikoen kan reduceres og 5 år funktions scoren kan forbedres (+).

## Litteratur:

Søgningen er gennemført d 0903.2023 (Se Søgestreng, Bilag 1). Alle søgninger er foretaget af minimum 2 fra arbejdsgruppen. Vi har søgt på metaanalyser og RCT-studier. Der blev i litteratursøgning identificeret 30 RCT-studier som kunne besvare PICO spørgsmålene (Bilag 2). Der foreligger 2 nyere metanalyser, som er publiceret henholdsvis 2021 og 2023 og som begge er omfatter alle 30 RCT-studier[2,3]. Der er ikke siden publiceret relevante RCT'er. Vi har vurderet den metaanalyse som bedst svarerede på vores PICO-spørgsmål vha. Amstar 2 (Bilag 3). Der foreligger endvidere NICE-guideline fra 2020 hvor mange af de samme RCT er inkl., denne var inkonklusiv ift. til anbefaling af patella resurfacing [4-33].

### *Reoperation total*

5391 knæ cases fra de 30 RCT-studier blev inkluderet i metaanalysen til vurdering af risiko for reoperation, resurfacing 2702 cases, 2689 non-resurfacing cases. Der var signifikant forskel mellem de 2 grupper med større risiko for reoperation i non-resurfacing gruppen. Det konkluderedes at brugen af patellakomponent kunne nedsætte risikoen for reoperation. Gennemsnits follow-up for de publicerede RCT-studier var 3,6 (0,5-10,8) år.

Short term outcome med 10 inkluderede studier <3 års follow-up fandt ingen signifikant forskel på reoperations risiko. Af de 30 RCT-studier, præsenterede 18 data på reoperation mere end 5 års follow-up, her fandt man signifikant forskel med mindre reoperations risiko i gruppen med patella komponent.

### *Reoperation indenfor 1 og 5 år*

De publicerede RCT-studer kan ikke belyse pico spørgsmålen med reoperation opdelt på 1 og 5 år.

### *Patient reporteret funktionsscore (PROM) og smerter 1 år postoperativt*

18 RCT-studier med 2265 cases rapporterede Knee Society Score (KSS). Der var signifikant forskel med højere score i patella komponent gruppen.

16 RCT-studier med 1989 cases rapporterede funktions score fra KSS. Der var signifikant forskel med højere score i patella komponent gruppen.

6 RCT-studier med 2569 cases rapporterede Oxford Knee Score (OKS). Der var ingen signifikant forskel.

3 RCT-studier med 277 cases rapporterede The Knee Injury and Osteoarthritis Outcome Score (KOOS). Der var ingen signifikant forskel.

16 RCT-studier med 2163 cases rapporterede Anterior Knee Pain (AKP). Der var ingen signifikant forskel.

3 RCT-studier med 217 cases rapporterede Visual Analog Scale (VAS) for smerter. Ingen signifikant forskel.

## Evidens:

Data er indhentet fra randomiserede studier. Der foreligger 30 publicerede RCT-studier af varierende kvalitet. Der foreligger metanalyser som inkludererede relevante publicerede RCT-studier. Kvaliteten af evidensen er præsenteret for inkludere RCT med GRADE vurderinger for alle outcomes (Bilag 4). Generelt er risikoen for bias i RCT studierne vurderet lavt. I metaanalysens blev der dog ikke konkluderet kun på studier med lav RoB, og heller ikke diskuteret evt. bias indflydelse på resultatet (Bilag 5).

### *Reoperation indenfor 1 år og 5 år (Kritisk outcome)*

De publicerede RCT-studer kan ikke belyse PICO spørgsmålen med reoperation opdelt på 1 og 5 år. Der anvendes forskellige observationsperioder i de forskellige studier. Der ses en signifikant forskel

mellem de 2 grupper med større risiko for reoperation i non-resurfacing gruppen. Der er ikke inkluderet en liste over samlede indikationer for reoperation. Der var ingen signifikant forskel for reoperation indenfor 3,6 år. Hyppigste årsag til nedgradering af GRAD er unøjagtighed (imprecision) på grund af brede konfidensintervaller

Derfor vurderes evidensen til at være meget svag (+)

*Patient reporteret funktionsscore (PROM) og smerter 1 år postoperativt (sekundært outcome)*

De er brugt flere forskellige scorere for at vurdere knæ smerter, hvilket kan medføre observations bias. Som eneste score fandt man i Knee Society Score (KSS) signifikant forskel med højere score i patella komponent gruppen.

I hverken Oxford Knee Score (OKS), The Knee Injury and Osteoarthritis Outcome Score (KOOS; Anterior Knee Pain (AKP) eller Visual Analog Scale (VAS) fandt man en signifikant forskel. Der var gennemgående høj grad af imprecision grundet brede konfidensintervaller.

Derfor vurderes evidensen til at være meget svag (+)

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## Abstract

### Background:

The usage of patella resurfacing in total knee replacement (TKA) is optional and the two methods are considered equals. In Denmark in 2020 71.8 % of total knee replacement was made with patella resurfacing. The high percentage of resurfacing reflects the assumption that the revision rate due to anterior knee pain is higher with the patella not resurfaced. DSHK (Danish society of hip and knee arthroplasty) therefore decided to assess the literature and make recommendations in a short clinical guideline (KKR).

### Aim:

To investigate if patella resurfacing in primary TKA has better results concerning short and long term follow up revision rate, patient reported outcome and pain score, than non-resurfaced primary TKA.

### Materials and methods:

Two meta-analysis was found, publiced in 2021 and 2023. Both included the same 30 RCT studys and no further RCT studys has been publiced since. AMSTAR II critical appraisal tool was used to assess the quality of the meta-analysis. GRADE assessment was used to evaluate the strength of evidence for the relevant outcomes.

### Interpretation/Conclusion:

This KKR is a weak recommendation towards using patella resurfacing in TKA due to a significant lower revision rate after 5 years follow up.

## Bilag 1: Søgestrategi og søgestreng

### **Patient**

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

### **Intervention + Comparison**

AND ("patella"[MeSH Terms] OR "patella\*"[Text Word]) AND "resurfacing"[Text Word]

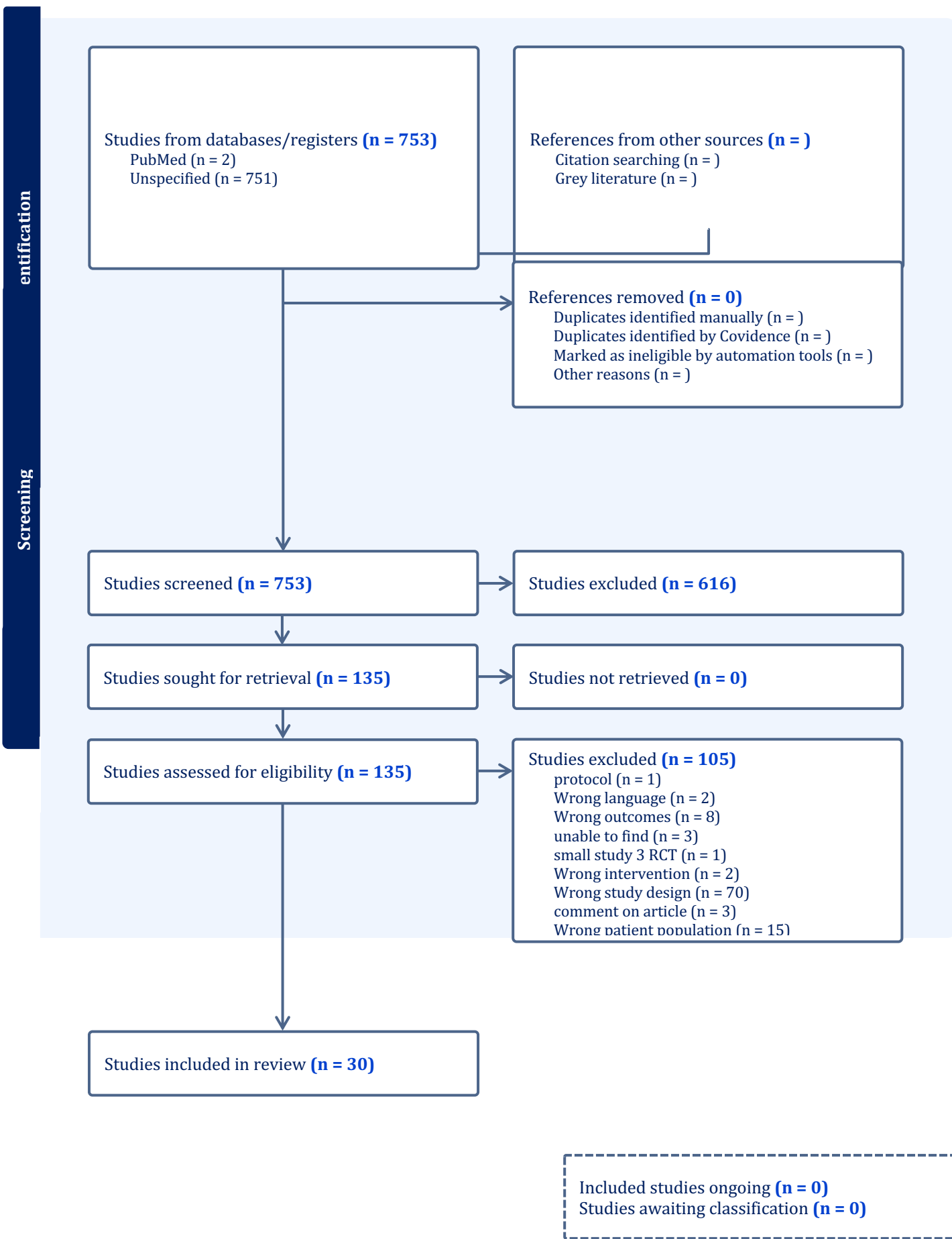
### **Samlet søgestreng:**

("arthroplasty, replacement, knee"[MeSH Terms] OR "knee Prosthesis"[MeSH Terms] OR ("knee"[Text Word] AND ("arthroplast\*"[Text Word] OR "prothes\*"[Text Word] OR "implant\*"[Text Word] OR "replacement\*"[Text Word]))) AND ("patella"[MeSH Terms] OR "patella\*"[Text Word]) AND "resurfacing"[Text Word]

Søgning foretaget d 9 marts 2023 i Pubmed



## Bilag 2: Flowskema over litteraturudvælgelse



Bilag 3: AMSTAR 2 vurdering

Chen K, Dai X, Li L, Chen Z, Cui H, Lv S. Patellar resurfacing versus nonresurfacing in total knee arthroplasty: an updated meta-analysis of randomized controlled trials. J Orthop Surg Res. 2021;16(1):83.

1.	Did the research questions and inclusion criteria for the review include the components of PICO?	YES
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?	Partial YES
3.	Did the review authors explain their selection of the study designs for inclusion in the review?	YES
4.	Did the review authors use a comprehensive literature search strategy?	Partial YES
5.	Did the review authors perform study selection in duplicate?	YES
6.	Did the review authors perform data extraction in duplicate?	YES
7.	Did the review authors provide a list of excluded studies and justify the exclusions?	Partial YES
8.	Did the review authors describe the included studies in adequate detail?	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?	YES
10.	Did the review authors report on the sources of funding for the studies included in the review	NO
11.	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	YES
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?	YES
13.	Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	NO
14.	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	YES
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?	YES
16.	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	YES
	AMSTAR 2: 10/16 YES; 3/16 Partial Yes	

Bilag 4: Vurdering af evidens/GRADE

Quality assessment (GRADE) - RCT studier								
Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication	Quality		
<b>Outcome: Reoperation (Kritisk outcome)</b>								
RCT 30 studier	Overvejende Lav. Et par studier med moderat risiko	Nej	Nej, svarer på vores PICO spørgsmål, dog uden de ønskede follow-up grænser.	Ja, RCT-studierne er kendetegnet ved store konfidensintervaller (CI), flere med få patienter og non- signifikante estimater.	Nej	Moderat	Nedgraderes grundet imprecision	
<b>Outcome: Knee Society Score (KSS) (sekundært outcome)</b>								
RCT 18 studier	Overvejende lav.	Nej	Nej, svarer på vores PICO spørgsmål.	Ja, små patient antal, store CI	Nej	Moderat	Nedgraderes grundet imprecision	
<b>Outcome: KSS function (sekundært outcome)</b>								
RCT 16 studier	Lav	Nej	Nej svarer på vores PICO spørgsmål.	Ja, små patient antal, store CI	Nej	Moderat	Nedgraderes grundet imprecision	
<b>Outcome: Oxford Knee Score (OKS) (sekundært outcome)</b>								
RCT 6 studier	Lav risiko	Nej	Nej svarer på vores PICO spørgsmål.	Ja, få studier brede konfidensintervaller	Nej	Meget lav	Nedgraderes grundet imprecision	
<b>Outcome: The Knee Injury and Osteoarthritis Outcome Score (KOOS) sekundært outcome)</b>								
RCT 3 studier	Lav	Nej	Nej svarer på vores PICO spørgsmål.	Ja, få studier brede konfidensintervaller	Nej	Meget lav	Nedgraderes grundet imprecision	
<b>Outcome: Anterior Knee Pain (sekundært outcome)</b>								
RCT 16 studier	Lav	Nej	Nej svarer på vores PICO spørgsmål.	Ja, flere studier brede konfidensintervaller	Nej	Moderat	Nedgraderes grundet imprecision	
<b>Outcome: VAS pain (sekundært outcome)</b>								
RCT 3 studier	Lav	Nej	Nej svarer på vores PICO spørgsmål.	Ja, få studier brede konfidensintervaller	Nej	Lav	Nedgraderes grundet imprecision	

Bilag 5: Det metodiske kvalitet; bias-risikoen for hver RCT

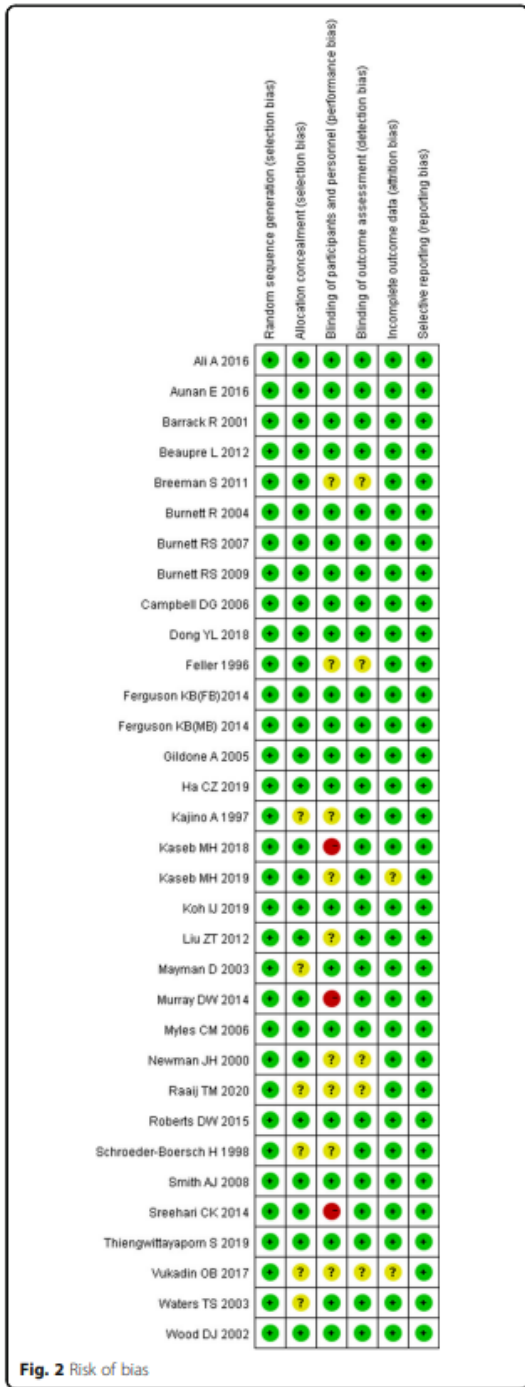


Fig. 2 Risk of bias

## Bilag 6: Høringskommentarer og svar

Bilag

## Høringssvar KKR 2023

### TKA – Patellakomponent til primære TKA

Høringssvar 1:

”Der mangler præcis angivelse af diagnosekoder og relevante behandlingskoder.”

Forfattergruppens respons:

Forfattergruppen har diskuteret høringssvaret og finder ikke grund til at ændre den oprindelige version af retningslinjen.

Høringssvar 2:

”Jeg tror mange TKA kirurger worldwide er enige i at der ikke er noget ultimativt svar på spørgsmålet resurfacing, selektiv resurfacing, no resurfacing. I har som jeg ser det ikke fået den pragmatiske selektive løsning med i jeres gennemgang.”

Forfattergruppens respons:

Forfattergruppen har diskuteret høringssvaret og finder ikke grund til at ændre den oprindelige version af retningslinjen. Det er korrekt at selektiv patella resurfacing som intervention ved TKA ikke er belyst i denne KKR.